STATUTORY INSTRUMENTS

2012 No. 1916

MEDICINES

The Human Medicines Regulations 2012

Made - - - -	*19th July 2012*
Laid before Parliament	*24th July 2012*
Coming into force - -	*14th August 2012*

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in exercise of the powers conferred by section 2(2) and (5) of the European Communities Act 1972[M1], having been designated for the purposes of section 2(2) of that Act in relation to medicinal products[M2] and to measures in the veterinary and phytosanitary fields for the protection of public health[M3]. They do so in exercise also of the powers conferred by sections 87(1), 88(1) and (2), 91(2), and 129(1), (2) and (5) of the Medicines Act 1968[M4], having consulted such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of that Act.

Modifications etc. (not altering text)

C1 Instrument modified (10.5.2013) by The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I. 2013/898), **reg. 2(5)**

Marginal Citations

M1 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 (2006 c,51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the Northern Ireland Constitution Act 1973 (1973 c.36).

M2 S.I. 1972/1811.

M3 S.I. 1999/2027.

M4 1968 c.67.

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Human Medicines Regulations 2012.

(2) These Regulations come into force on 14th August 2012.

Medicinal products

2.—(1) In these Regulations "medicinal product" means—

(a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or

(b) any substance or combination of substances that may be used by or administered to human beings with a view to—

(i) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or

(ii) making a medical diagnosis.

(2) These Regulations do not apply to—

(a) whole human blood; or

(b) any human blood component, other than plasma prepared by a method involving an industrial process.

Modifications etc. (not altering text)

C2 Reg. 2 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

[F1Definition of advanced therapy medicinal product etc.

2A.—(1) In these Regulations, in their application to products for sale or supply in Great Britain only, "advanced therapy medicinal product" means any of the following products—

(a) a gene therapy medicinal product;

(b) a somatic cell therapy medicinal product; or

(c) a tissue engineered product.

(2) A "gene therapy medicinal product" is a biological medicinal product which has the following characteristics—

(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and

(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

(3) A vaccine against infectious diseases is not to be treated as a gene therapy medicinal product.

(4) A "somatic cell medicinal product" is a medicinal product which has the following characteristics—

(a) it contains or consists of cells or tissues that—

(i) have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or

(ii) are not intended to be used for the same essential function in the recipient as in the donor; and

(b) it is presented as having properties for, or is used in or administered to human beings with a view to, treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.

(5) A "tissue engineered product" is a medicinal product which—

(a) contains or consists of engineered cells or tissues; and

(b) is presented as having properties for, or is used in or administered to human beings with a view to, regenerating, repairing or replacing a human tissue.

(6) A tissue engineered product may contain—

(a) cells or tissues of human or animal origin;

(b) viable or non-viable cells or tissues; and

(c) additional substances, including cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.

(7) A product is not a tissue engineered product if it—

(a) contains or consists exclusively of non-viable human or animal cells or tissues;

(b) does not contain any viable cells or tissues; and

(c) does not act principally by pharmacological, immunological or metabolic action.

(8) Cells or tissues are engineered if they—

(a) have been subject to substantial manipulation, so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved; or

(b) are not intended to be used for the same essential function in the recipient as in the donor.

(9) The following manipulations are not substantial manipulations for the purposes of paragraphs (4)(a) and (8)(a)—

(a) cutting;

(b) grinding;

(c) shaping;

(d) centrifugation;

(e) soaking in antibiotic or antimicrobial solutions;

(f) sterilisation;

(g) irradiation;

(h) cell separation, concentration or purification;

(i) filtering;

(j) lyophilisation;

(k) freezing;

(l) cryopreservation; and

(m) vitrification.

(10) In these Regulations, in their application to products for sale or supply in Great Britain only, "combined advanced therapy medicinal product" means an advanced therapy medicinal product—

(a) which incorporates, as an integral part of the product, one or more medical devices or one or more active implantable medical devices; and

(b) the cellular part of which—

(i) contains viable cells or tissues; or

(ii) contains non-viable cells or tissues which are liable to act upon the human body with action that can be considered as primary to that of the medical devices.

(11) Where an advanced therapy medicinal product contains viable cells or tissues, the pharmacological, immunological or metabolic action of those cells or tissues is to be treated as the principal mode of action of the product.

(12) An advanced therapy medicinal product containing both autologous and allogeneic cells or tissues is to be treated as being for allogeneic use.

(13) A product which falls within the definition of a tissue engineered product and within the definition of a somatic cell therapy medicinal product is to be treated as a tissue engineered product.

(14) A product which falls within the definition of—

(a) a somatic cell therapy medicinal product or a tissue engineered product; and

(b) a gene therapy medicinal product,

is to be treated as a gene therapy medicinal product.**]**

Textual Amendments

F1 Reg. 2A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **4** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 1**); 2020 c. 1, **Sch. 5 para. 1(1)**

Scope of these Regulations: special provisions

3.—(1) Regulation 17(1) (manufacturing of medicinal products: requirement for licence) shall not apply in circumstances where paragraph (4) applies.

(2) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) shall not apply in circumstances where paragraph (5) or (6) applies.

(3) These Regulations do not apply where paragraph (7) applies.

(4) This paragraph applies where a medicinal product is assembled by a registered nurse or a registered midwife if—

(a) the nurse or midwife is acting in the course of his or her profession; and

(b) the conditions in paragraphs (8) and (9) are met.

(5) This paragraph applies where a medicinal product is manufactured or assembled by a doctor or dentist and the conditions in paragraphs (8) and (9) are met.

(6) This paragraph applies where a herbal medicinal product is manufactured or assembled by a person ("A") if—

(a) the manufacture or assembly takes place on premises occupied by A and from which A can exclude the public;

(b) the product is for administration to a person ("B") and A has been requested by or on behalf of B, and in B's presence, to use A's judgment as to the treatment required;

(c) the product does not contain a substance specified in Part 1 of Schedule 20;

(d) the product does not contain a substance listed in Part 2 of that Schedule, unless the product is sold or supplied—

(i) in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in column 2 of that Part, or

(ii) in the case of a product for external use only, with a percentage of the substance in the product that does not exceed the percentage specified in column 3 of that Part; and

(e) the condition in paragraph (9) is met.

(7) This paragraph applies where the product is a radionuclide that is in the form of a sealed source.

(8) This condition is that the medicinal product is supplied—

(a) to a patient in the course of the treatment of that patient; or

(b) in a case to which paragraph (5) applies, to a patient of another doctor or dentist who is a member of the same medical or dental practice.

(9) This condition is that the medicinal product is not manufactured or, as the case may be, assembled—

(a) on a large scale; or

(b) by an industrial process.

(10) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products) does not apply to a medicinal product that is sold or supplied in circumstances where paragraph (11) or (12) applies in relation to the product, except to the extent set out in paragraph (14), but the requirements of paragraph (13) shall apply.

(11) This paragraph applies where a medicinal product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of paragraph (5) or (6).

(12) This paragraph applies in the case of a medicinal product where—

(a) the product is the result of a process of assembly of an authorised medicinal product;

(b) regulation 17(1) does not apply to the process of assembly by virtue of paragraph (4) or (5);

(c) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(d) by reason of that change the product so assembled is not sold or supplied in accordance with the terms of—

(i) the **[**[F2]UK**]** marketing authorisation,

[[F3](ia) the EU marketing authorisation,**]**

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

(13) The information specified in Part 1 of Schedule 26 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product that is sold or supplied in circumstances—

(a) where paragraph (11) applies to the product, except in the case of a product manufactured in accordance with paragraph (6); or

(b) where paragraph (12) applies in relation to the product.

(14) Regulations 269 (offences relating to packaging and package leaflets: other persons) and 271 (offences: penalties) shall have effect in relation to paragraph (13) as if that paragraph were a requirement of Part 13.

(15) For the purposes of this regulation and regulation 4 (special provisions for pharmacies etc), a medicinal product is authorised if there is in force for the product—

(a) a **[**F4UK**]** marketing authorisation;

[F5(aa) an EU marketing authorisation;**]**

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

Textual Amendments

F2 Word in reg. 3(12)(d)(i) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **5(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 3(12)(d)(ia) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **5(2)(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 2(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Word in reg. 3(15)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **5(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Reg. 3(15)(aa) inserted (3.8.2021) by The Human Medicines (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/834), regs. 1(2), **2**

[F6**Preparation and assembly of medicinal products used for vaccination or immunisation against coronavirus or in the reformulation of such products**

3A.—(1) Regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) do not apply in circumstances where a medicinal product used for vaccination or immunisation against coronavirus is manufactured, prepared or assembled by or under the supervision of a doctor, a registered nurse or a pharmacist—

(a) who is acting in the course of his or her profession; and

(b) for the purposes of the supply or administration of the medicinal product to a patient under relevant arrangements.

(2) Regulation 46 does not apply in respect of a medicinal product—

(a) which is the result of the assembly of an authorised medicinal product;

(b) which is used for the reformulation of a medicinal product used for vaccination or immunisation against coronavirus; and

(c) the assembly of which (as mentioned in sub-paragraph (a)) is—

(i) in accordance with a manufacturer's licence, or

(ii) undertaken in circumstances where regulation 17(1) does not apply by virtue of regulation 3 (scope of these regulations: special provisions) or regulation 4 (special provisions for pharmacies etc.).

(3) Regulation 17(1) does not apply in circumstances where a medicinal product used for vaccination or immunisation against coronavirus is labelled by a holder of a wholesale dealer's licence to take account of a change to the shelf life of the product because of the thawing of the product.

(4) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products)—

(a) does not apply to a medicinal product that is the result of a process of manufacture, preparation or assembly in accordance with paragraph (1) or (2); and

(b) is to be construed as permitting labelling in accordance with paragraph (3), in the case of a product which is otherwise labelled in accordance with that Part.

(5) For the purposes of this regulation—

"authorised" has the meaning given in regulation 3(15); and

"relevant arrangements" has the meaning given in regulation 19(4C) (exemptions from requirement for wholesale dealer's licence).

(6) This regulation ceases to have effect on 1st April **[**F7**]**2024**.]**

Textual Amendments

F6 Reg. 3A inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **4** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **4**

F7 Word in reg. 3A(6) substituted (31.3.2022) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **3**

Special provisions for pharmacies etc

4.—(1) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) do not apply where any provision of section 10 of the Medicines Act 1968 **M5** so provides.

(2) Chapter 1 of Part 13 (requirements for packaging and package leaflets relating to medicinal products) does not apply to a medicinal product that is sold or supplied in circumstances where paragraph (3) or (4) applies in relation to the product, except to the extent set out in paragraph (6), but the requirements of paragraph (5) shall apply.

(3) This paragraph applies in a case where a medicinal product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of any provision of section 10 of the Medicines Act 1968.

(4) This paragraph applies in the case of a medicinal product where—

(a) the product is the result of a process of assembly of a medicinal product that is an authorised medicinal product within the meaning of regulation 3(15);

(b) regulation 17(1) does not apply to the process of assembly by virtue of any provision of section 10 of the Medicines Act 1968;

(c) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(d) by reason of that change the product so assembled is not sold or supplied in accordance with the terms of—

(i) the **[**F8**]**UK**]** marketing authorisation,

[F9**]**(ia) the EU marketing authorisation,**]**

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

(5) The information specified in Part 2 of Schedule 26 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product that is sold or supplied in circumstances where paragraph (3) or (4) applies in relation to the product.

(6) Regulations **[**F10269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**]** and 271 (offences: penalties) shall have effect in relation to paragraph (5) as if that paragraph were a requirement of Part 13.

Textual Amendments

F8 Word in reg. 4(4)(d)(i) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **6(a)(i)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 3**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Reg. 4(4)(d)(ia) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **6(a)(ii)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 3**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Words in reg. 4(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **6(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 3**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marginal Citations

M5 Section 10(1) was amended by paragraph 10(a) of Part 1 of Schedule 8 to S.I. 2006/2407, paragraph 5(a) of Schedule 3 to the Regulation of Care (Scotland) Act 2001, and article 3 of S.I. 1971/1445. Section 10(2) was repealed by paragraph 10(b) and (3)(b) was repealed by paragraph 10(c) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(4) was amended and section 10(5) and (6) inserted by article 3 of S.I. 1971/1445. Section 10(6A) was repealed by paragraph 10(d) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(7) was inserted by article 3 of S.I. 1971/1445, and amended by regulation 3 of S.I. 1993/834. Section 10(7A) to (7C) was inserted by the Health Act 2006 section 26(1), and section 10(7A) was amended by paragraph 10(e) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(8) was inserted by S.I. 1971/1445 article 3. Section 10(9) was inserted by paragraph 5(a) of Schedule 3 to the Regulation of Care (Scotland) Act 2001.

Classification of medicinal products

5.—(1) In these Regulations references to a medicinal product subject to general sale are to a product that is not a prescription only medicine or a pharmacy medicine but is—

(a) a product that is covered by an authorisation of which it is a term that the product is to be available on general sale; or

(b) **[**F11in the case of a medicinal product for sale or supply in Northern Ireland,**]** a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine, and

(iii) the licensing authority has determined should be available on general sale.

(2) In paragraphs (1)(a) and (5)(a) "authorisation" means—

(a) a UK marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) **[**F12in the case of a medicinal product for sale or supply in Northern Ireland,**]** an Article 126a authorisation.

(3) In these Regulations references to a prescription only medicine are to any of the following—

(a) a medicinal product that is covered by an authorisation of which it is a term that the product is to be available only on prescription;

(b) **[**F13in the case of a medicinal product for sale or supply in Northern Ireland **[**F14(that is not a listed NIMAR product)**]**,**]** a medicinal product that—

(i) is covered by an EU marketing authorisation, and

(ii) is classified in the authorisation as a prescription only medicine;

(c) a medicinal product that is a prescription only medicine by virtue of Part 1 of Schedule 1; or

(d) a medicinal product that is the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a prescription only medicine by virtue of sub-paragraph (a) or (b).

(4) In paragraph (3)(a) "authorisation" means—

(a) a UK marketing authorisation; or

(b) **[**F15in the case of a medicinal product for sale or supply in Northern Ireland **[**F16(that is not a listed NIMAR product)**]**,**]** an Article 126a authorisation.

(5) In these Regulations references to a pharmacy medicine are to a medicinal product that is not a prescription only medicinal product or a medicinal product subject to general sale but is—

(a) covered by an authorisation of which it is a term that the product is to be available only from a pharmacy;

(b) **[**F17in the case of a medicinal product for sale or supply in Northern Ireland,**]** a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine,

other than a product to which paragraph (1)(b)(iii) applies;

(c) available only from a pharmacy by virtue of Part 2 of Schedule 1; or

(d) the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a pharmacy medicine by virtue of sub-paragraph (a) or (b).

Textual Amendments

F11 Words in reg. 5(1)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **7(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 4(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Words in reg. 5(2)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **7(3)(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 4(b)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 5(3)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **7(4)(a)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 4(c)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 5(3)(b) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **3**

F15 Words in reg. 5(4)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **7(5)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 4(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 5(4)(b) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **3**

F17 Words in reg. 5(5)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **7(6)(a)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 4(e)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

The licensing authority and the Ministers

6.—(1) The licensing authority is responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates **[**[F18], designations, opinions**]** and registrations under these Regulations.

(2) In these Regulations "the licensing authority" means either or both of the Ministers.

(3) Any function that—

(a) is conferred on "the licensing authority" by these Regulations; or

(b) is a function within paragraph (4),

may be exercised by either of the Ministers acting alone or by both of them acting jointly.

(4) The functions of a member State, or of the competent authority of a member State, under any of the relevant EU provisions are to be exercised by the licensing authority if—

(a) they relate to medicinal products; and

(b) they are to be exercised by, or by any authority of, the United Kingdom.

(5) Paragraph (4) does not apply to any function that is conferred by these Regulations on a person or body other than the licensing authority.

(6) In these Regulations "the Ministers" means—

(a) the Secretary of State; and

(b) the Minister for Health, Social Services and Public Safety.

(7) Any function that is conferred on "the Ministers" by these Regulations is to be exercised by the Ministers acting jointly.

(8) Paragraph (7) does not apply where these Regulations provide for a function of the Ministers to be exercised by either of them acting alone or both of them acting jointly.

Textual Amendments

F18 Words in reg. 6(1) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **3** (with reg. 19)

Advertisements relating to medicinal products

7.—(1) In these regulations "advertisement", in relation to a medicinal product, includes anything designed to promote the prescription, supply, sale or use of that product.

(2) This includes, in particular, the following activities—

(a) door-to-door canvassing;

(b) visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;

(c) the supply of samples;

(d) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except where the intrinsic value of such inducements is minimal;

(e) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

(f) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, including the payment of their travelling and accommodation expenses in that connection.

(3) But references in these Regulations to an "advertisement" do not include any of the following—

(a) a medicinal product's package or package leaflet;

(b) reference material and announcements of a factual and informative nature, including—

(i) material relating to changes to a medicinal product's package or package leaflet,

(ii) adverse reaction warnings,

(iii) trade catalogues, and

(iv) price lists,

provided that no product claim is made; or

(c) correspondence, which may be accompanied by material of a non-promotional nature, answering a specific question about a medicinal product.

(d) In this regulation "person qualified to prescribe or supply medicinal products" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

General interpretation

8.—(1) In these Regulations (unless the context otherwise requires)—

[[F19]"the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use;**]**

[[F20]"the 2018 Regulations" means the Health Service Products (Provision and Disclosure of Information) Regulations 2018;**]**

[[F21]"active implantable medical device"—

(a) has the meaning given in regulation 2 of the Medical Devices Regulations 2002; or

(b) to the extent necessary for the practical application of that definition, also or instead has the meaning given in regulation 137 of those Regulations;**]**

[[F22]"active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;**]**

"administer" means administer to a human being—

(a) orally, by injection, or by introduction into the body in any other way; or

(b) by external application (whether or not by direct application to the body),

and any reference in these Regulations to administering anything is to administering it in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, a substance used as a vehicle;

"advanced therapy medicinal product" means **[**F23, in the case of a medicinal product for sale or supply by the holder of a UKMA(NI) or UKMA(UK),**]** a medicinal product described in Article 2(1)(a) of Regulation (EC) No 1394/2007;

"adverse reaction" means a response to a medicinal product that is noxious and unintended;

"advisory body" has the meaning given by regulation 12(1);

[F21"agreed paediatric investigation plan" means a paediatric investigation plan which the licensing authority has agreed in accordance with regulation 50B;**]**

[F21"Annex I to the 2001 Directive" means, in relation to UKMA(GB), Annex I to the 2001 Directive, as modified in accordance with Schedule 8B;**]**

[F21"approved country for batch testing list" means the list published by the licensing authority under paragraph 14(3) of Schedule 7 (obligations of qualified persons) and "approved country for batch testing" means a country included in that list;**]**

[F21"approved country for import list" means the list published by the licensing authority under regulation 18A (approved country for import) and "approved country for import" means a country included in that list;**]**

"appropriate practitioner" means an appropriate practitioner within the meaning of regulation 214;

"Article 126a authorisation" means an authorisation granted by the licensing authority under Part 8 of these Regulations;

[F24"assemble", in relation to a medicinal product or an active substance, includes the various processes of dividing up, packaging and presentation of the product or substance, and "assembly" has a corresponding meaning;**]**

"biological medicinal product" and "biological substance" have the meaning given in the third indent of paragraph 3.2.1.1.(b) of Annex I to the 2001 Directive;

"blood component" means any of the following—

(a) red cells;

(b) white cells;

(c) platelets; and

(d) plasma;

"the British Pharmacopoeia" means the British Pharmacopoeia referred to in regulation 317;

[F25"brokering" means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;**]**

"business" includes—

(a) a professional practice;

(b) any activity carried on by a body of persons whether corporate or unincorporated; and

(c) the provision of services by or on behalf of the Secretary of State, the Minister for Health, Social Services and Public Safety, the Welsh Ministers or the Scottish Ministers as the case may be under the following enactments—

(i) the National Health Service Act 2006 [M6],

(ii) the Health and Personal Social Services (Northern Ireland) Order 1972 [M7] and the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M8],

(iii) the National Health Service (Wales) Act 2006 [M9],

(iv) the National Health Service (Scotland) Act 1978 [M10];

[F26]...

"certificate of registration" means a certificate of registration granted by the licensing authority under Part 6 of these Regulations **[**[F27]and—

(a) "COR(UK)" means such a certificate in force in the whole United Kingdom;

(b) "COR(GB)" means such a certificate in force in Great Britain only;

(c) "COR(NI)" means such a certificate in force in Northern Ireland only;**]**

"clinical management plan" means a written plan relating to the treatment of an individual patient and agreed by—

(a) the patient;

(b) the doctor or dentist who is a party to the plan; and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

"clinical trial" has the meaning given by regulation 2 of the Clinical Trials Regulations;

"the Clinical Trials Directive" means Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [M11];

"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004 [M12];

"the Commission" has the meaning given by regulation 9(1);

[[F28]"Commission Regulation 2016/161" means Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use;**]**

"common name" in relation to a medicinal product, active substance or excipient means—

(a) its international non-proprietary name recommended by the World Health Organisation; or

(b) if such a name does not exist, its usual common name;

[[F21]"the Committee for Medicinal Products for Human Use" means the committee established under Article 5(1) of Regulation (EC) No 726/2004;**]**

[[F21]"conditional marketing authorisation" means a UKMA(GB) granted under regulation 49(1)(a) in accordance with regulation 58F;**]**

"community practitioner nurse prescriber" means a person—

(a) who is a registered nurse or a registered midwife; and

(b) against whose name is recorded in the professional register an annotation signifying that the person is qualified to order drugs, medicines and appliances from the Nurse

Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;

"contravention" includes failure to comply (and "contravene" has a corresponding meaning);

[F29"coronavirus" and "coronavirus disease" have the meanings given in section 1(1) of the Coronavirus Act 2020;**]**

"cosmetic" means any substance or preparation intended to be applied to the surfaces of the human body (including the epidermis, pilary system and hair, nails, lips and external genital organs), or the teeth or buccal mucosa, wholly or mainly for the purpose of—

(a) perfuming them;

(b) cleansing them;

(c) protecting them;

(d) caring for them or keeping them in condition;

(e) modifying their appearance (for aesthetic purposes or otherwise); or

(f) combating body odours or normal body perspiration;

[F21"country" means a country or territory;**]**

"dentist" means a person registered in the dentists register under section 14 of the Dentists Act 1984 M13;

[F21"Directive 2001/18/EC" means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration;**]**

F30 …

F31 …

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

"doctor" means a registered medical practitioner;

[F32"EAMS medicinal product" means a medicinal product that—

(a) has been included in the Early Access to Medicines Scheme by means of the licensing authority issuing an EAMS scientific opinion in respect of it; and

(b) remains in the scheme by virtue of the EAMS scientific opinion not ceasing to have effect in respect of it by virtue of regulation 167D;**]**

[F32"EAMS scientific opinion" is to be construed in accordance with regulation 167C(2)(b);**]**

[F32"EAMS scientific opinion holder" means the holder of a EAMS scientific opinion, and accordingly, is the person who places on the market the product to which the opinion relates;**]**

[F32"Early Access to Medicines Scheme" means the scheme of that name established and operated under regulation 167C(1);**]**

"effervescent", in relation to a tablet or capsule, means containing not less than 75 per cent, by weight of the tablet or capsule, of ingredients included wholly or mainly for the purpose of releasing carbon dioxide when the tablet or capsule is dissolved or dispersed in water;

"electronic communication" means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

(a) by means of an electronic communications network within the meaning of section 32(1) of the Communications Act 2003 M14; or

(b) by other means but while in an electronic form;

[F33"electronic signature" has the meaning given within Article 3(10) of Regulation (EU) 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market;**]**

"the EMA" means the European Medicines Agency established by Regulation (EC) No 726/2004;

"enactment" includes primary and secondary legislation of the devolved administrations in Wales, Scotland and Northern Ireland;

"enforcement authority" means the Secretary of State, the Minister for Health, Social Services and Public Safety or a person on whom a function of enforcing a provision of these Regulations has been conferred by virtue of regulations 323 or 324;

[F21"EU agreed paediatric investigation plan" means a paediatric investigation plan agreed in accordance with the Paediatric Regulation;

[F32"EU Clinical Trials Regulation" means Regulation EU No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products, and repealing Directive 2001/20/EC;**]**

"EU Exit Regulations" means the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019; **]**

"EU marketing authorisation" means a marketing authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004;

"European Economic Area" or "EEA" means the European Economic Area created by the EEA agreement;

"the European Pharmacopoeia" means the European Pharmacopoeia published by the European Directorate for the Quality of Medicines;

[F34"excipient" means any constituent of a medicinal product other than the active substance and the packaging material;**]**

"exempt advanced therapy medicinal product" has the meaning given in regulation 171;

"expert advisory group" has the meaning given by regulation 14(1);

[F35"export" means export, or attempt to export, from the United Kingdom, whether by land, sea or air;**]**

[F36"external use" in relation to a medicinal product—

(a) means its use by application to the skin, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal in circumstances where local action only is necessary and systemic absorption is unlikely to occur; but

(b) does not include its use by means of a throat spray, nasal spray, nasal inhalation or teething preparation or by means of throat pastilles, throat lozenges, throat tablets or nasal drops;**]**

[F37"falsified medicinal product" means any medicinal product with a false representation of—

(a) its identity, including its packaging and labelling, its name or its composition (other than any unintentional quality defect) as regards any of its ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) its history, including the records and documents relating to the distribution channels used;

"Fees Regulations" means **[**F38the Medicines (Products for Human Use) (Fees) Regulations 2016**]**;**]**

"the Good Manufacturing Practice Directive" means **[**F39—

(a) in the case of a medicinal product manufactured or assembled in, or imported into, Great Britain—

(i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use, as modified by Schedule 2A, or

(ii) if Regulations have been made under the powers in regulation B17(1), and have come into force, those Regulations;

(b) in the case of a medicinal product manufactured or assembled in, or imported into, Northern Ireland, Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use;**]**

"the Health and Care Professions Council register" means the register established and maintained by the Health and Care Professions Council under article 5 of the **[**F40Health Professions Order 2001**]**M15;

"health care professional" means—

(a) a doctor;

(b) a dentist;

(c) a pharmacist;

(d) a pharmacy technician registered in Part 2 F41... of the Register of pharmacists and pharmacy technicians established and maintained under article 19(2) of the Pharmacy Order 2010 M16;

(e) a registered nurse;

(f) a registered midwife;

(g) a registered optometrist;

(h) a registered osteopath as defined in section 41 of the Osteopaths Act 1993 M17;

(i) a registered chiropractor as defined in section 43 of the Chiropractors Act 1994 M18;

(j) a person registered as a member of a relevant profession within the meaning of article 2 and paragraph 1 of Schedule 3 to the **[**F42Health Professions Order 2001**]**, in the Health and Care Professions Council register; or

(k) a person registered in the dental care professionals register established and maintained under section 36B of the Dentists Act 1984 M19 as a member of a profession complementary to dentistry specified by regulation 2 of the General Dental Council (Professions Complementary to Dentistry) Regulations 2006 M20;

"health centre" means a health centre maintained under—

(a) section 2 or 3 of the National Health Service Act 2006 M21;

(b) section 2 or 3 of the National Health Service (Wales) Act 2006 M22;

(c) section 36(1)(b) of the National Health Service (Scotland) Act 1978 M23; or

(d) article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972 M24;

[F28"healthcare institution" has the meaning given by Article 3(2) of Commission Regulation 2016/161;**]**

"herbal medicinal product" means a medicinal product whose only active ingredients are herbal substances or herbal preparations (or both);

"herbal preparation" means a preparation obtained by subjecting herbal substances to processes such as extraction, distillation, expression, fractionation, purification, concentration or fermentation, and includes a comminuted or powdered herbal substance, a tincture, an extract, an essential oil, an expressed juice or a processed exudate;

"herbal substance" means a plant or part of a plant, algae, fungi or lichen, or an unprocessed exudate of a plant, defined by the plant part used and the botanical name of the plant, either fresh or dried, but otherwise unprocessed;

"homoeopathic medicinal product" means a medicinal product prepared from homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by—

(a) the European Pharmacopoeia; or

(b) in the absence of such a description in the European Pharmacopoeia,

(i) **[**F43 in relation to a certificate of registration or marketing authorisation for a national homoeopathic product in force in Great Britain only, the British Pharmacopoeia, or in an pharmacopoeia used officially in an country that is included in a list published by the licensing authority for this purpose;

(ii) in relation to a certificate of registration or marketing authorisation for a national homoeopathic product in force in the whole United Kingdom or in Northern Ireland only, in the British Pharmacopoeia or in any pharmacopoeia used officially in an EEA State;**]**

[F28"hospice" means an institution whose primary function is the provision of palliative care to persons resident there who are suffering from a progressive disease in its final stages;**]**

"hospital" includes a clinic, nursing home or similar institution;

"immediate packaging" in relation to a medicinal product means the container or other form of packaging immediately in contact with the medicinal product;

[F44"import" means import, or attempt to import, into the United Kingdom, whether by land, sea or air **[**F45and "imported" is to be construed accordingly**]**;**]**

"inspector" means a person authorised in writing by an enforcement authority for the purposes of Part 16 (enforcement) (and references to "the enforcement authority", in relation to an inspector, are to the enforcement authority by whom the inspector is so authorised);

"intermediate product" means a substance which—

(a) has been manufactured for use in the manufacture of medicinal products; and

(b) is intended for further processing by a manufacturer of such products;

"investigational medicinal product" has the meaning given in regulation 2(1) of the Clinical Trials Regulations;

"labelling" in relation to a container or package of medicinal products means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents (and "label" has a corresponding meaning);

"the licensing authority" has the meaning given by regulation 6(2);

[F20"listed NIMAR product" means a product included in a list maintained in accordance with regulation 167B on the date it is dispatched from Great Britain to Northern Ireland;**]**

"manufacture", in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, a substance used as a vehicle for the purpose of administering it;

"manufacturer's licence" has the meaning given by regulation 17(1);

"marketing authorisation" means—

(a) a UK marketing authorisation; or

(b) an EU marketing authorisation;

"medicinal product subject to general sale" has the meaning given in regulation 5(1) (classification of medicinal products);

[[F21]"medical device"—

(a) has the meaning given in regulation 2 of the Medical Devices Regulations 2002; or

(b) to the extent necessary for the practical application of that definition, also or instead has the meaning given in regulation 69 of those Regulations;**]**

"the Ministers" is to be construed in accordance with regulation 6(6) to (8);

"name" in relation to a medicinal product means—

(a) where the product has a UK marketing authorisation or traditional herbal registration, the name—

(i) as approved by the licensing authority in granting the authorisation or registration, or

(ii) where that name has been varied since that approval, as so amended;

(b) where the product has an EU marketing authorisation, the name—

(i) as approved by the European Commission in granting the authorisation, or

(ii) where that name has been varied since that approval, as so amended; and

(c) where the product has an Article 126a authorisation, the name—

(i) as approved by the licensing authority to appear on the packaging and any package leaflet of the product under the authorisation, or

(ii) where that name has been varied since that approval, as so amended;

"the Narcotic Drugs Convention" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30thMarch 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972;

"NHS primary dental services" means—

(a) in relation to England, primary dental services under the National Health Service Act 2006;

(b) in relation to Wales, primary dental services under the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, dental services under the National Health Service (Scotland) Act 1978 or personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997 [M25]; and

(d) in relation to Northern Ireland, general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972 or personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997 [M26];

"NHS primary medical services" means—

(a) in relation to England, primary medical services under the National Health Service Act 2006;

(b) in relation to Wales, primary medical services under the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, primary medical services under the National Health Service (Scotland) Act 1978; and

(d) in relation to Northern Ireland, primary medical services under the Health and Personal Social Services (Northern Ireland) Order 1972;

[[F20]"NIMAR" means Northern Ireland MHRA authorised route;**]**

"nurse independent prescriber" means a person who—

(a) is a registered nurse or registered midwife; and

(b) is noted in the professional register as qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent / supplementary prescriber;

[[F21]"nursing home" has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; **]**

[[F29]"occupational health vaccinator" means a person who is employed or engaged by a person operating an occupational health scheme, who is—

(a) a registered nurse, a registered midwife or, in England, a registered nursing associate;

(b) an operating department practitioner, a paramedic or a physiotherapist who is registered in Part 13, 8 or 9 of the Health and Care Professions Council register; or

(c) a pharmacist;**]**

"optometrist independent prescriber" means a person—

(a) who is a registered optometrist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

[[F21]"orphan criteria" means the criteria listed in regulation 50G(2);**]**

[[F21]"orphan marketing authorisation" means a UK marketing authorisation granted under regulation 49(1)(a) in accordance with regulation 58C;**]**

[[F21]"Orphan Regulation" means Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products as it has effect in EU law;**]**

"outer packaging" in relation to a medicinal product means any packaging into which the immediate packaging of the medicinal product is placed;

"package" in relation to a medicinal product, includes—

(a) a container of the product;

(b) any box, packet or other article in which one or more containers of the product are or are to be enclosed; and

(c) any box, packet or other article in which a box, packet or other article mentioned in paragraph (b) or this paragraph is or is to be enclosed;

"package leaflet" in relation to a medicinal product, means a leaflet that accompanies the product and contains information for the user of the product;

"paediatric clinical trial" means a clinical trial conducted in whole or in part on persons under the age of 18 years;

[[F21]"paediatric indication" means a term of a UK marketing authorisation enabling the medicinal product to which the authorisation relates to be used by or administered to persons under the age of 18 years;**]**

"paediatric investigation plan" means a research and development programme with the purpose of generating data determining the conditions in which a medicinal product may be authorised to treat persons under the age of 18 years;

[F21"paediatric population" means that part of the population consisting of persons under the age of 18 years;**]**

"the Paediatric Regulation" means Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004M27;

[F21"parallel import licence" has the meaning given in regulation 48(2);**]**

[F46"paramedic independent prescriber" means a person—

(a) who is a registered paramedic; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a paramedic independent prescriber;**]**

"periodic safety update report" or "PSUR" has the meaning given in regulation 191 (obligation on holder to submit periodic safety update reports: general requirements);

"pharmacist" means—

(a) in relation to Great Britain a person registered in Part 1 F47... of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010 M28; and

(b) in relation to Northern Ireland a person registered in the register of pharmaceutical chemists for Northern Ireland F48... maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 M29;

"pharmacist independent prescriber" means a person who—

(a) is a pharmacist; and

(b) is noted in the relevant register as qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"the Pharmacovigilance Risk Assessment Committee" means the committee of the EMA established by Article 56(1)(aa) of Regulation (EC) No 726/2004;

"pharmacovigilance system" means a system used by the holder of a **[**F49UK marketing authorisation, EU marketing authorisation**]**, traditional herbal registration or Article 126a authorisation, or by the licensing authority, to fulfil the tasks and responsibilities set out in Part 11 and designed to monitor the safety of authorised or registered medicinal products and detect any change to their risk-benefit balance;

"pharmacovigilance system master file" means a detailed description of the pharmacovigilance system used by the holder of a **[**F49UK marketing authorisation, EU marketing authorisation**]**, traditional herbal registration or Article 126a authorisation with respect to one or more authorised or registered medicinal products;

"pharmacy medicine" has the meaning given in regulation 5(5) (classification of medicinal products);

[F50"physiotherapist independent prescriber" means a person—

(a) who is a registered physiotherapist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"podiatrist independent prescriber" means a person—

(a) who is a registered podiatrist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a podiatrist independent prescriber;**]**

"post-authorisation efficacy study" means any study relating to a medicinal product to which a **[**F51UK**]** marketing authorisation relates that is conducted with the aim of considering the efficacy of that product;

"post-authorisation safety study" means any study relating to a medicinal product to which a **[**F49UK marketing authorisation, EU marketing authorisation**]**, traditional herbal registration or Article 126a authorisation relates that is conducted with the aim of—

(a) identifying, characterising or quantifying a safety hazard;

(b) confirming the safety profile of the medicinal product; or

(c) measuring the effectiveness of risk management measures;

"prescription only medicine" has the meaning given in regulation 5(3) (classification of medicinal products);

"product information" in relation to a medicinal product means—

(a) the summary of the product characteristics;

(b) the immediate and outer packaging; and

(c) the package leaflet;

"the professional register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 M30;

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971;

"qualified person", except in relation to the expression "appropriately qualified person", means—

(a) a person who satisfies the requirements specified in Part 1 or 2 of Schedule 7; or

(b) where an application for a licence is made before 30th April 2013, in so far as the application relates to activities in respect of traditional herbal medicinal products, a person who has been engaged in activities in respect of traditional herbal medicinal products equivalent to those in Part 3 of Schedule 7 on or before 30th April 2011 and continues to be so engaged at the time when the application is made;

[F21"qualifying Northern Ireland goods" has the same meaning that it has in the European Union (Withdrawal) Act 2018, including any meaning defined for the purposes of that Act from time to time by regulations made under the power conferred by section 8C(6) of that Act;**]**

[F52"radiation emergency" has the meaning given by regulation 2(1) of the **[**F53Radiation (Emergency Preparedness and Public Information) Regulations 2019**]**;**]**

"radionuclide" means a radioactive isotope;

"radionuclide generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

"radionuclide kit" means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;

"radionuclide precursor" means any radionuclide produced for the radio-labelling of another substance prior to administration, other than a radionuclide that is incorporated in or produced from a generator or is included in a radiopharmaceutical;

"radiopharmaceutical" means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

[F54"registered dietitian" means a person registered in Part 4 of the Health and Care Professions Council register;**]**

"registered midwife" means a person registered in the Midwives Part of the professional register;

"registered nurse" means a person registered in the Nurses Part or the Specialist Community Public Health Nurses Part of the professional register;

"registered optometrist" means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989 M31F55...;

[F56"registered paramedic" means a person who is registered in Part 8 of the Health and Care Professions Council register;**]**

"registered pharmacy" means—

(a) in relation to Great Britain, premises entered in the register required to be kept under article 19 of the Pharmacy Order 2010 for the purposes of sections 74A and 74J of the Medicines Act 1968 M32; and

(b) in relation to Northern Ireland, premises entered in the register required to be kept under section 75 M33 of the Medicines Act 1968;

[F57"registered physiotherapist" means a person registered in Part 9 of the Health and Care Professions Council register;

"registered podiatrist" means a person registered in Part 2 of the Health and Care Professions Council register;

"registered radiographer" means a person registered in Part 11 of the Health and Care Professions Council register;**]**

"registrable homoeopathic medicinal product" means a homoeopathic medicinal product to which regulation 102 applies;

[F58"Regulation (EC) No 726/2004" means Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency **[**F59, as it has effect in EU law**]**;**]**

"Regulation (EC) No 1394/2007" means Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004M34;

"Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products M35**[**F60, as it has effect in EU law**]**;

"the relevant EU provisions" means the provisions of legislation of the European Union relating to medicinal products for human use, except to the extent that any other enactment

provides for any function in relation to any such provision to be exercised otherwise than by the licensing authority;

"relevant European State" means an EEA State or Switzerland;

"relevant medicinal product" has the meaning given by regulation 48;

"the relevant register" means—

(a) in relation to a pharmacist—

(i) in Great Britain, Part 1 of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010, or

(ii) in Northern Ireland, the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

(b) in relation to a registered nurse or registered midwife, the professional register;

(c) in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989 F61...; and

(d) in relation to a chiropodist or podiatrist, a physiotherapist**[**F62, an orthoptist**][**F63, a paramedic**]** or a radiographer, the part of the Health and Care Professions Council register relating to—

(i) chiropodists and podiatrists,

(ii) physiotherapists, F64...

(iii) radiographers**[**F65, F66...

(iv) orthoptists**][**F67, or

(v) paramedics;**]**

"retail pharmacy business" means a business (other than a professional practice carried on by a doctor or dentist) which consists of or includes the retail sale of medicinal products that are not subject to general sale;

"risk management plan" means a detailed description of the risk management system;

"risk management system" means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including an assessment of the effectiveness of those activities and interventions;

"serious adverse reaction" means an adverse reaction that—

(a) results in a person's death;

(b) threatens a person's life;

(c) results in a person being hospitalised as an inpatient or prolongs a person's existing stay in hospital;

(d) results in a person's persistent or significant disability or incapacity; or

(e) results in a congenital anomaly or birth defect;

"special medicinal product" means a product within the meaning of regulation 167 or any equivalent legislation in **[**F68a country**]** other than the United Kingdom;

"substance" means any matter regardless of its origins and includes—

(a) human substances (such as human blood and human blood products);

(b) animal substances (such as micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts and blood products);

(c) vegetable substances (such as micro-organisms, plants, parts of plants, vegetable secretions and extracts);

(d) chemical substances (such as elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis); and

(e) gases and vapours;

"the summary of the product characteristics" in relation to a medicinal product means—

(a) where the product has a UK marketing authorisation or traditional herbal registration, the summary of the product characteristics—

(i) as approved by the licensing authority in granting the authorisation or registration, or

(ii) where the summary has been varied since that approval, as so amended; or

(b) where the product has an EU marketing authorisation, the summary of the product characteristics—

(i) as approved by the European Commission in granting the authorisation, or

(ii) where the summary has been varied since that approval, as so amended;

"supplementary prescriber" means a person who is noted in the relevant register as qualified to order drugs, medicines and appliances as a supplementary prescriber (or, in the case of a registered nurse or registered midwife, as a nurse independent/supplementary prescriber) and is—

(a) a pharmacist;

(b) a registered midwife;

(c) a registered nurse;

(d) a chiropodist, podiatrist, physiotherapist**[**F69, paramedic**]** or radiographer; F70...

(e) a registered optometrist; **[**F71or

(f) a registered dietitian;**]**

[F21"supplementary protection certificate" has the meaning given in section 128B(2) of the Patents Act 1977;**]**

"suspected" in relation to an adverse reaction means that there is at least a reasonable possibility of there being a causal relationship between a medicinal product and an adverse event;

[F72"therapeutic radiographer independent prescriber" means a person—

(a) who is a registered radiographer; and

(b) against whose name is recorded in the relevant register—

(i) an entitlement to use the title "therapeutic radiographer"; and

(ii) an annotation signifying that the person is qualified to order drugs, medicines and appliances as a therapeutic radiographer independent prescriber;**]**

F73...

"traditional herbal medicinal product" means a herbal medicinal product to which regulation 125 applies;

"traditional herbal registration" means a traditional herbal registration granted by the licensing authority under these Regulations **[**F74and—

(a) "THR(UK)" means such a registration in force in the whole United Kingdom;

(b) "THR(GB)" means such a registration in force in Great Britain only;

(c) "THR(NI)" means such a registration in force in Northern Ireland only;**]**

[[F75]"UK marketing authorisation" means a marketing authorisation granted by the licensing authority under Part 5 of these Regulations or Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure) and—

(a) "UKMA(UK)" means such an authorisation in force in the whole United Kingdom;

(b) "UKMA(GB)" means such an authorisation in force in Great Britain only;

(c) "UKMA(NI)" means such an authorisation in force in Northern Ireland only.**]**

[[F21]"under the unfettered access route" means an application for—

(a) a UKMA(GB) under reduced or alternative requirements specified in Part 5 (as referred to in regulation 49(1A));

(b) a COR(GB) under reduced or alternative requirements specified in Part 6 (as referred to in regulation 103(1A));

(c) a THR(GB) under reduced or alternative requirements specified in Part 7 (as referred to in regulation 127(1A));**]**

"vaccine" means an antigenic substance which consists wholly or partly of—

(a) any micro-organisms, viruses or other organisms in any state;

(b) any toxins of microbial origin which have been detoxified (toxoids); or

(c) any extracts or derivatives of any micro-organisms or of any viruses,

being substances which, when administered to human beings, are used for the prevention of specific diseases;

[[F21]"variation to the terms of a UK marketing authorisation" means any change to—

(a) the information provided in accordance with regulations 50 to 57 and Schedule 8; or

(b) the terms of the decision granting the UK marketing authorisation, including the summary of the product characteristics and any conditions, obligations, or restrictions affecting that UK marketing authorisation, or changes to the labelling or the package leaflet connected with changes to the summary of the product characteristics,

and "vary" and "variation" in relation to a UK marketing authorisation are to be construed accordingly;.**]**

[[F21]"withdrawal agreement" has the meaning given in section 39 of the European Union (Withdrawal Agreement) Act 2020;**]**

"wholesale dealer's licence" has the meaning given by regulation 18(1).

(2) In these Regulations, references to distribution of a product by way of wholesale dealing are to be construed in accordance with regulation **[**[F76]18(4) and (5)**]**.

(3) In these Regulations, references to selling by retail, or to retail sale, are references to selling a product to a person who buys it otherwise than for a purpose specified in regulation **[**[F77]18(5)**]**.

(4) In these Regulations, references to supplying anything in circumstances corresponding to retail sale are references to supplying it, otherwise than by way of sale, to a person who receives it otherwise than for a purpose specified in regulation **[**[F78]18(5)**]**;

(5) References in these Regulations to the terms of—

(a) a **[**[F79]UK**]** marketing authorisation include the information supplied in relation to the authorisation in accordance with—

(i) regulation 50 and Schedule 8, and

(ii) (if appropriate) Schedule 10 (national homoeopathic products),

as updated in accordance with regulation 57, as approved upon grant under regulation 49 and as varied under regulation 68;

(b) a certificate of registration include the information supplied in relation to the certificate in accordance with regulation 103, as approved upon grant under regulation 103 and as varied under regulation 110; and

(c) a traditional herbal registration include the information supplied in relation to the registration in accordance with regulation 128 and Schedule 12, as updated in accordance with regulation 129, as approved upon grant under regulation 127 and as varied under regulation 135.

(6) References in these Regulations to a condition of—

(a) a **[**F80UK**]** marketing authorisation is to a condition to which the authorisation is subject by virtue of regulation 59(1) **[**F81, 60(1) or 60A**]**; and

(b) a certificate of registration is to a condition to which the certificate is subject by virtue of regulation 105(1).

(7) For the purposes of these Regulations medicinal products are of the same description if—

(a) they are manufactured to the same specification, and

(b) they are in the same pharmaceutical form.

[F82(8) **[**F83Subject to regulation C17(6), references**]** in these Regulations to—

(a) good manufacturing practice for active substances relate to the principles and guidelines for good manufacturing practice adopted by the European Commission under the third paragraph of Article 47 of the 2001 Directive;

(b) good distribution practice for active substances relate to the guidelines on good distribution practices for active substances adopted by the European Commission under the fourth paragraph of Article 47 of the 2001 Directive.**]**

[F84(9) Unless otherwise provided, any provision of an EU Regulation made applicable to a UKMA(NI), COR(NI) or THR(NI) by virtue of Article 5(4) of, and Annex 2 to, the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement applies equally in respect of a UKMA(UK), COR(UK) or THR(UK).**]**

Textual Amendments

F19 Words in reg. 8(1) substituted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **2(2)**

F20 Words in reg. 8(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **4**

F21 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(i)**

F23 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(za)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in reg. 8(1) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(ii)**

F25 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(iii)**

F26 Words in reg. 8(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(4)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(zb)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F28 Words in reg. 8(1) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **3** and words in reg. 8(1) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **3**

F29 Words in reg. 8(1) inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **3** and inserted (N.I) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **3**

F30 Words in reg. 8(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(4)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in reg. 8(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(4)(vi)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in reg. 8(1) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **4** (with reg. 19)

F33 Words in reg. 8(1) inserted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 8(1)**

F34 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(iv)**

F35 Words in reg. 8(1) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(v)**

F36 Words in reg. 8(1) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **3(2)(a)** and words in reg. 8(1) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **3(2)(a)**

F37 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(vi)**

F38 Words in reg. 8(1) substituted (1.4.2016) by The Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190), regs. 1, **62**

F39 Words in reg. 8(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(a)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F40 Words in reg. 8(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 30(a)**; S.I. 2019/1436, reg. 2(b)

F41 Words in reg. 8(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 42(a)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F42 Words in reg. 8(1) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 2 para. 30(b)**; S.I. 2019/1436, reg. 2(b)

F43 Words in reg. 8(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F44 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(vii)**

F45 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F46 Words in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(a)** and words in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(a)**

F47 Words in reg. 8(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 42(b)(i)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F48 Words in reg. 8(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 42(b)(ii)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F49 Words in reg. 8(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(e)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F50 Words in reg. 8(1) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(a)(viii)**

F51 Word in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(b)** and words in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(b)**

F53 Words in reg. 8(1) substituted (E.W.S.) (22.5.2019) by The Radiation (Emergency Preparedness and Public Information) Regulations 2019 (S.I. 2019/703), reg. 1(1), **Sch. 10 para. 10(2)** (with reg. 3)

F54 Words in reg. 8(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **3(2)(b)** and words in reg. 8(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **3(2)(b)**

F55 Words in reg. 8(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 5 para. 24(a)** (with reg. 12A, Sch. 5 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 13); 2020 c. 1, Sch. 5 para. 1(1)

F56 Words in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(c)** and words in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(c)**

F57 Words in reg. 8(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **3(2)(c)** and words in reg. 8(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **3(2)(c)**

F58 Words in reg. 8(1) substituted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **2(3)**

F59 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

F60 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(h)**; 2020 c. 1, Sch. 5 para. 1(1)

F61 Words in reg. 8(1) omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 5 para. 24(b)** (with reg. 12A, Sch. 5 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 13); 2020 c. 1, Sch. 5 para. 1(1)

F62 Words in reg. 8(1) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **3(2)(b)(i)** and words in reg. 8(1) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **3(2)(b)(i)**

F63 Words in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(d)(i)** and words in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(d)(i)**

F64 Word in reg. 8(1) omitted (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **3(2)(b)(ii)** and word in reg. 8(1) omitted (N.I.) (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **3(2)(b)(ii)**

F65 Words in reg. 8(1) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **3(2)(b)(iii)** and words in reg. 8(1) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **3(2)(b)(iii)**

F66 Word in reg. 8(1) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(d)(ii)** and word in reg. 8(1) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(d)(ii)**

F67 Words in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(d)(iii)** and words in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(d)(iii)**

F68 Words in reg. 8(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F69 Word in reg. 8(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **3(2)(e)** and word in reg. 8(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **3(2)(e)**

F70 Word in reg. 8(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **3(2)(d)(i)** and word in reg. 8(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **3(2)(d)(i)**

F71 Words in reg. 8(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **3(2)(d)(ii)** and words in reg. 8(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **3(2)(d)(ii)**

F72 Words in reg. 8(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **3(2)(a)** and words in reg. 8(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **3(2)(a)**

F73 Words in reg. 8(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(4)(xiii)**; 2020 c. 1, Sch. 5 para. 1(1)

F74 Words in reg. 8(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(j)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(vi)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Words in reg. 8(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(3)(k)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(b)(vii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F76 Words in reg. 8(2) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **3(2)** and words in reg. 8(2) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **3(2)**

F77 Word in reg. 8(3) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **3(3)** and word in reg. 8(3) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **3(3)**

F78 Word in reg. 8(4) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **3(4)** and word in reg. 8(4) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **3(4)**

F79 Word in reg. 8(5)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Word in reg. 8(6)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F81 Words in reg. 8(6)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F82 Reg. 8(8) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **3(b)**

F83 Words in reg. 8(8) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(7)**; 2020 c. 1, Sch. 5 para. 1(1)

F84 Reg. 8(9) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **10(8)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 7(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Modifications etc. (not altering text)

C3 Reg. 8(1) applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M6 2006 c.41.
M7 S.I. 1972/1265 (N.I. 14).
M8 2009 c.1 (N.I.).
M9 2006 c.42.
M10 1978 c.29.
M11 OJ No L 121, 1.5.2001, p.34. Directive 2001/20/EC was last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).
M12 S.I. 2004/1031, to which there are amendments not relevant to these Regulations.
M13 1984 c.24. Section 14 was substituted by the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) articles 2 and 6 and further amended by the European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regulations 109 and 111. Other amendments of the Dentists Act are not relevant to these Regulations.
M14 2003 c.21.
M15 S.I. 2002/254, as amended by S.I. 2009/1182. There are other amendments that are not relevant.
M16 S.I. 2010/231.
M17 1993 c.21. Section 41 was amended by S.I. 2007/3101 regulations 206 and 214.
M18 1994 c.17.
M19 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.
M20 S.I. 2006/1440, Schedule.
M21 2006 c.41.
M22 2006 c.42.
M23 1978 c.29. Concurrent functions under section 36(1) were transferred to the National Waiting Times Board by article 4(2)(c) and (4) of S.S.I. 2002/305.
M24 S.I. 1972/1265 (N.I. 14), as amended by S.I. 1984/1158 (N.I. 8), S.I. 1986/595 (N.I. 4) and 2004/311 (N.I. 2).
M25 1997 c.46.
M26 S.I. 1997/1177 (N.I. 7).
M27 OJ No L 378, 27.12.2006, p.1. Regulation (EC) No 1901/2006, as amended by Regulation (EC) No 1902/2006 (OJ No L 378, 27.12.2006, p.20) .
M28 S.I. 2010/231.
M29 S.I. 1976/1213 (N.I. 22), as amended by S.R. 2008 No. 192.
M30 S.I. 2002/253, as amended by S.I. 2009/1182.
M31 1989 c.44; section 7(a) was amended by S.I. 2005/848, articles 2 and 7(1).
M32 1968 c.67. Sections 74A and 74J were inserted by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231.
M33 Section 75 was amended by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231
M34 OJ No L 324, 10.12.2007, p.121.
M35 OJ No L 334, 12.12.2008, p.7.

PART 2

Administration

Commission on Human Medicines

9.—(1) There is to continue to be a body known as the Commission on Human Medicines (referred to in these Regulations as "the Commission").

(2) The Commission is to perform the functions conferred on it by these Regulations.

(3) The Commission is to have at least eight members.

(4) The members of the Commission are to be appointed by the Ministers.

(5) The Ministers must appoint one of the members of the Commission to chair it.

(6) The Ministers must consult the Scottish Ministers before exercising their functions under paragraphs (4) and (5).

Functions of the Commission

10.—(1) The Commission must give advice to either or both of the Ministers in relation to the matters listed in paragraph (2) if—

(a) the Minister, or Ministers, request it; or

(b) the Commission considers it appropriate to give it.

(2) The matters mentioned in paragraph (1) are matters—

(a) relating to the execution of any duty imposed by these Regulations or the Clinical Trials Regulations;

(b) relating to the exercise of any power conferred by these Regulations or the Clinical Trials Regulations; or

(c) otherwise relating to medicinal products.

(3) Without prejudice to paragraphs (1) and (2), or to any other functions conferred on the Commission by or under these Regulations, the Commission must—

(a) give advice with respect to the safety, quality and efficacy of medicinal products; and

(b) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given.

(4) The Commission must also advise the licensing authority if—

(a) the licensing authority is required under Schedule 11 (advice and representations) or the Clinical Trials Regulations to consult the Commission about any matter arising under those provisions; or

(b) the licensing authority consults the Commission about any matter arising under those provisions.

British Pharmacopoeia Commission

11.—(1) There is to continue to be a committee called the British Pharmacopoeia Commission (referred to as "the BPC" in this regulation).

(2) The BPC is to continue to have the following functions—

(a) the preparation under regulation 317(1) of editions of the British Pharmacopoeia;

(b) the preparation of compendia under regulation 317(3);

(c) the preparation under regulation 318 (which provides for the preparation and publication of lists of names to be used as headings to monographs in the British Pharmacopoeia) of lists of names; and

(d) the preparation of any other document under regulation 319.

(3) The BPC is to have at least eight members.

(4) The members of the BPC are to be appointed by the Ministers.

(5) The Ministers must appoint one of the members of the BPC to chair it.

(6) The Ministers must consult the Scottish Ministers before exercising their functions under paragraphs (4) and (5).

(7) In this regulation, a reference to preparation includes revision or amendment.

Reporting to Ministers

12.—(1) In this Part "advisory body" means—

(a) the Commission, or

(b) the British Pharmacopoeia Commission.

(2) Each advisory body must give a report to the Ministers each year about—

(a) the performance of its functions; and

(b) the performance of the functions of any expert advisory group appointed by it under regulation 14 (including any expert advisory group appointed jointly with the other advisory body).

(3) Each advisory body must give its report to the Ministers at the time specified by the Ministers.

(4) The Secretary of State must lay a copy of each report before Parliament.

Co-option of additional members of advisory bodies

13.—(1) An advisory body may co-opt one or more additional members for the purposes of a meeting.

(2) A person co-opted as a member of an advisory body for the purposes of a meeting ceases to be a member at the end of the meeting.

Appointment of expert advisory groups

14.—(1) An advisory body, or the advisory bodies acting jointly, may with the approval of the licensing authority appoint one or more sub-committees, to be known as expert advisory groups.

(2) The licensing authority may direct an advisory body to appoint an expert advisory group to advise on the matters specified in the direction.

(3) An expert advisory group may include, or consist of, persons who are not members of the advisory body or bodies which appointed the expert advisory group.

(4) The advisory body or bodies which appointed the expert advisory group must appoint a member of the group as its chair.

(5) The chair of an expert advisory group may co-opt additional members of the group for the purposes of a meeting.

(6) Before co-opting additional members under paragraph (5) the chair of the group must consult the chair of the advisory body or bodies which appointed the group.

(7) A person co-opted as a member of an expert advisory group for the purposes of a meeting ceases to be a member of the group at the end of the meeting.

Delegation of functions to expert advisory groups

15.—(1) An advisory body may delegate any of its functions, other than the functions specified in paragraph (2), to an expert advisory group.

(2) The functions which may not be delegated are functions of providing advice to the licensing authority in any case where the licensing authority is required to consult the advisory body under—

(a) Schedule 11 (advice and representations); and

(b) the Clinical Trials Regulations.

(3) But an advisory body may arrange for an expert advisory group to provide advice to the advisory body in relation to the performance of a function referred to in paragraph (2).

Further provision about advisory bodies and expert advisory groups etc

16. Schedule 2 (which makes further provision about advisory bodies and expert advisory groups, and provision about payment and expenses of expert committees appointed by the licensing authority) has effect.

PART 3

[F85Manufacture and distribution of medicinal products and active substances

Textual Amendments

F85 Pt. 3 heading and Pt. 3 Ch. 1 inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **4**

CHAPTER 1

Interpretation

Interpretation

A17. In this Part "manufacture", in relation to an active substance, includes any process carried out in the course of making the substance and the various processes of dividing up, packaging, and presentation of the active substance.**]**

[F86Chapter 1A

Good manufacturing practice and good distribution practice

Textual Amendments

F86 Pt. 3 Ch. 1A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **13** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 8**); 2020 c. 1, **Sch. 5 para. 1(1)**

Regulations on good manufacturing practice

B17.—(1) The Secretary of State may by regulations in respect of Great Britain set out principles and guidelines of good manufacturing practice in respect of medicinal products and investigational medicinal products.

(2) Regulations under paragraph (1) may in particular make provisions as to—

(a) inspections;

(b) compliance with good manufacturing practice and, where relevant, the UK marketing authorisation or EU marketing authorisation;

(c) quality assurance systems;

(d) personnel;

(e) premises and equipment;

(f) documentation;

(g) production;

(h) quality control;

(i) the contracting out of work;

(j) complaints and product recall;

(k) self-inspection.

(3) Subject to any provision made in regulations under paragraph (1), the principles and guidelines set out in the Good Manufacturing Practice Directive have effect in Great Britain on and after IP completion day as they had effect immediately before IP completion day, but subject to the modifications specified in Schedule 2A.

(4) The Secretary of State may by regulations in respect of Great Britain amend or revoke Schedule 2A.

Guidelines on good manufacturing practice and good distribution practice

C17.—(1) The licensing authority may publish in relation to the manufacture or assembly of a medicinal product in, or import to, Great Britain—

(a) detailed guidelines of good manufacturing practice in respect of medicinal products, and investigational medicinal products, referred to in Article 46(f) of the 2001 Directive, including guidelines as to the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients;

(b) principles and guidelines of good manufacturing practice for active substances, referred to in the first paragraph of point (f) of Article 46 and in Article 46b of that Directive;

(c) principles and guidelines of good distribution practice referred to in the first paragraph of point (f) of Article 46, and Article 84, of that Directive.

(2) Guidelines or principles under paragraph (1) may replace, amend or otherwise modify any guidelines or principles published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive.

(3) Unless replaced by principles or guidelines published under paragraph (1), principles and guidelines published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive, as they applied immediately before IP completion day, continue to apply on and after IP completion day (subject to any amendments or modifications published under paragraph (1)).

(4) Before exercising the power under paragraph (1), the licensing authority must consult such persons as it considers appropriate.

(5) The licensing authority may only exercise its power under paragraph (1) if it considers that it is necessary in order to take account of technical or scientific progress.

(6) If the licensing authority publishes principles and guidelines under paragraph (1), any reference in these Regulations to any principle or guideline adopted under the provisions of the

2001 Directive specified in those paragraphs is instead to be read as a reference to the principle or guideline published under paragraph (1), or that principle or guideline as amended or modified (as the case may be).**]**

[F87CHAPTER 2**]**

Manufacturing and wholesale dealing

Textual Amendments

F87 Pt. 3 Ch. 2 heading inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **4**

Grant etc of licences

Manufacturing of medicinal products

17.—**[**F88(1) A person may not except in accordance with a licence (a "manufacturer's licence")—

(a) manufacture a medicinal product,

(b) assemble a medicinal product,

(c) import a medicinal product into Great Britain from a country other than—

(i) Northern Ireland, or

(ii) an approved country for import,

(d) import a medicinal product into Northern Ireland from a country other than an EEA State, or

(e) possess a medicinal product for the purpose of any activity in sub-paragraphs (a) to (d).**]**

(2) Paragraph (1) is subject to **[**F89paragraphs (3) to (9)**]** .

(3) Paragraph (1) applies in relation to an investigational medicinal product only—

(a) if the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration; and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that authorisation, certificate or registration.

(4) In paragraph (3), "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

[F90(aa) a UK marketing authorisation; or**]**

(b) an EU marketing authorisation.

(5) Paragraph (1) does not apply to a person who, in connection with the importation of a medicinal product F91...—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(6) Paragraph (1) does not apply to a person who imports a medicinal product for administration to himself or herself or to any other person who is a member of that person's household.

[F92(7) Paragraph (1) does not apply to imports into Northern Ireland from Great Britain of—

(a) special medicinal products, and

(b) medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(8) For the purposes of paragraph (7) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.**]**

[[F93](9) Paragraph (1)(d) does not apply to the importation of a medicinal product into Northern Ireland from Great Britain by the holder of a wholesale dealer's licence, where the following conditions are met—

(a) the medicinal product has undergone—

(i) in an EEA State, the quality control testing provided for by Article 51 of the 2001 Directive, or

(ii) in the United Kingdom, checks in accordance with these Regulations and the requirements of the marketing authorisation relating to the product and that these are appropriately certified;

(b) the batch release of the medicinal product has been undertaken—

(i) in Northern Ireland or an EEA State, by a qualified person in accordance with Article 51(1) of the 2001 Directive, and it is accompanied by the appropriate control reports, or

(ii) in Great Britain, by a qualified person applying equivalent standards;

(c) the medicinal product has a UKMA(UK) or UKMA(NI);

(d) the importation of the medicinal product is with a view to its sale or supply in Northern Ireland only; and

(e) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive, that the features specified in paragraph 18A of Schedule 24 are affixed on the packaging.**]**

Textual Amendments

F88 Reg. 17(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F89 Words in reg. 17(2) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **3(2)**

F90 Reg. 17(4)(aa) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F91 Words in reg. 17(5) omitted (31.12.2020) by virtue of S.I. 2019/775, reg. 14(5) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(d)**)

F92 Reg. 17(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **14(6)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 9(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F93 Reg. 17(9) inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **3(3)**

[F94Wholesale dealing in medicinal products

18.—(1) A person may not except in accordance with a licence (a "wholesale dealer's licence")—

(a) distribute a medicinal product by way of wholesale dealing; F95...

(b) possess a medicinal product for the purpose of such [F96distribution; F97...]

[F98(c) import a medicinal product into Great Britain from an approved country for import][F99; or

(d) supply a listed NIMAR product from Great Britain to Northern Ireland.]

(2) Paragraph (1)—

(a) does not apply—

(i) to anything done in relation to a medicinal product by the holder of a manufacturer's licence in respect of that product,

(ii) where the product concerned is an investigational medicinal product, or

(iii) if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source; and

(b) is subject to regulation 19.

[F100(2A) Paragraph (1)(c) does not apply to imports into Great Britain from an EEA State of medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(2B) For the purposes of paragraph (2A) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.]

(3) Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, is not to be taken to be in accordance with a wholesale dealer's licence unless the distribution is carried on, or as the case may be the product held, at premises located in the UK and specified in the licence.

(4) In these Regulations a reference to distributing a product [F101(including a listed NIMAR product)] by way of wholesale dealing is a reference to—

(a) selling or supplying it; or

(b) procuring or holding it or exporting it for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (5).

(5) Those purposes are—

(a) selling or supplying the product; or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

[F102(6) A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession of a medicinal product for the purpose of such distribution, unless—

(a) in the case of a product for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration is in force in respect of the product, F103...

(b) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product, **[**[F104]or

(c) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) is in force in respect of the product,**]**

but this is subject to the exceptions in regulation 43(6).**]**

(7) In **[**[F105]paragraph (6)(b)**]**, "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority of a member State in accordance with the 2001 Directive; or

(b) an EU marketing authorisation.**]**

Textual Amendments

F94 Reg. 18 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **5**

F95 Word in reg. 18(1)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F96 Words in reg. 18(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F97 Word in reg. 18(1)(b) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(i)**

F98 Reg. 18(1)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(c)** (as amended S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(a)(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F99 Reg. 18(1)(d) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(ii)**

F100 Reg. 18(2A)(2B) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F101 Words in reg. 18(4) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(b)**

F102 Reg. 18(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(3)** (as substituted by (S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F103 Word in reg. 18(6)(a) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(i)**

F104 Reg. 18(6)(c) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(ii)**

F105 Words in reg. 18(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F106]Approved country for import

18A.—(1) The licensing authority must—

(a) publish a list of countries from which medicinal products may be imported under a wholesale dealing licence ("approved country for import list"); and

(b) only include in that list a country which is included in the approved country for batch testing list.

(2) In order to determine whether a country should be included in the approved country for import list, the licensing authority may, in particular, take into account—

(a) the country's system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product;

(b) the country's rules for good distribution practice;

(c) the regularity of inspections to verify compliance with good distribution practice;

(d) the effectiveness of enforcement of good distribution practice;

(e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributers of medicinal products;

(f) any on-site review of that country's regulatory system undertaken by the licensing authority;

(g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and

(h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

(a) remove a country from the approved country for import list if that country is removed from the approved country for batch testing list;

(b) in any event review the countries it has included in the approved country for import list to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(c) undertake that review at least every three years beginning with the date on which that country is included in that list.**]**

Textual Amendments

F106 Reg. 18A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **16**; 2020 c. 1, Sch. 5 para. 1(1)

Exemptions from requirement for wholesale dealer's licence

19.—(1) Regulation 18 does not apply to the sale or offer for sale of a medicinal product by way of wholesale dealing, or possession for the purpose of such sale or offer, where paragraph (2) applies and the person selling or offering the product for sale is—

[F107(a) the holder of—

(i) in the case of a product for sale or supply in Great Britain **[**F108(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation") which relates to the product, or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation") which relates to the product,

including a holder of an authorisation who manufactured or assembled the product; or**]**

(b) a person who is not the holder of an authorisation in relation to the product but manufactured or assembled the product **[**F109in the United Kingdom**]** to the order of a person who is the holder of an authorisation relating to the product.

(2) This paragraph applies if—

(a) until the sale, the medicinal product has been kept on the premises of the person who manufactured or assembled the product (in this regulation referred to as "authorised premises"); and

(b) those premises are premises authorised for use for manufacture or assembly by that person's manufacturer's licence.

(3) For the purposes of this regulation, a medicinal product is regarded as having been kept on authorised premises at a time when—

(a) it was being moved from one set of authorised premises to another, or from one part of authorised premises to another part; or

(b) it was being moved from authorised premises by way of delivery to a purchaser.

(4) Regulation 18 does not apply to a person who in connection with the importation of a medicinal product—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, handles the product where the product is imported solely to the order of another person who intends to sell the product or offer it for sale by way of wholesale dealing or to distribute it in any other way.

[F110(4A) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be used for vaccination or immunisation against coronavirus or influenza virus, where the person distributing the medicinal product—

(a) was supplied with the medicinal product for the purposes of the administration of it under relevant arrangements;

(b) is supplying the medicinal product for the purposes of the administration of it by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and

(c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4B) Regulation 18 does not apply in connection with the distribution by way of wholesale dealing of a medicinal product to be supplied or administered in accordance with a protocol of the type mentioned in regulation 247, where the person distributing the medicinal product—

(a) was supplied with the medicinal product for the purposes of the supply or administration of it to a patient under relevant arrangements;

(b) is supplying the medicinal product for the purposes of the supply or administration of it to a patient by the person to whom it is being supplied (or by a person employed or engaged by them) under relevant arrangements; and

(c) is authorised by the body making the arrangements to supply the medicinal product as mentioned in sub-paragraph (b) under the relevant arrangements.

(4C) In this regulation, "relevant arrangements" means—

(a) arrangements for the provision of services as part of—

(i) in England, the health service as defined by section 275(1) of the National Health Service Act 2006,

(ii) in Scotland, the health service as defined by section 108(1) of the National Health Service (Scotland) Act 1978,

(iii) in Wales, the health service as defined by section 206(1) of the National Health Service (Wales) Act 2006, and

(iv) in Northern Ireland, the system of health and social care promoted under section 2(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009; or

(b) arrangements for the provision of services (otherwise than as mentioned in sub-paragraph (a)) as part of the medical services of Her Majesty's Forces.

(4D) Paragraphs (4A) to (4C) cease to have effect on 1st April **[**F111**]**2024**.]**

F112(5) . . . . . .

[F113(6) Regulation 18 does not apply to a person ("P") who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P's household.**]**

Textual Amendments

F107 Reg. 19(1)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **17(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(a)**)

F108 Words in reg. 19(1)(a)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **6**

F109 Words in reg. 19(1)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **17(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F110 Reg. 19(4A)-(4D) inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **4** and reg. 19(4A)-(4D) inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **4**

F111 Word in reg. 19(4D) substituted (31.3.2022) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **4**

F112 Reg. 19(5) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **6**

F113 Reg. 19(6) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **17(4)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(b)**)

Mixing of medicines

20.—(1) Regulation 17(1) (manufacturing of medicinal products) does not apply to the mixing of medicines by—

(a) a nurse independent prescriber;

(b) a pharmacist independent prescriber;

(c) a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient;

[F114(ca) physiotherapist independent prescriber;

(cb) podiatrist independent prescriber;**]**

[F115(cc) a therapeutic radiographer independent prescriber;**]**

[F116(cd) a paramedic independent prescriber;**]**

(d) a person acting in accordance with the written directions of a—

(i) doctor,

(ii) dentist,

(iii) nurse independent prescriber, [F117]...

[[F118](iv) pharmacist independent prescriber,

(v) physiotherapist independent prescriber, [F119]...

(vi) podiatrist independent prescriber; or]

[[F120](vii) therapeutic radiographer independent prescriber; or]

[[F121](viii) paramedic independent prescriber; or]

(e) a person acting in accordance with the written directions of a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient.

(2) In this regulation "mixing of medicines" means the combining of two or more medicinal products together for the purposes of administering them to meet the needs of an individual patient.

Textual Amendments

F114 Reg. 20(1)(ca)(cb) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(a)**

F115 Reg. 20(1)(cc) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(a)** and reg. 20(1)(cc) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(a)**

F116 Reg. 20(1)(cd) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **4(2)(a)** and reg. 20(1)(cd) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **4(2)(a)**

F117 Word in reg. 20(1)(d)(iii) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(b)**

F118 Reg. 20(1)(d)(iv)-(vi) substituted for reg. 20(1)(d)(iv) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **7(c)**

F119 Word in reg. 20(1)(d)(v) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(b)(i)** and word in reg. 20(1)(d)(v) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(b)(i)**

F120 Reg. 20(1)(d)(vii) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **5(2)(b)(ii)** and reg. 20(1)(d)(vii) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **5(2)(b)(ii)**

F121 Reg. 20(1)(d)(viii) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **4(2)(b)** and reg. 20(1)(d)(viii) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **4(2)(b)**

Application for manufacturer's or wholesale dealer's licence

21.—(1) An application for a grant of a licence under this Part must—

(a) be made to the licensing authority;

(b) be made in the way and form specified in Schedule 3; and

(c) contain or be accompanied by the information, documents, samples and other material specified in that Schedule.

(2) An application must indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

Factors relevant to determination of application for manufacturer's or wholesale dealer's licence

22.—(1) In dealing with an application for a manufacturer's licence the licensing authority must in particular take into consideration—

(a) the operations proposed to be carried out under the licence;

(b) the premises in which those operations are to be carried out;

(c) the equipment which is or will be available on those premises for carrying out those operations;

(d) the qualifications of the persons under whose supervision the operations will be carried out; and

(e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.

(2) In dealing with an application for a wholesale dealer's licence the licensing authority must in particular take into consideration—

(a) the premises on which medicinal products of the descriptions to which the application relates will be stored;

(b) the equipment which is or will be available for storing medicinal products on those premises;

(c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and

(d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

Grant or refusal of licence

23.—(1) Subject to the following provisions of these Regulations, on an application to the licensing authority for a licence under this Part the licensing authority may—

(a) grant a licence containing such provisions as it considers appropriate; or

(b) refuse to grant a licence if having regard to the provisions of these Regulations [F122]... it considers it necessary or appropriate to do so.

(2) The licensing authority must grant or refuse an application for a licence under this Part within the period of 90 days beginning immediately after the day on which it receives the application.

(3) Paragraph (2) applies to an application only if the requirements of Schedule 3 have been met.

(4) If a notice under regulation 30 requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (2).

(5) In paragraph (4), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(6) The licensing authority must give the applicant a notice stating the reasons for its decision in any case where—

(a) the licensing authority refuses to grant an application for a licence; or

(b) the licensing authority grants a licence otherwise than in accordance with the application and the applicant requests a statement of its reasons.

Textual Amendments

F122 Words in reg. 23(1)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **19**; 2020 c. 1, Sch. 5 para. 1(1)

Standard provisions of licences

24.—(1) The standard provisions set out in Schedule 4 may be incorporated by the licensing authority in a licence under this Part granted on or after the date on which these Regulations come into force.

(2) The standard provisions may be incorporated in a licence with or without modifications and either generally or in relation to medicinal products of a particular class.

[F123(3) In Schedule 4, in relation to a licence holder in Great Britain, references to the principles and guidelines set out in the Good Manufacturing Practice Directive are to those principles and guidelines as they apply under or by virtue of regulation B17.**]**

Textual Amendments

F123 Reg. 24(3) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **19A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 13**)

Duration of licence

25. A licence granted under this Part remains in force until—

(a) the licence is revoked by the licensing authority; or

(b) the licence is surrendered by the holder.

General power to suspend, revoke or vary licences

26.—(1) The licensing authority may in accordance with the procedure specified in regulation 27—

(a) suspend a licence under this Part for such period as the authority thinks fit;

(b) revoke a licence under this Part; or

(c) vary the provisions of a licence under this Part.

(2) The suspension or revocation of a licence may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the grounds specified in—

(a) paragraph (4) (in relation to either a manufacturer's licence or a wholesale dealer's licence);

(b) paragraph (5) (in relation to a manufacturer's licence); or

(c) paragraph (6) (in relation to a wholesale dealer's licence).

(4) Those grounds are that—

(a) the information in the application as a result of which the licence was granted was false or incomplete in a material respect;

(b) a material change of circumstances has occurred in relation to any of the matters stated in the application;

(c) the holder of the licence has materially contravened a provision of it; or

(d) the holder of the licence has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the licence relates when required to do so under regulation 30(2).

(5) In relation to a manufacturer's licence, the powers conferred by this regulation may also be exercised on either or both of the following grounds—

[F124(a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), F125...

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI) or a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation"), **[**F126or

(iii) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) (an "authorisation"),**]**

and has habitually failed to comply with the provisions of that authorisation; or**]**

(b) that the holder of the manufacturer's licence does not have appropriate facilities to carry out processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this regulation may also be exercised on the grounds that the equipment and facilities available to the holder of the licence for storing or distributing medicinal products are inadequate to maintain the quality of medicinal products of one or more descriptions to which the licence relates.

Textual Amendments

F124 Reg. 26(5)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **21** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 15**)

F125 Word in reg. 26(5)(a)(i) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **7(a)**

F126 Reg. 26(5)(a)(iii) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **7(b)**

Procedure where licensing authority proposes to suspend, revoke or vary licence

27.—(1) This regulation applies where—

(a) the provisions of regulation 28 do not apply; and

(b) the licensing authority proposes to suspend, vary or revoke a licence under regulation 26.

(2) The licensing authority must notify the licence holder in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The licence holder may before the date specified in the notice—

(a) make written representations to the licensing authority with respect to the proposal; or

(b) notify the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations.

(4) If the licence holder makes written representations in accordance with paragraph 3(a) the licensing authority must take those representations into account before making a decision in the matter.

[F127(5) If the licence holder notifies the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph (3)(b)—

(a) Schedule 5 has effect; and

(b) the licence holder must pay a fee for a review upon oral representations in accordance with the Fees Regulations.**]**

(6) If the licensing authority proceeds to suspend, revoke or vary a licence in accordance with the provisions of regulation 26 it must give a notice to the licence holder.

(7) The notice must—

(a) give particulars of the suspension, revocation or variation; and

(b) give reasons for the decision to suspend, revoke or vary the licence.

(8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Textual Amendments

F127 Reg. 27(5) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **8**

Suspension of licence in cases of urgency

28.—(1) Notwithstanding anything in the preceding provisions of this Part, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under this Part with immediate effect, the licensing authority may do so for a period not exceeding three months.

(2) This paragraph applies where—

(a) a licence has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether the licence should be further suspended, revoked or varied.

(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 27 (but this is subject to paragraphs (4) and (5)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 27 and any proceedings under that regulation have not been finally disposed of before the end of the period for which the licence was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 27 to suspend, vary or revoke the licence is made on an application to the High Court under regulation 322(4) paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a).

Variation of licence on the application of the holder

29.—(1) This regulation applies if the holder of a licence under this Part applies to the licensing authority for a variation of the licence.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant;

(d) be accompanied by such information as may be required to enable the licensing authority to consider the application; and

(e) be accompanied by the required fee (if any).

(3) The licensing authority must consider an application made in accordance with this regulation.

(4) If paragraph (5) applies, the licensing authority must vary the licence or refuse to vary it before the end of the period allowed for considering the application.

(5) This paragraph applies to a variation which would have the effect of altering—

(a) the types of medicinal product in respect of which the licence was granted;

(b) any operation carried out under the licence; [F128]...

(c) any premises, equipment or facilities in respect of which the licence was **[**[F129]granted; or**]**

[[F130](d) the responsible person (import) under regulation 45AA.**]**

(6) The period allowed for consideration of an application under this regulation is—

(a) in a case where the licensing authority considers that it is necessary to inspect premises to which the licence relates, 90 days beginning with the day after the date when the licensing authority receives the application; and

(b) in any other case 30 days beginning with that day.

(7) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application.

(8) If a notice under paragraph (7) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (6).

(9) In paragraph (8), the "information period" means the period—

(a) beginning with the day on which the notice is given; and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(10) Nothing in this regulation affects the powers conferred by regulation 26.

Textual Amendments

F128 Word in reg. 29(5)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F129 Words in reg. 29(5)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F130 Reg. 29(5)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **23(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Provision of information

30.—(1) Where an application has been made to the licensing authority for a licence under this Part, the licensing authority may, before determining the application, require the applicant to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(2) The licensing authority may give a notice to the holder of a licence under this Part, requiring the holder to provide information of a kind specified in the notice within the period specified in the notice.

(3) A notice under paragraph (2) may not be given to the holder of a licence unless it appears to the licensing authority, or representations are made to the licensing authority by the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, that it is necessary for the licensing authority to consider whether the licence should be varied, suspended or revoked.

(4) A notice under paragraph (2) may specify information which the licensing authority, or the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, thinks necessary for considering whether the notice should be varied, suspended or revoked.

Miscellaneous and offences

Certification of manufacturer's licence

31.—(1) The licensing authority must issue a certificate in accordance with the following paragraphs of this regulation in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products if requested to do so by—

(a) subject to paragraph (5), the holder of the licence;

(b) a person who intends to export a medicinal product manufactured or assembled by the holder under the licence; or

(c) the competent authorities of a country other than **[**F131the United Kingdom**]** into which a medicinal product manufactured or assembled under the licence is, or is proposed to be, imported.

(2) The certificate must contain —

(a) information sufficient to identify the holder of the manufacturer's licence;

(b) details of the medicinal products that may be manufactured or assembled under the licence; and

(c) any other information concerning the holder, the product or the licence that the licensing authority thinks it appropriate to include, including information relating to clinical trials.

(3) If—

(a) a request is made—

(i) under paragraph (1)(a) in relation to the export or the proposed export of a product, or

(ii) under paragraph (1)(b) or (c); and

(b) there is a **[**F132UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]** or a traditional herbal registration in force for any product to which the licence relates,

the certificate must be accompanied by the summary of the product characteristics relating to that product.

(4) The licensing authority may restrict the information provided under sub-paragraphs (2)(a) and (b) and paragraph (3) to information relating to the specific medicinal products mentioned in the request made under paragraph (1).

(5) A licence holder who makes a request under paragraph (1) must—

(a) produce to the licensing authority a **[**F133UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]**, certificate of registration or traditional herbal registration in relation to any product to which the certificate is to relate; or

(b) make a declaration to the licensing authority explaining why no **[**F134UK marketing authorisation, EU marketing authorisation, Article 126a authorisation**]**, certificate of registration or traditional herbal registration is available.

(6) The licensing authority must have regard to the prevailing administrative arrangements of the World Health Organisation when issuing the certificate.

Textual Amendments

F131 Words in reg. 31(1)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F132 Words in reg. 31(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F133 Words in reg. 31(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F134 Words in reg. 31(5)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **24(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 16**); 2020 c. 1, **Sch. 5 para. 1(1)**

Sale and supply of starting materials

F135**32.** . . . . . .

Textual Amendments

F135 Reg. 32 revoked (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **35**

Offence concerning data for advanced therapy medicinal products

33.—(1) A person who is, or immediately before its revocation or suspension was, the holder of a manufacturer's licence relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) keep the data referred to in **[**[F136]paragraph 8 of Schedule 6**]** in accordance with the requirements of **[**[F137]paragraph 9 of that Schedule**]**; or

(b) transfer the data referred to in **[**[F138]paragraph 8**]** to the licensing authority in the event of that person's bankruptcy or liquidation,

but this is subject to paragraphs (2) and (3).

(2) Sub-paragraph (1)(b) does not apply if—

(a) the person is bankrupt or in liquidation and has transferred the data to another person; or

(b) the period for which the person was required to keep the data in accordance with the requirements of **[**[F139]paragraph 9**]** mentioned in sub-paragraph (1)(a) has expired.

(3) It is a defence for a person charged with an offence under paragraph (1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Textual Amendments

F136 Words in reg. 33(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F137 Words in reg. 33(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F138 Words in reg. 33(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F139 Words in reg. 33(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **25(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Offences: breach of regulations and false information and defence concerning starting materials

34.—(1) A person is guilty of an offence if the person contravenes the provisions of regulation 17(1) **[**[F140]or 18(1)**]**.

(2) A person is guilty of an offence if the person knowingly gives false information in response to a notice under regulation 30(1).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 30(2).

(4) The defence in paragraph (5) applies to a person who is charged under paragraph (1) with an offence of contravening regulation 17(1) (prohibition on manufacturing a medicinal product except in accordance with a licence) by virtue of a breach of regulation **[**[F141]37(3)**]** (requirement that active substances used as starting materials are manufactured or assembled in accordance with the Good Manufacturing Practice Directive).

(5) It is a defence for the person to show that the person could not, by taking all reasonable precautions and exercising all due diligence, have discovered that an active substance was not manufactured in accordance with regulation **[**F141**]**37(3)**]**.

Textual Amendments

F140 Words in reg. 34(1) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **9(a)**

F141 Word in reg. 34(4)(5) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **9(b)**

Penalties

35.—(1) A person guilty of an offence under regulation 33(1) or regulation 34(1) or (2) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 34(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Conditions for holding a manufacturer's licence

Conditions for manufacturer's licence

36.—(1) Regulations 37 to 41 apply to the holder of a manufacturer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products).

(2) Those provisions are regulations **[**F142**]**37(3)**]**, 38, 39(6)(a) and (8) , 40 and 41.

(3) The requirements of Part 1 of Schedule 6 apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

[F143**]**(4) **[**F144**]**Where a manufacturer's licence relates to the manufacture or assembly of a medicinal product in, or import of a medicinal product into, Northern Ireland, the requirements**]** and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were **[**F145**]**provisions of that**]** licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

(a) Article 4 (composition of the unique identifier);

(b) Article 5 (carrier of the unique identifier);

(c) Article 6 (quality of the printing of the two-dimensional barcode);

(d) Article 7 (human-readable format);

(e) Article 10 (verification of the safety features) insofar as it relates to manufacturers;

(f) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to manufacturers;

(g) Article 12 (unique identifiers which have been decommissioned);

(h) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to manufacturers;

(i) Article 14 (verification of the two-dimensional barcode);

(j) Article 15 (record keeping);

(k) Article 16 (verifications to be performed before removing or replacing the safety features);

(l) Article 17 (equivalent unique identifier); and

(m) Article 18 (actions to be taken in case of tampering or suspected falsification).

(6) In distributing a medicinal product by way of wholesale dealing **[**F146in Northern Ireland**]**, the requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (7) shall apply to the holder of a manufacturer's licence and have effect as if they were provisions of the licence.

(7) The provisions mentioned in paragraph (6) are—

(a) Article 20 (verification of the authenticity of the unique identifier by wholesalers), subject to the exemption contained in Article 21 (derogations from Article 20(b));

(b) Article 22 (decommissioning of unique identifiers by wholesalers); and

(c) Article 24 (actions to be taken by wholesalers in case of tampering or suspected falsification).**]**

Textual Amendments

F142 Word in reg. 36(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **10**

F143 Reg. 36(4)-(7) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **4** and reg. 36(4)-(7) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **4**

F144 Words in reg. 36(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(a)(i)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F145 Words in reg. 36(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(a)(ii)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F146 Words in reg. 36(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **27(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 17**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F147**Manufacturing and assembly**

37.—(1) This regulation applies in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The licence holder must comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive **[**F148which apply under or by virtue of regulation B17**]**.

(3) Unless paragraph (10) applies, the licence holder shall use active substances as starting materials only if—

(a) those substances have been manufactured in accordance with good manufacturing practice for active substances; and

(b) those substances have been distributed in accordance with the guidelines on good distribution practice for active substances.

(4) The licence holder shall verify—

(a) that the manufacturer or distributor of an active substance used by the licence holder has complied with the requirements of good manufacturing practice and good distribution practice for active substances by means of audits performed—

(i) directly by the licence holder, or

(ii) by a person acting on behalf of the licence holder under a contract;

[F149(b) that unless the active substance is imported into Great Britain from a country other than an approved country for import or into Northern Ireland from a country other than an EEA State from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder—

(i) in the case of a product imported into Great Britain, are registered with the appropriate authority for the registration of such persons in the approved country for import, and

(ii) in the case of a product imported into Northern Ireland, are registered with the competent authority of a member State in which they are established; and**]**

(c) the authenticity and quality of the active substance.

(5) The licence holder shall ensure that—

(a) excipients are suitable for use in a medicinal product by—

(i) ascertaining what the appropriate good manufacturing practice is, and

(ii) ensuring that the ascertained good manufacturing practice is applied;

(b) the suitability of the excipient is ascertained on the basis of a formalised risk assessment as described **[**F150in the case of a product for sale or supply in Great Britain **[**F151(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, in the guidelines which apply under or by virtue of regulation C17 and, in the case of a product for sale or supply in Northern Ireland,**]** in paragraph 5 of Article 47 of the 2001 Directive;

(c) the assessment under sub-paragraph (b) takes account of—

(i) the source,

(ii) requirements under other quality systems,

(iii) intended use of the excipients, and

(iv) previous instances of quality defects,

(d) the authenticity and quality of any excipient used is verified; and

(e) the measures taken under this paragraph are documented by the licence holder.

(6) The licence holder must maintain such staff, premises and equipment as are necessary for the stages of manufacture and assembly of medicinal products undertaken by the licence holder in accordance with—

(a) the manufacturer's licence; F152...

[F153(aa) in the case of a product for supply as an EAMS medicinal product, the conditions attached to the EAMS scientific opinion in respect of the product; and**]**

(b) **[**F154in the case of a product for sale or supply—

(i) in Great Britain **[**F155(including a listed NIMAR product for sale or supply from Great Britain to Northern Ireland)**]**, the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK), or

(ii) in Northern Ireland, the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisations or Article 126a authorisations,

applying to the medicinal products.**]**

(7) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.

(8) The licence holder must not manufacture or assemble medicinal products on premises other than those specified in the licence as approved by the licensing authority for the purpose.

(9) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—

(a) the standards of quality and safety specified in **[**F156the Blood Quality and Safety Regulations 2005**]**; or

(b) equivalent standards.

(10) The requirements in paragraphs (3) to (5) do not apply in relation to the manufacture or assembly of special medicinal product to which regulation 167 (supply to fulfil special needs) applies **[**F157or an EAMS medicinal product to which regulation 167E(1) to (4) (EAMS medicinal product: manufacture, assembly, importation, distribution and supply) applies**]**.

(11) The licence holder must immediately inform the **[**F158licensing authority**]** and, where applicable, the **[**F159UK**]** marketing authorisation holder, of medicinal products which come within the scope of manufacturing authorisation which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.**]**

Textual Amendments

F147 Reg. 37 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **11**

F148 Words in reg. 37(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(1A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 18(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F149 Reg. 37(4)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **28(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(b)**)

F150 Words in reg. 37(5)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 18(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F151 Words in reg. 37(5)(b) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **8**

F152 Word in reg. 37(6)(a) omitted (15.4.2022) by virtue of The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **5(2)(a)** (with reg. 19)

F153 Reg. 37(6)(aa) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **5(2)(b)** (with reg. 19)

F154 Reg. 37(6)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **28(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(d)**)

F155 Words in reg. 37(6)(b)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **8**

F156 Words in reg. 37(9)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(5)**; 2020 c. 1, Sch. 5 para. 1(1)
F157 Words in reg. 37(10) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **5(3)** (with reg. 19)
F158 Words in reg. 37(11) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
F159 Word in reg. 37(11) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **28(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Imports from states other than EEA States [F160/ countries other than approved countries for import]

38.—(1) This regulation applies in relation to a manufacturer's licence relating to the import of medicinal products.

(2) The licence holder must comply with the conditions set out in this regulation in relation to the import of medicinal products **[**F161from—

(a) in the case of an import into Great Britain, a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State**]**.

(3) The licence holder must—

(a) comply with the principles and guidelines on good manufacturing practice in the Good Manufacturing Practice Directive in so far as they are relevant to the import of medicinal products; and

(b) ensure that active substances have been used as starting materials in the manufacture of medicinal products, other than special medicinal products, imported from **[**F162, in the case of an import into Great Britain, a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]** only if those substances have been manufactured or assembled in accordance with **[**F163good manufacturing practice for active substances**]**.

Textual Amendments

F160 Words in reg. 38 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
F161 Reg. 38(2)(a)(b) substituted for words in reg. 38(2) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
F162 Words in reg. 38(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **29(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 19(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**
F163 Words in reg. 38(3)(b) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **4** and words in reg. 38(3)(b) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **4**

Further requirements for manufacturer's licence

39.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of medicinal products under the licence as are appropriate in order to maintain the quality of the medicinal products.

(3) The licence holder must ensure that any arrangements made for the handling, control, storage and distribution of medicinal products are adequate to maintain the quality of the products.

(4) The licence holder must not handle, control, store or distribute medicinal products on any premises other than those specified in the licence as approved by the licensing authority for the purpose.

(5) The licence holder must inform the licensing authority before making a material alteration to the premises or facilities used under the licence, or to the purposes for which those premises or facilities are used.

(6) The licence holder must inform the licensing authority of any proposed change to—

(a) the qualified person; and

(b) any person named in the licence as having responsibility for quality control.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority to do anything that the licensing authority could have done for the purposes of verifying a statement made in an application for a licence.

[F164(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with the following as if they are a holder of a wholesale dealer's licence—

(a) regulations 43(1), (2) and (5), 43ZA and 44(5) and (6), and

(b) regulation 43A, if applicable, where the product is being distributed in NI.**]**

Textual Amendments

F164 Reg. 39(8) substituted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **9**

Obligation to provide information relating to control methods

40.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licensing authority may require the licence holder to provide the authority with proof of the control methods employed by the holder in relation to a medicinal product.

Requirements as to qualified persons

41.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must ensure that there is at the disposal of the holder at all times at least one qualified person who is responsible for carrying out, in relation to medicinal products manufactured, assembled or imported under the licence, the duties specified in Part 3 of Schedule 7.

(3) If the licence holder satisfies the requirements of Part 1 or 2 of Schedule 7 the licence holder may act as a qualified person.

(4) A qualified person may be treated by the licence holder as satisfying the requirements of Part 1 or 2 of Schedule 7 if that person produces evidence that he or she—

(a) is a member of a body specified in paragraph (5); and

(b) is regarded by that body as satisfying those requirements.

(5) Those bodies are—

(a) the Society of Biology;

(b) the Royal Pharmaceutical Society;

(c) the Pharmaceutical Society of Northern Ireland;

(d) the Royal Society of Chemistry; and

(e) such other body as may be specified by the licensing authority for the purpose of this paragraph.

(6) Where the qualified person changes, the licence holder must give the licensing authority advance notification of—

(a) that change; and

(b) the name, address and qualifications of the new qualified person.

(7) The licence holder must not permit any person to act as a qualified person other than the person named in the licence or another person notified to the licensing authority under paragraph (6).

(8) Paragraph (9) applies if the licensing authority thinks, after giving the licence holder and a person acting as a qualified person the opportunity to make representations (orally or in writing), that the person—

(a) does not satisfy the requirements of Part 1 or 2 of Schedule 7 in relation to qualifications or experience;

(b) does not satisfy paragraph (b) of the definition of "qualified person" in regulation 8; or

(c) is failing to carry out the duties referred to in paragraph (2) adequately or at all.

(9) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a qualified person.

(10) The licence holder must at all times provide and maintain such staff, premises and equipment as are necessary to enable the qualified person to carry out the duties referred to in paragraph (2).

(11) The licence holder is not obliged to meet the requirements of this regulation in relation to any activity under the licence which relates to special medicinal products or **[**[F165], unless conditions attached in accordance with regulation 174A(1) provide otherwise,**]** to products authorised on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc).

[[F166](12) The licence holder is not obliged to meet the requirements of this regulation in relation to any activities under the licence which relate to EAMS medicinal products, unless the conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) provide otherwise.**]**

Textual Amendments

F165 Words in reg. 41(11) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **5** and words in reg. 41(11) inserted (N.I) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **5**

F166 Reg. 41(12) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **6** (with reg. 19)

Conditions for holding a wholesale dealer's licence

Conditions for wholesale dealer's licence

42.—(1) Regulations 43 to 45 **[**[F167](not including regulation 43ZA)**]****[**[F168](in the case of a wholesale dealer's licence held in Northern Ireland) or regulations 43 to 45AA **[**[F169](including regulation 43ZA)**]** (in the case of a wholesale dealer's licence held in Great Britain)**]** apply to the holder of a wholesale dealer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products).

[[F170](2) Those provisions are regulations 43(2) and (8) and 44.**]**

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

[[F171](4) **[**[F172]Where a wholesale dealer's licence relates to wholesale dealings in Northern Ireland, the requirements**]** and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were **[**[F173]provisions of that**]** licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

(a) Article 10 (verification of the safety features) insofar as it relates to wholesalers;

(b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to wholesalers;

(c) Article 12 (unique identifiers which have been decommissioned);

(d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to wholesalers;

(e) Article 20 (verification of the authenticity of the unique identifier), subject to the exemption contained in Article 21 (derogations from Article 20(b));

(f) Article 22 (decommissioning of unique identifiers); and

(g) Article 24 (actions to be taken in case of tampering or suspected falsification).**]**

[[F174](6) Paragraph (4) does not apply in relation to listed NIMAR products in Northern Ireland.**]**

Textual Amendments

F167 Words in reg. 42(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(a)(i)**

F168 Words in reg. 42(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F169 Words in reg. 42(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(a)(ii)**

F170 Reg. 42(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **13**

F171 Reg. 42(4)(5) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **6** and reg. 42(4)(5) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **6**

F172 Words in reg. 42(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(3)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F173 Words in reg. 42(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **31(3)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 21(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F174 Reg. 42(6) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **10(b)**

Obligations of licence holder

43.—**[**F175(1) The licence holder must comply with the guidelines on good distribution practice—

(a) in the case of a licence holder in Great Britain, published under, or that apply by virtue of, regulation C17;

(b) in the case of a licence holder in Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive.**]**

(2) The licence holder must ensure, within the limits of the holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met.

(3) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(4) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(5) Subject to paragraph (6), the licence holder must not sell or supply a medicinal product, or offer it for sale or supply, unless—

[F176(a) in the case of a product for sale or supply—

(i) in Great Britain, there is a UKMA(GB), UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), or

(ii) in Northern Ireland, there is a UKMA(NI), UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), and EU marketing authorisation or an Article 126a authorisation (an "authorisation"),

in force in relation to the product; and**]**

(b) the sale or supply, or offer for sale or supply, is in accordance with the authorisation.

(6) The restriction in paragraph (5) does not apply to—

(a) the sale or supply, or offer for sale or supply, of a special medicinal product **[**F177in the United Kingdom**]**;

[F178(aa) the supply, or offer for supply, of an unauthorised EAMS medicinal product in the United Kingdom;**]**

(b) the export **[**F179from Northern Ireland**]** to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; **F180**...

[F181(ba) the export from Great Britain to an approved country for import, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that country without—

(i) a marketing authorisation, certificate of registration or traditional herbal registration within the meaning of the 2001 Directive, by virtue of legislation adopted by that country under Article 5(1) of that Directive, where the approved country for import is an EEA State, or

(ii) such equivalent authorisation, certificate or registration in the approved country for import, under legislation in that country that makes provision that is equivalent to Article 5(1) of the 2001 Directive, where the approved country for import is not an EEA State.**]**

(c) the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174; **[**F182or

[F183(d) the wholesale distribution of medicinal products—

(i) from Northern Ireland to a person in a country other than Great Britain or a country other than an EEA State; or

(ii) from Great Britain to a person in a country other than Northern Ireland or a country other than an approved country for import.**]**

(7) The licence holder must—

(a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—

[F184(i) ordered by the licensing authority or—

(aa) in the case of a licence holder in Great Britain, by an appropriate authority for the licensing of medicinal products in an approved country for import;

(bb) in the case of a licence holder in Northern Ireland, by the competent authority of any EEA State, or**]**

[F185(ii) carried out in co-operation with the manufacturer of, or the holder of—

(aa) in the case of a product for sale or supply in Great Britain, the UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration, or

(bb) in the case of a product for sale or supply in Northern Ireland, the UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

for, the product; and**]**

[F186(c) keep records in relation to the receipt, dispatch or brokering of medicinal products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the date of brokering,

(iv) the name of the medicinal product,

(v) the quantity of the product received, dispatched or brokered,

(vi) the name and address of the person from whom the products were received or to whom they are dispatched,

(vii) **[**F187where the receipt, dispatch or brokering of medicinal products takes places in Northern Ireland,**]** the batch number of medicinal products bearing safety features referred to in point (o) of Article 54 of the 2001 Directive.**/**

[F186(8) A licence holder **[**F188in Northern Ireland**]** ("L") who imports from another EEA State a medicinal product in relation to which L is not the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration shall—

(a) notify the intention to import that product to the holder of the authorisation and—

(i) in the case of a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004, to the EMA; or

(ii) in any other case, the licensing authority; and

(b) pay a fee to the EMA in accordance with Article 76(4) of the 2001 Directive or the licensing authority as the case may be, in accordance with the Fees Regulations,

but this paragraph does not apply in relation to the wholesale distribution of medicinal products to a person in a **[**F189country other than an EEA State**]**.**]**

[

F190(8A) Paragraph (8B) applies to a person ("P") who—

(a) imports into Great Britain a medicinal product, other than for the sole purpose of wholesale distribution of that product to a person in a country other than the United Kingdom; but

(b) is not the holder of a UK marketing authorisation, certificate of registration or traditional herbal registration in respect of that product.

(8B) Where this paragraph applies, P must—

(a) notify—

(i) the holder of any authorisation, certificate or registration, granted by an authority in the country from which the product is exported, to sell or supply that product in that country, and

(ii) the licensing authority,

of the intention to import that product; and

(b) pay a fee to the licensing authority in accordance with the Fees Regulations.**]**

(9) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

[F191(10) The holder **[**F192of a licence relating to wholesale dealings in Northern Ireland**]** ("L") must verify in accordance with paragraph (11) that any medicinal products received by L that are required by Article 54a of the Directive to bear safety features are not falsified but this paragraph does not apply in relation to the distribution of medicinal products received from a third country by a person to a person in a third country.

(11) Verification under this paragraph is carried out by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted under Article 54a(2) of the 2001 Directive.

(12) The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

(13) The licence holder must immediately inform the licensing authority and, where applicable, the **[**[F193]UK marketing authorisation holder or EU marketing authorisation holder**]**, of medicinal products which the licence holder receives or is offered which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.

(14) **[**[F194]Where the medicinal product is obtained through brokering—

(a) a licence holder in Great Britain must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b);

(b) a licence holder in Northern Ireland must verify that the broker involved is validly registered with the licensing authority or the competent authority of an EEA State.**]**

(15) In this regulation **[**[F195]as it applies in the case of a product for sale or supply in Northern Ireland**]**, "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

(b) an EU marketing authorisation.**]]**

Textual Amendments

F175 Reg. 43(1) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(a)**)

F176 Reg. 43(5)(a) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(b)**)

F177 Words in reg. 43(6)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F178 Reg. 43(6)(aa) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **7** (with reg. 19)

F179 Words in reg. 43(6)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(aa)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F180 Word in reg. 43(6)(b) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **6(2)(a)** and word in reg. 43(6)(b) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **6(2)(a)**

F181 Reg. 43(6)(ba) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(d)(i)(ii)(aa)(bb)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F182 Reg. 43(6)(d) and preceding word inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **6(2)(b)** and reg. 43(6)(d) and preceding word inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **6(2)(b)**

F183 Reg. 43(6)(d) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(4)(c)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F184 Reg. 43(7)(b)(i) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(5)(a)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(i)**)

F185 Reg. 43(7)(b)(ii) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **33(5)(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(ii)**)

F186 Reg. 43(7)(c)(8) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **14(a)**

F187 Words in reg. 43(7)(c)(vii) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F188 Words in reg. 43(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5A)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F189 Words in reg. 43(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(5A)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F190 Reg. 43(8A)(8B) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F191 Reg. 43(10)-(15) substituted for reg. 43(10) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **14(b)**

F192 Words in reg. 43(10) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(7)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(j)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F193 Words in reg. 43(13) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(8)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(k)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F194 Reg. 43(14) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(9)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(l)**)

F195 Words in reg. 43(15) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **33(10)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 23(l)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F196Obligations of licence holder in Great Britain supplying listed NIMAR products to Northern Ireland

43ZA.—(1) This regulation applies only to licence holders in Great Britain supplying listed NIMAR products to Northern Ireland.

(2) A licence holder must comply with the guidelines on good distribution practice, published under, or that apply by virtue of, regulation C17.

(3) So that the needs of patients in Northern Ireland are met, the licence holder must ensure, within the limits of the holder's responsibility, the continued supply of listed NIMAR products to—

(a) registered pharmacies in Northern Ireland;

(b) any person who may lawfully sell those products by retail sale or may lawfully supply them in circumstances corresponding to retail sale in Northern Ireland;

(c) any person who may lawfully administer prescription only medicines in Northern Ireland.

(4) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of listed NIMAR products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(5) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(6) The licence holder must not sell or supply, or offer for sale or supply, listed NIMAR products to a person in Northern Ireland, unless—

(a) there is a UKMA(UK) or UKMA(GB) in force in relation to that product; and

(b) the sale or supply is in accordance with that authorisation (except for the fact the product will be in Northern Ireland).

(7) The licence holder must—

(a) keep documents relating to the sale or supply of listed NIMAR products under the licence which may facilitate the withdrawal or recall from sale of such products in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a listed NIMAR product where recall is—

(i) ordered by the licensing authority or

(ii) carried out in co-operation with the manufacturer of, or the holder of the corresponding UKMA(GB) or UKMA(UK) for the product; and

(c) keep records in relation to the receipt, dispatch or brokering of listed NIMAR products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the date of brokering,

(iv) the name of the listed NIMAR product,

(v) the quantity of the product received, dispatched or brokered,

(vi) the name and address of the person from whom the products were received or to whom they are dispatched; and

(d) provide the records in sub-paragraph (c) to the licensing authority on request.

(8) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

(9) The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

(10) The licence holder must immediately inform the licensing authority of medicinal products which the licence holder receives or is offered which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified.

(11) Where the listed NIMAR product is obtained through brokering, a licence holder must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b).**]**

Textual Amendments

F196 Reg. 43ZA inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **11**

[F197Requirement for wholesale dealers to decommission the unique identifier

43A.—(1) This regulation applies only to medicinal products that are required to bear safety features pursuant to Article 54a of the 2001 Directive.

(2) Before supplying a medicinal product to a person **[**F198in Northern Ireland**]** who falls within one of the classes specified in paragraph (3), the licence holder must verify the safety features and decommission the unique identifier of that medicinal product in accordance with the requirements laid down in Commission Regulation 2016/161.

(3) The classes of person mentioned in paragraph (2) are—

(a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;

(b) persons who receive the product for the purpose of selling, supplying or administering it as a veterinary medicinal product;

(c) dentists;

(d) registered optometrists or registered dispensing opticians;

(e) registered paramedics;

(f) persons who are members of Her Majesty's armed forces;

(g) F199... the Police Service of Northern Ireland;

(h) government institutions maintaining stocks of medicinal products for the purposes of civil protection or disaster control;

(i) universities or other institutions concerned with higher education or research, other than healthcare institutions;

(j) a prison service;

(k) persons carrying on the business of a school;

(l) **[**F200nursing**]** homes;

(m) hospices.**]**

Textual Amendments

F197 Reg. 43A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **7** and reg. 43A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **7**

F198 Words in reg. 43A(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F199 Words in reg. 43A(3)(g) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(b)(i)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

F200 Word in reg. 43A(3)(l) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **34(b)(ii)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 24**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F201Requirement for wholesale dealers to deal only with specified persons

44.—F202(1) . . . . . .

(2) **[**F203The**]** licence holder must not obtain supplies of medicinal products from anyone except—

(a) the holder of a manufacturer's licence or wholesale dealer's licence in relation to products of that description;

(b) the person who holds an authorisation granted by **[**F204an approved country for import (in the case of a licence holder in Great Britain) or by an EEA State (in the case of a licence holder in Northern Ireland)**]** authorising the manufacture of products of the description or their distribution by way of wholesale dealing; **[**F205or**]**

[F206(c) where the medicinal product is directly received—

(i) in the case of a licence holder in Great Britain, from a country that is not an approved country for import ("A"), for export to a country that is not an approved country for import ("B"), and

(ii) in the case of a licence holder in Northern Ireland, from a country other than an EEA State ("A") for export to another country other than an EEA State ("B"),

the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.**]**

F207(d) . . . . . .

(3) Where a medicinal product is obtained in accordance with paragraph F208... (2)(a) or (b), the licence holder must verify that—

(a) the wholesale dealer who supplies the product complies with the principles and guidelines of good distribution practices; or

(b) the manufacturer or importer who supplies the product holds a manufacturing authorisation.

F209(4) . . . . . .

(5) **[**F210The**]** licence holder may distribute medicinal products by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence relating to those products;

[F211(b) the holder of an authorisation granted by—

(i) in the case of a licence holder in Great Britain, the appropriate authority of an approved country for import;

(ii) in the case of a licence holder in Northern Ireland, the competent authority of an EEA State,

that is responsible for authorising the supply of those products by way of wholesale dealing;**]**

(c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale;

(d) a person who may lawfully administer those products; or

[F212(e) in relation to supply—

(i) in the case of a licence holder in Great Britain to persons in countries other than approved countries for import, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country to which the product is supplied;

(ii) in the case of a licence holder in Northern Ireland to persons in a country other than an EEA State, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country other than an EEA State concerned.**]**

(6) Where a medicinal product is supplied to a person who is authorised or entitled to supply medicinal products to the public in accordance with paragraph F213... (5)(c) or (e), the licence holder must enclose with the product a document stating the—

(a) date on which the supply took place;

(b) name and pharmaceutical form of the product supplied;

(c) quantity of product supplied; **[**F214and**]**

(d) name and address of the licence holder; and

(e) batch number of the medicinal products bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive **[**F215, in the case of a licence holder in Northern Ireland.**]**

(7) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (6) for at least five years beginning immediately after the date on which the information is supplied; and

(b) ensure that the record is available to the licensing authority for inspection.**]**

[F216(8) A licence holder in Great Britain may only obtain a medicinal product in respect of which a UKMA(GB) was granted under the unfettered access route if the product satisfies the definition of qualifying Northern Ireland goods.

(9) Paragraph (2)(c) does not apply to—

(a) in the case of a licence holder in Great Britain, products received from Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products received from Great Britain.

(10) Paragraph (5)(e) does not apply to—

(a) in the case of a licence holder in Great Britain, products supplied to Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products supplied to Great Britain.**]**

Textual Amendments

F201 Reg. 44 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **15**

F202 Reg. 44(1) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(2)** and reg. 44(1) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(2)**

F203 Word in reg. 44(2) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(a)** and word in reg. 44(2) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(a)**

F204 Words in reg. 44(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 25(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F205 Word in reg. 44(2) inserted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(b)** and word in reg. 44(2) inserted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(b)**

F206 Reg. 44(2)(c) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(a)(ii)**)

F207 Reg. 44(2)(d) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(d)** and reg. 44(2)(d) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(d)**

F208 Word in reg. 44(3) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(4)** and word in reg. 44(3) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(4)**

F209 Reg. 44(4) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(5)** and reg. 44(4) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(5)**

F210 Word in reg. 44(5) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(6)** and word in reg. 44(5) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(6)**

F211 Reg. 44(5)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(b)**)

F212 Reg. 44(5)(e) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(c)**)

F213 Word in reg. 44(6) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **7** and word in reg. 44(6) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **7**

F214 Word in reg. 44(6)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F215 Words in reg. 44(6)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(5)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 25(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F216 Reg. 44(8)-(10) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **35(6)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(e)**)

Requirement as to responsible persons

45.—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person") who in the opinion of the licensing authority—

(a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and

(b) has adequate experience relating to those activities and procedures.

[[F217](1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.**]**

(2) Those functions are—

(a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and

[F218(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

(i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and

(ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, [F219requirements of regulation 167A,] Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.]

(3) The licence holder must notify the licensing authority of—

(a) any change to the responsible person; and

(b) the name, address, qualifications and experience of the responsible person.

(4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

(a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or

(b) is failing to carry out the functions referred to in paragraph (2) adequately or at all.

(6) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a responsible person.

Textual Amendments

F217 Reg. 45(1A) inserted (31.12.2022) The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **36(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F218 Reg. 45(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **36(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F219 Words in reg. 45(2)(b)(ii) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **12**

[F220Requirement as to responsible persons where licence holder imports from an approved country for import

45AA.—(1) Subject to paragraph (2), this regulation applies to a licence holder in Great Britain where the licence holder imports a medicinal product from an approved country for import under a wholesale dealer's licence.

(2) The requirements of this regulation do not apply where an unlicensed medicinal product falling under paragraph (1) is imported—

(a) from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product; or

(b) for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

(3) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person (import)") whose name is included in the register established under regulation 45AB.

(4) A responsible person (import) must—

(a) carry out the functions under regulation 45(2), unless a responsible person under regulation 45 is performing those functions in respect of the licence; ...

(b) ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in Article 51 of the 2001 Directive, or such equivalent certification procedure as applies in the approved country for import; and

(c) ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by—

(i) the appropriate authority, or

(ii) where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority's own examination.

(5) The licensing authority must publish guidance on the documentation that it considers to be appropriate evidence for the purposes of paragraph (4)(b).

(6) Guidance published under paragraph (5) may be taken into account by the licensing authority in determining whether it considers there has been a failure to comply with this regulation.

(7) The licence holder must apply to vary the licence if a change is proposed to the responsible person (import).

(8) The licence holder must not permit any person to act as a responsible person (import) other than the person named in the licence.

(9) Paragraph (10) applies if—

(a) the person acting as responsible person (import) in respect of the licence is no longer included in the register under 45AB;

(b) the licensing authority thinks, after giving the licence holder and a person acting as a responsible person (import) the opportunity to make representations (orally or in writing), that the responsible person (import) is failing to carry out the functions referred to in paragraph (4) adequately or at all.

(10) Where this paragraph applies the licensing authority—

(a) must notify the licence holder in writing that the person is not permitted to act as a responsible person (import) in respect of that licence; and

(b) may, subject to regulation 45AB(3)(b), remove that person's name from the register under regulation 45AB.

(11) In this regulation, "unlicensed medicinal product" means a medicinal product in respect of which—

(a) there is no marketing authorisation, within the meaning of the 2001 Directive, in any EEA State in respect of that product, where the product is imported from an approved country for import that is an EEA State; or

(b) there is no licence or authorisation in respect of that product as regards its sale or supply in the approved country for import, where the product is imported from an approved country for import that is not an EEA State.

Textual Amendments

F220 Regs. 45AA, 45AB inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **37** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 27**); 2020 c. 1, **Sch. 5 para. 1(1)**

Register for responsible persons (import)

45AB.—(1) The licensing authority must maintain a register of persons ("the responsible person (import) register") who may carry out the role of responsible person (import) under regulation 45AA.

(2) The licensing authority may only include a person's name in the responsible person (import) register if that person—

(a) holds—

(i) a diploma, certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, or

(ii) such other qualification as the licensing authority is satisfied is equivalent;

(b) is a member of—

(i) the Royal Society of Biology,

(ii) the Royal Pharmaceutical Society,

(iii) the Pharmaceutical Society of Northern Ireland,

(iv) the Royal Society of Chemistry, or

(v) such other body as may be specified by the licensing authority for the purpose of this paragraph; and

(c) has a minimum of 2 years' experience in performing the functions of a responsible person under regulation 45, or in performing such other functions that appear to the licensing authority to be equivalent.

(3) The licensing authority—

(a) may remove a person's name from the responsible person (import) register if it no longer considers that the person satisfies the requirements of paragraph (2); but

(b) it may not exercise that power unless it has given that person the opportunity to make representations to it (orally or in writing).]

Textual Amendments

F220 Regs. 45AA, 45AB inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **37** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 27**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F221CHAPTER 3

Brokering

Textual Amendments

F221 Pt. 3 Chs. 3, 4 inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **16**

Brokering in medicinal products

45A.—[F222(1) A person may not broker a medicinal product in Great Britain unless—

(a) the product is covered by an authorisation granted—

(i) by the licensing authority, or

(ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, and

(b) that person—

(i) is validly registered as a broker with the licensing authority,

(ii) has a permanent address in the United Kingdom, and

(iii) complies with the guidelines on good distribution practice which apply under, or by virtue of, regulation C17 insofar as those guidelines apply to brokers.

(1A) A person may not broker a medicinal product in Northern Ireland unless—

(a) the product is covered by an authorisation granted—

(i) under Regulation (EC) No 726/2004,

(ii) by the licensing authority, or

(iii) by a competent authority of a member State, and

(b) that person—

(i) is validly registered as a broker with the licensing authority or a competent authority of a member State,

(ii) except where the person is validly registered with the competent authority of an EEA State, has a permanent address in the United Kingdom, and

(iii) complies with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive insofar as those guidelines apply to brokers.**]**

(2) A person is not validly registered for the purpose of paragraph (1)(b) **[**F223or (1A)(b)**]** if—

(a) the person's permanent address is not entered into a register of brokers kept by a competent authority of a member State **[**F224or the licensing authority (as appropriate)**]**;

(b) the registration is suspended; or

(c) the person has notified the competent authority of a member State **[**F225or the licensing authority (as appropriate)**]** to remove that person from the register.

F226(3) . . . . . .

Textual Amendments

F222 Reg. 45A(1)(1A) substituted for reg. 45A(1) (31.12.2020) by S.I. 2019/775, regs. 1, **38(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 28(a)**)

F223 Words in reg. 45A(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **38(3)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 28(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F224 Words in reg. 45A(2)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **38(3)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 28(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F225 Words in reg. 45A(2)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **38(3)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 28(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F226 Reg. 45A(3) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **38(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Application for brokering registration

45B.—(1) The licensing authority may not register a person as a broker unless paragraphs **[**[F227](2)**]** to (7) are complied with.

(2) An application for registration must be made containing—

(a) the name of the person to be registered;

(b) the name under which that person is trading (if different to the name of that person);

(c) that person's—

(i) permanent address in the United Kingdom,

(ii) e-mail address, and

(iii) telephone number;

(d) a statement of whether the medicinal products to be brokered are—

(i) prescription only medicines,

(ii) pharmacy medicines, or

(iii) medicines subject to general sale;

(e) an indication of the range of medicinal products to be brokered;

(f) evidence that that person can comply with regulations 45A(1)(b)(iii), 45E(3)(a) to (f) and 45F(1); and

(g) any fee payable in connection with the application in accordance with the Fees Regulations.

(3) Where the address at which the emergency plan, documents or record necessary to comply with regulation 45E(3)(b) to (d) are kept is different from the address notified in accordance with sub-paragraph (2)(c)(i), the application must contain—

(a) that address where the plan or records are to be kept;

(b) the name of a person who can provide access to that address for the purpose of regulation 325 (rights of entry); and

(c) that person's—

(i) address,

(ii) e-mail address, and

(iii) telephone number.

(4) Unless paragraph (6) applies, the application for registration must—

(a) be in English; and

(b) be signed by the person seeking a brokering registration.

(5) The pages of the application must be serially numbered.

(6) Where the application is made on behalf of the person seeking a brokering registration by another person ("A"), the application must—

(a) contain the name and address of A; and

(b) be signed by A.

Textual Amendments

F227 Word in reg. 45B(1) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **4** and word in reg. 45B(1) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **4**

Procedure for determining an application for broker's registration

45C.—(1) The licensing authority must grant or refuse an application for registration under regulation 45B within the period of 90 days beginning immediately after the day on which it receives the application.

(2) Paragraph (1) applies to an application only if the requirements of regulation 45B(2) have been met.

(3) Before determining an application for a brokering registration, the licensing authority may notify the applicant of a requirement to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(4) If a notice under paragraph (3) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (1).

(5) In paragraph (4), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

Grant or refusal of broker's registration

45D.—(1) Subject to regulations 45E and 45F, on an application to the licensing authority for a brokering registration, the licensing authority must, if it considers it necessary and appropriate to do so—

(a) register the applicant as a broker; or

(b) refuse registration as a broker, having regard to—

(i) the provisions of these Regulations, [F228]...

[F228](ii) . . . . . .

(2) The licensing authority must give the applicant a notice stating the reasons for its decision in any case where the licensing authority—

(a) refuses to grant an application for registration; or

(b) grants registration otherwise than in accordance with the application and the applicant requests a statement of its reasons.

(3) The licensing authority must register the applicant or refuse registration under this Chapter within the period of 90 days beginning immediately after the day on which it receives the application.

(4) Where the licensing authority registers a person as a broker, the licensing authority must enter the following information into a publicly available register—

(a) the person's name;

(b) the name under which that person is trading (if different from the person's name);

(c) the person's permanent address in the United Kingdom.

(5) The licensing authority must make the register of brokers publicly available.

Textual Amendments

F228 Reg. 45D(1)(b)(ii) and word omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **39**; 2020 c. 1, Sch. 5 para. 1(1)

Criteria of broker's registration

45E.—(1) Registration of a broker is conditional on that broker—

(a) complying with regulation 45A(1); and

(b) satisfying—

(i) the criteria in paragraphs (3), (4) and (7), and

(ii) such other criteria as the licensing authority considers appropriate and notifies the broker of.

(2) The criteria referred to in paragraph (1)(b)(ii) may include (but are not limited to) the criteria specified in paragraphs (5) and (6).

(3) The broker must—

(a) have a permanent address in the United Kingdom;

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—

[F229(i) ordered by—

(aa) in the case of a broker in Great Britain, the licensing authority or by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or

(bb) in the case of a broker in Northern Ireland, the licensing authority or by the competent authority of any EEA State, or**]**

(ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation, for the product;

(c) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with sub-paragraph (b);

(d) record in relation to the brokering of each medicinal product—

(i) the name of the medicinal product,

(ii) the quantity of the product brokered,

(iii) [F230where the sale or supply of the medicinal product is in Northern Ireland,] the batch number of the medicinal product bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive,

(iv) the name and address of the—

(aa) supplier, or

(bb) consignee, and

(v) the date on which the sale or purchase of the product is brokered;

(e) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities; and

(f) keep the documents or record required by sub-paragraph (c) or (d) available to the licensing authority for a period of five years; and

(g) comply with regulation 45F(1), (2) and (4).

(4) Where the address at which the plan or records necessary to comply with paragraph (3)(b) to (d) are kept is different from the address notified in accordance with regulation 45B(2)(c)(i), the broker must—

(a) ensure that the plan or records are kept at an address in the United Kingdom; and

(b) inform the licensing authority of the address at which the plan or records are kept.

(5) The broker must provide such information as may be requested by the licensing authority concerning the type and quantity of medicinal products brokered within the period specified by the licensing authority.

(6) The broker must take all reasonable precautions and exercise all due diligence to ensure that any information provided by that broker to the licensing authority in accordance with regulation 45F is not false or misleading.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the registration, the broker must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any copies, which an inspector may carry out or take under regulations 325 (rights of entry) and 327 (powers of inspection, sampling and seizure).

Textual Amendments

F229 Reg. 45E(3)(b)(i) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **40(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 29(a)**)

F230 Words in reg. 45E(3)(d)(iii) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **40(b)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 29(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Provision of information

45F.—(1) A broker registered in the UK must immediately inform—

(a) the licensing authority; and

[F231(b) in the case of a broker in—

(i) Great Britain, either—

(aa) the UK marketing authorisation holder, or

(bb) where applicable, the holder of the licence or authorisation granted by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or

(ii) Northern Ireland, either—

(aa) the UK marketing authorisation holder, or

(bb) where applicable, the EU marketing authorisation holder,]

of medicinal products which the broker identifies as, suspects to be, or has reasonable grounds for knowing or suspecting to be, falsified.

(2) On or before the date specified in paragraph (3), a broker who is, or has applied to the licensing authority to become, a registered broker in the United Kingdom must submit a report to the licensing authority, which—

(a) includes a declaration that the broker has in place an appropriate system to ensure compliance with regulations 45A, 45B and this regulation; and

(b) details the system which the broker has in place to ensure such compliance.

(3) The date specified for the purposes of this paragraph is—

(a) in relation to any application made before 31st March 2014, the date of the application; and

(b) in relation to each subsequent reporting year, 30th April following the end of that year.

(4) The broker must without delay notify the licensing authority of any changes to the matters in respect of which evidence has been supplied in relation to paragraph (2) which might affect compliance with the requirements of this Chapter.

(5) Any report or notification to the licensing authority under paragraph (2) or (4) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(6) The licensing authority may give a notice to a registered broker requiring that broker to provide information of a kind specified in the notice within the period specified in the notice.

(7) A notice under paragraph (6) may not be given to a registered broker unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether the registration should be varied, suspended or revoked.

(8) A notice under paragraph (6) may specify information which the licensing authority thinks necessary for considering whether the registration should be varied, suspended or revoked.

(9) In paragraph (3)(b), "reporting year" means a period of twelve months ending on 31st March.

Textual Amendments

F231 Reg. 45F(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **41** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 30**); 2020 c. 1, **Sch. 5 para. 1(1)**

Power to suspend or vary a broker's registration or remove a broker from the register

45G.—(1) The licensing authority may in accordance with regulation 45H—

(a) suspend a broker's registration for such period as the authority thinks fit;

(b) vary a broker's registration; or

(c) remove a person from the register.

(2) The suspension of registration or removal from the register may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to a broker's registration except on one or more of the following grounds—

(a) the information in the application as a result of which the broker's registration was granted was false or incomplete in a material respect;

(b) a material change of circumstances has occurred in relation to any of the matters stated in the application;

(c) the broker has materially contravened a criterion of registration; or

(d) the broker has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the registration relates when required to do so under regulation 45F(6).

Procedure where licensing authority proposes to suspend or vary a broker's registration or remove a broker from the register

45H.—(1) This regulation applies where—

(a) regulation 45I does not apply; and

(b) the licensing authority proposes to exercise the power in regulation 45G(1).

(2) The licensing authority must notify the broker in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, variation or revocation should take effect.

(3) The registered broker may before the date specified in the notice—

(a) make written representations to the licensing authority with respect to the proposal; or

(b) notify the licensing authority that the broker wishes the licensing authority to submit the proposal to review upon oral representations.

(4) If the broker makes written representations in accordance with paragraph (3)(a) the licensing authority must take those representations into account before making a decision in the matter.

(5) Schedule 5 has effect if the registered broker—

(a) notifies the licensing authority of the proposal to review upon oral representations in accordance with paragraph (3)(b); and

(b) pays the fee for a review upon oral representations in accordance with the Fees Regulations.

(6) If the licensing authority proceeds to suspend or vary a registration or remove a broker from the register in accordance with the provisions of regulation 45G it must give a notice to the broker.

(7) A notice under paragraph (6) must—

(a) give particulars of the suspension, variation or removal; and

(b) give reasons for the decision to suspend, vary or remove a broker from the register.

(8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of a broker registration in cases of urgency

45I.—(1) The licensing authority may immediately suspend a broker's registration for a period not exceeding three months where it appears to the licensing authority that in the interests of safety it is appropriate to do so.

(2) This paragraph applies where—

(a) a broker's registration has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether the broker's registration should be—

(i) further suspended or varied, or

(ii) removed from the brokers' register.

(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 45H (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 45H and any proceedings under that regulation have not been finally disposed of before the end of the period for which the registration was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the registration for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 45H to suspend, vary or revoke the registration is made on an application under regulation 322(4), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (validity of decisions and proceedings).

Variation of a broker's registration on the application of the broker

45J.—(1) This regulation applies if the person registered as a broker applies to the licensing authority for a variation of the registration.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant;

(d) be accompanied by such information as may be required to enable the licensing authority to consider the application;

(e) include the appropriate fee in accordance with the Fees Regulations.

(3) The licensing authority must vary a broker's registration or refuse to vary it within 30 days beginning with the day after the date when the licensing authority receives the application.

(4) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which notice is given; and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 45G and 45I.

Offences: breach of regulations and false information

45K.—(1) A person is guilty of an offence if the person—

(a) contravenes regulation 45A(1); or

(b) brokers a medicinal product otherwise than in accordance with the criteria under regulation 45E relating to that person's brokering registration.

(2) A person is guilty of an offence if the person knowingly gives false information in—

(a) an application for a broker registration under regulation 45B(2);

(b) a notification to the licensing authority under regulation 45F(4);

(c) an application for a variation under regulation 45J(1); or

(d) response to a notice under regulation 45C(3) or 45J(5).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 45F(6) or 45J(5).

Penalties

45L.—(1) A person guilty of an offence under regulation 45K(1) or (2) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 45K(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.**]**

[F221CHAPTER 4

Importation, manufacture and distribution of active substances

Criteria for importation, manufacture or distribution of active substances

45M.—(1) A person may not—

(a) import;

(b) manufacture; or

(c) distribute,

an active substance unless that person is registered with the licensing authority in accordance with regulation 45N and the requirements in regulation 45O are met.

(2) Paragraph (1) applies in relation to an active substance which is to be used in an investigational medicinal product only—

[F232(a) if—

(i) in the case of a product for sale or supply in Great Britain, the product has a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in the case of a product for sale or supply in Northern Ireland, the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, and**]**

(b) to the extent that the manufacture of the active substance is in accordance with the terms and conditions of that authorisation, certificate or registration.

(3) Paragraph (1)(a) does not apply to a person who, in connection with the importation of an active substance F233...—

(a) provides facilities solely for transporting the active substance; or

(b) acting as an import agent, imports the active substance solely to the order of another person who holds a certificate of good manufacturing practice issued by the licensing authority.

Textual Amendments

F232 Reg. 45M(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **42(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 31**); 2020 c. 1, **Sch. 5 para. 1(1)**

F233 Words in reg. 45M(3) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **42(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Registration in relation to active substances

45N.—(1) For registration in relation to active substances, the licensing authority must have received a valid registration form from the applicant for import, manufacture or, as the case may be, distribution of an active substance and—

(a) 60 days have elapsed since receipt and the licensing authority have not notified the applicant that an inspection will be carried out; or

(b) the licensing authority—

(i) notified the applicant within 60 days of receipt of a registration form that an inspection will be carried out; and

(ii) within 90 days of that inspection the licensing authority have issued that person with a certificate of good manufacturing practice or, as the case may be, of good distribution practice; and

(c) that person has not instructed the licensing authority to end that person's registration.

(2) The person applying for registration under paragraph (1) must notify the licensing authority of any changes which have taken place as regards the information in the registration form—

(a) immediately where such changes may have an impact on quality or safety of the active substances that are manufactured, imported or distributed;

(b) in any other case, on each anniversary of the receipt of the application form by the licensing authority.

(3) For the purpose of paragraph (2), changes which are notified in accordance with that paragraph shall be treated as incorporated in the application form.

(4) Any notification to the licensing authority under paragraph (2) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(5) A registration form is valid for the purpose of paragraph (1) if—

(a) it is provided to the licensing authority; and

(b) is completed in the way and form specified in Schedule 7A.

(6) Paragraph (1) does not apply until 20th October 2013 in relation to a person who had, before 20th August 2013, commenced the activity for which the person would, apart from this provision, need to send a registration form to the licensing authority.

Requirements for registration as an importer, manufacturer or distributor of an active substance

45O.—[F234(1) Where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance manufactured in Great Britain, a manufacturer in Great Britain must comply with the principles and guidelines of good manufacturing practice for active substances.

(1A) Where the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies to an active substance manufactured in Northern Ireland, a manufacturer in Northern Ireland must comply with the principles and guidelines of good manufacturing practice for active substances.**]**

[F235(2) Where principles and guidelines of good distribution practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance distributed in Great Britain, a distributor in Great Britain must comply with the principles and guidelines of good distribution practice for active substances.

(2A) Where the Commission has adopted principles and guidelines of good distribution practice under the fourth paragraph of Article 47 of the 2001 Directive which applies to an active substance distributed in the Northern Ireland, a distributor in Northern Ireland must comply with the principles and guidelines of good distribution practice for active substances.**]**

(3) Without prejudice to regulation 37(4) (manufacture and assembly in relation to active substances) and paragraph 9A of Schedule 8 (material to accompany an application for a UK marketing authorisation in relation to an active substance), where the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies to an active substance imported into **[**F236Northern Ireland**]** and where an active substance is imported **[**F237into Northern Ireland from a country other than an EEA State**]**—

(a) the importer must comply with good manufacturing practice and good distribution practice in relation to the active substance;

(b) the active substances must have been manufactured in accordance with standards which are at least equivalent to good manufacturing practice; and

(c) the active substances must be accompanied by a written confirmation from the competent authority of the **[**F238exporting country**]** of the following—

(i) the standards of manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to good manufacturing practice,

(ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of standards of manufacturing practice at least equivalent to good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in **[**F239Northern Ireland**]**, and

(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the **[**F238exporting country**]** to the Union without any delay.

[F240(3A) Without prejudice to regulation 37(4) and paragraph 9A of Schedule 8, where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance imported into Great Britain other than from Northern Ireland and where an active substance is so imported—

(a) the importer must comply with good manufacturing practice and good distribution practice in relation to the active substance,

(b) the active substances must have been manufactured in accordance with standards which are at least equivalent to good manufacturing practice, and

(c) the active substances must be accompanied by a written confirmation from the competent authority of the exporting country of the following—

(i) the standards of manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to good manufacturing practice,

(ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of standards of manufacturing practice at least equivalent to good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in Great Britain, and

(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting country to the licensing authority without any delay.**]**

(4) Paragraph **[**F241(3)(c) and (3A)(c) do**]** not apply—

(a) where the country from where the active substance is exported is included in the list referred to in Article 111b of the 2001 Directive **[**F242(in the case of an import into Northern Ireland) or paragraph (6) (in the case of an import into Great Britain)**]**; or

(b) for a period not exceeding the validity of the certificate of good manufacturing practice, where—

(i) in relation to a plant where active substances are manufactured where the competent authority of a member State **[**F243or licensing authority (in the case of an import into Northern Ireland) or licensing authority or an appropriate authority responsible for the licensing of medicinal products in a country included in a list under paragraph (6) (in the case of an import into Great Britain)**]** has found, upon inspection, that a plant complies with the principles and guidelines of good manufacturing practice, and

(ii) the licensing authority is of the opinion that it is necessary to waive the requirement to ensure availability of the active substance.

(5) The criteria in this regulation apply regardless of whether an active substance is intended for export.

[F244(6) The licensing authority may publish a list of countries which it is satisfied have a regulatory framework applicable to active substances exported to Great Britain that is equivalent to the regulatory framework in Great Britain, in that the respective control and enforcement activities in those countries ensures an equivalent level of protection of public health.

(7) Before including a country in the list under paragraph (6), the licensing authority must assess the equivalence referred to in that paragraph by—

(a) reviewing relevant documentation; and

(b) unless the country is included in the approved country for batch testing list, carrying out—

(i) an on-site review of the country's regulatory system, and

(ii) if the licensing authority considers it necessary, an inspection of one or more of that country's manufacturing sites for active substances.

(8) In carrying out an assessment under paragraph (7) the licensing authority must in particular take account of the—

(a) country's rules for good manufacturing practice;

(b) regularity of inspections to verify compliance with good manufacturing practice;

(c) effectiveness of enforcement of good manufacturing practice; and

(d) regularity and rapidity of information provided by that country relating to non-compliant producers of active substances.

(9) The licensing authority must—

(a) review the list under paragraph (6) to determine if a country included in it still satisfies the requirements for inclusion in the list, and if it is not so satisfied, remove that country; and

(b) undertake such a review at least every three years, beginning with the date on which a country is included in the list .**]**

Textual Amendments

F234 Reg. 45O(1)(1A) substituted for reg. 45O(1) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F235 Reg. 45O(2)(2A) substituted for reg. 45O(2) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F236 Words in reg. 45O(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(4)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F237 Words in reg. 45O(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(4)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F238 Words in reg. 45O(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(4)(c)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F239 Words in reg. 45O(3)(c)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(4)(d)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F240 Reg. 45O(3A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(4A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(d)**)

F241 Words in reg. 45O(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(5)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F242 Words in reg. 45O(4)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(5)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F243 Words in reg. 45O(4)(b)(i) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(5)(c)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 32(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F244 Reg. 45O(6)-(9) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **44(6)** (as amended by S.I. 2020/1488, **Sch. 2 para. 32(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Provision of information

45P.—(1) In this regulation—

"R" means a person who is, or has applied to the licensing authority to become, a registered importer, manufacturer or distributor of active substances;

"reporting year" means a period of twelve months ending on 31st March.

(2) On or before the date specified in paragraph (3), R must submit a report to the licensing authority which—

(a) includes a declaration that R has in place an appropriate system to ensure compliance with regulations 45N, 45O and this regulation; and

(b) details the system which R has in place to ensure such compliance.

(3) The date specified for the purposes of this paragraph is—

(a) in relation to any application made before 31st March 2014, the date of the application; and

(b) in relation to each subsequent reporting year, 30th April following the end of that year.

(4) R must without delay notify the licensing authority of any changes to the matters in respect of which evidence has been supplied in relation to paragraph (2) which might affect compliance with the requirements of this Chapter.

(5) Any report or notification to the licensing authority under paragraph (2) or (4) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(6) The licensing authority may give a notice to R, requiring R to provide information of a kind specified in the notice within the period specified in the notice.

(7) A notice under paragraph (6) may not be given to R unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether the registration should be varied, suspended or removed from the active substance register.

(8) A notice under paragraph (6) may specify information which the licensing authority thinks necessary for considering whether the registration should be varied, suspended or removed from the active substance register.

Power to suspend or vary or remove an active substance registration

45Q.—(1) The licensing authority may in accordance with regulation 45R—

(a) suspend an active substance registration for such period as the authority thinks fit;

(b) vary an active substance registration; or

(c) remove a person from the active substance register.

(2) The suspension of registration may be—

(a) total;

(b) limited to active substances of one or more descriptions; or

(c) limited to active substances imported, manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to an active substance registration except on one or more of the following grounds—

(a) the information in the application as a result of which the active substance registration was granted was false or incomplete in a material respect;

(b) a material change of circumstances has occurred in relation to any of the matters stated in the application;

(c) the person with an active substance registration has materially contravened a criterion of registration; or

(d) the person with an active substance registration has without reasonable excuse failed to supply information to the licensing authority with respect to active substances of a description to which the registration relates when required to do so under regulation 45P(6).

Procedure where licensing authority proposes to suspend or vary an active substance registration or remove a person from the active substance register

45R.—(1) This regulation applies where—

(a) the provisions of regulation 45S do not apply; and

(b) the licensing authority proposes to exercise the power in regulation 45Q(1).

(2) The licensing authority must notify the person with an active substance registration in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, variation or removal from the active substance register should take effect.

(3) The person with an active substance registration may before the date specified in the notice—

(a) make written representations to the licensing authority with respect to the proposal; or

(b) notify the licensing authority that the person wishes the licensing authority to submit the proposal to review upon oral representations.

(4) If the person with an active substance registration makes written representations in accordance with sub-paragraph (3)(a) the licensing authority must take those representations into account before making a decision in the matter.

(5) If the person with an active substance registration notifies the licensing authority that the person wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph (3)(b)—

(a) Schedule 5 has effect; and

(b) the person with an active substance registration must pay a fee for a review upon oral representations in accordance with the Fees Regulations.

(6) If the licensing authority proceeds to suspend or vary a registration or remove a person from the active substance register in accordance with the provisions of regulation 45Q it must give a notice to that person.

(7) The notice must—

(a) give particulars of the suspension, variation or removal; and

(b) give reasons for the decision to suspend, vary or remove a person's entry on the active substance register.

(8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of an active substance registration in cases of urgency

45S.—(1) The licensing authority may immediately suspend a person's active substance registration for a period not exceeding three months where it appears to the licensing authority that in the interests of safety it is appropriate to do so.

(2) This paragraph applies where—

(a) a person's active substance registration has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether a person's active substance registration should be—

(i) further suspended or varied, or

(ii) removed from the active substance register.

(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 45R (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 45R and any proceedings under that regulation have not been finally disposed of before the end of the period for which the registration was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the registration for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 45R to suspend, vary or remove a person's active substance registration is made on an application to the High Court under regulation 322(4), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (validity of decisions and proceedings).

Variation of an active substance registration on an application from the registered person

45T.—(1) This regulation applies if a person with an active substance registration applies to the licensing authority for a variation of the registration.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant;

(d) be accompanied by such information as may be required to enable the licensing authority to consider the application; and

(e) include the appropriate fee in accordance with the Fees Regulations.

(3) The licensing authority must vary an active substance registration or refuse to vary it within 30 days beginning with the day after the date when the licensing authority receives the application.

(4) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which notice is given; and

(b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 45Q and 45S.

Offences: breach of regulations and false information

45U.—(1) A person is guilty of an offence if the person imports, manufactures or distributes an active substance in breach of regulation 45M(1).

(2) A person is guilty of an offence if the person knowingly gives false information in—

(a) a registration form received by the licensing authority under regulation 45N(1);

(b) a notification to the licensing authority under regulation 45N(2) or 45P(4);

(c) an application for a variation under regulation 45T(2); or

(d) response to a notice under regulation 45T(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 45P(6) or 45T(4).

Penalties

45V.—(1) A person guilty of an offence under regulation 45U(1) or (2) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 45U(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.**]**

PART 4

Requirement for authorisation

Requirement for authorisation

46.—(1) A person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product.

(2) A person may not sell or supply, or offer to sell or supply, a medicinal product otherwise than in accordance with the terms of—

(a) a **[**F245UK**]** marketing authorisation;

[F246(aa) an EU marketing authorisation;**]**

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(3) A person may not possess an unauthorised medicinal product if the person knows or has reasonable cause to believe that the product is intended to be sold or supplied to another person within the **[**F247United Kingdom or the**]** European Economic Area.

(4) A person may not in the circumstances mentioned in paragraph (5)—

(a) manufacture or assemble a medicinal product; or

(b) procure the sale, supply, manufacture or assembly of a medicinal product.

(5) Those circumstances are that the person knows or has reasonable cause to believe that the medicinal product has been or is intended to be sold or supplied contrary to paragraph (1).

(6) For the purposes of this regulation a medicinal product is unauthorised if none of the following is in force for the product **[**F248in the country in which the product is intended to be sold or supplied, or offered for sale or supply**]**—

(a) a **[**F249UK**]** marketing authorisation;

[F250(aa) an EU marketing authorisation;**]**

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(7) This regulation is subject to—

(a) Part 10 (exceptions to requirement for marketing authorisation etc); and

(b) Article 83 of Regulation (EC) No 726/2004 (authorisation of placing on the market of medicinal product for compassionate reasons).

(8) A medicinal product is not unauthorised for the purposes of this regulation if—

(a) it is sold or supplied, or offered for sale or supply, for export to an EEA State; and

(b) the product may lawfully be sold or supplied in that state by virtue of legislation adopted by that state in compliance with the 2001 Directive.

(9) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of a medicinal product to a person outside the **[**F251United Kingdom or the**]** European Economic Area.

(10) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of an investigational medicinal product to a person specified in regulation 13(1) of the Clinical Trials Regulations for the purposes of administering that product in a clinical trial, provided that the conditions specified in regulation 13(2) of those Regulations are satisfied.

(11) Paragraph (3) does not apply to possession of an investigational medicinal product by a person who knows or has reasonable cause to believe—

(a) that the investigational medicinal product is intended to be sold or supplied within the **[**F252United Kingdom or the**]** European Economic Area; and

(b) that paragraph (10) will apply to the sale or supply.

Textual Amendments

F245 Word in reg. 46(2)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F246 Reg. 46(2)(aa) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **45(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 33(a)**)

F247 Words in reg. 46(3) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F248 Words in reg. 46(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(4)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 33(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F249 Word in reg. 46(6)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(4)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 33(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F250 Reg. 46(6)(aa) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(4)(c)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 33(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F251 Words in reg. 46(9) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(6)**; 2020 c. 1, Sch. 5 para. 1(1)

F252 Words in reg. 46(11)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **45(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Breach of requirement

47.—(1) A person who breaches regulation 46 is guilty of an offence.

(2) A person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment not exceeding two years or to both.

(3) It is to be presumed for the purposes of regulation 46(3) that, if a person ("P") knows or has reasonable cause to believe that a medicinal product is intended to be sold or supplied to another person, P knows or has reasonable cause to believe that the other person is within the **[**F253United Kingdom or the**]** European Economic Area.

(4) Paragraph (3) does not apply if P proves that P did not know or have reasonable cause to believe that the person was within the **[**F254United Kingdom or the**]** European Economic Area.

(5) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (4), the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

(6) Paragraph (7) applies if the holder of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation is charged with an offence under this regulation in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation, certificate or registration.

(7) Where this paragraph applies, it is a defence for the holder to prove that—

(a) the holder communicated the terms of the authorisation, certificate or registration to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

Textual Amendments

F253 Words in reg. 47(3) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **46(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F254 Words in reg. 47(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **46(2)**; 2020 c. 1, Sch. 5 para. 1(1)

PART 5

Marketing authorisations

Application of this Part

48.—(1) This Part applies to relevant medicinal products.

(2) In this Part—

[F255"EU reference medicinal product" means a medicinal product which falls within paragraph (b)(ii) or (iii) of the definition of "reference medicinal product;**]**

[F255"excluded reference product" means—

(a) a medicinal product authorised on the basis that it was a generic medicinal product;

(b) a medicinal product authorised on the basis that one or more of the circumstances listed in Article 10(3) of the 2001 Directive or regulation 52(1)(b) applied; or

(c) a biological medicinal product authorised on the basis that it did not meet a condition for being a generic medicinal product for any of the reasons described in Article 10(4) of the 2001 Directive or regulation 53A(1);**]**

[[F256]"generic medicinal product", in relation to a reference medicinal product for an application for—

(a) a UKMA(NI) or UKMA(UK), has the meaning given in Article 10(2)(b) of the 2001 Directive;

(b) a UKMA(GB), means a medicinal product—

(i) that has the same qualitative and quantitative composition in active substances as the reference medicinal product;

(ii) that has the same pharmaceutical form as the reference medicinal product; and

(iii) whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies;**]**

[[F257]"parallel import licence" means a licence that is granted by the licensing authority under this Part authorising the holder to place on the market a medicinal product imported in to the United Kingdom from an EEA State where that product—

(a) has been granted an EU marketing authorisation or a marketing authorisation in an EEA State under the 2001 Directive; and

(b) is essentially similar to a product that has been granted a UK marketing authorisation;**]**

"relevant medicinal product" means a medicinal product that is not—

(a) a registrable homoeopathic medicinal product; or

(b) a traditional herbal medicinal product; and

[[F258]"reference medicinal product" means—

(a) in relation to an application for a UKMA(NI), a medicinal product—

(i) authorised for sale or supply in Northern Ireland under regulation 49(1)(a), in accordance with the provisions of regulation 50; or

(ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,

but which is not an excluded reference product;

(b) in relation to an application for a UKMA(GB), a medicinal product—

(i) authorised under regulation 49(1)(a), in accordance with the provisions of regulation 50;

(ii) in relation to which an EU marketing authorisation was in force on IP completion day, but in relation to which no UK marketing authorisation is in force because the holder of the EU marketing authorisation notified the licensing authority in accordance with paragraph 6(3) of Schedule 33A that it did not wish to be the holder of a converted EU marketing authorisation; or

(iii) in relation to which an EU marketing authorisation had ceased to be in force before IP completion day for reasons not related to safety, quality or efficacy,

but which is not an excluded reference product;

(c) in relation to an application for a UKMA(UK), a medicinal product—

(i) authorised under regulation 49(1)(a) for sale or supply in the whole of the United Kingdom, whether by virtue of one or more UK marketing authorisations, in accordance with the provisions of regulation 50; or

(ii) in relation to which an EU marketing authorisation or a marketing authorisation granted by a member State pursuant to the 2001 Directive is or has been in force,

but which is not an excluded reference product;**]**

[[F259](3) In this Part, references to a medicinal product to be imported that is "essentially similar to a product that has been granted a UK marketing authorisation" are to be read as references to a medicinal product to be imported that—

(a) has been manufactured to the same formulation as a product that has been granted a UK marketing authorisation ("the UK product");

(b) contains the same active ingredients as the UK product;

(c) has the same therapeutic effect as the UK product,

and for the purposes of sub-paragraph (a), any differences in a product's formulation are to be ignored in so far as they are considered to be immaterial by the licensing authority.

(4) For the purposes of the definition of generic medicinal product—

(a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b) the various immediate-release oral pharmaceutical forms are considered to be the same pharmaceutical form.

(5) When a medicinal product has been granted a UK marketing authorisation under regulation 49(1)(a) in accordance with the provisions of regulation 50 ("initial marketing authorisation"), any additional strengths, pharmaceutical forms, administration routes, presentations, variations and extensions in relation to which a UK marketing authorisation is granted under regulation 49(1)(a), or which are included in the initial UK marketing authorisation, belong to the same "global marketing authorisation".

(6) Paragraph (7) applies if a medicinal product—

(a) belongs to a global marketing authorisation but is not the initial marketing authorisation; and

(b) is used as a reference medicinal product in accordance with regulations 51 to 53B.

(7) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51A(1) and (6) as if it had been authorised on the date of authorisation of the medicinal product to which the initial marketing authorisation relates.

(8) Paragraph (9) applies in relation to a medicinal product if—

(a) it is an EU reference medicinal product;

(b) it is used as a reference medicinal product in accordance with regulations 51 to 53B; and

(c) it belongs to a global marketing authorisation, as described in the second paragraph of Article 6(1) of the 2001 Directive; but

(d) it is not the initial marketing authorisation for the purposes of that global marketing authorisation.

(9) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51A(1) and (6) as if it had been authorised on the date of authorisation of the initial marketing authorisation for the purposes of the global marketing authorisation to which the product belongs.**]**

Textual Amendments

F255 Words in reg. 48(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **47(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 35(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F256 Words in reg. 48(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **47(2)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 35(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F257 Words in reg. 48(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **47(2)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F258 Words in reg. 48(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **47(2)(d)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 35(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F259 Reg. 48(3)-(9) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **47(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 35(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for UK marketing authorisation

Application for grant of UK marketing authorisation [F260or parallel import licence]

49.—[F261(1) The licensing authority may grant—

(a) subject to regulation 58, [F26258C, 58E, 58F and 58G,] a UK marketing authorisation; or

(b) a parallel import licence,

for a relevant medicinal product in response to an application made in accordance with this Part.]

[F263(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a UKMA(GB) only where—

(a) there is already in place, or will be at the time the UKMA(GB) is granted, a marketing authorisation in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in regulation 50(1A), and

(c) the medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) The licensing authority may only grant a parallel import licence if it is able to obtain the information necessary, whether from a competent authority of an EEA State or otherwise, to satisfy itself that the medicinal product to be imported—

(a) has been granted an EU marketing authorisation or a marketing authorisation under the 2001 Directive; and

(b) is essentially similar to a product that has already been granted a UK marketing authorisation.

(1C) A marketing authorisation or parallel import licence must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that authorisation or licence being "in force" is limited to that territory.]

(2) A marketing authorisation **[**F264or parallel import licence**]** granted under paragraph (1) shall contain terms approved by the licensing authority.

[F265(3) The applicant, where it is applying for—

[F266(a) a UKMA(UK) or UKMA(NI), must be established in the United Kingdom or an EEA State;**]**

(b) a UKMA(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom **[**F267or an EEA State**]**;

(c) a **[**F268parallel import licence**]**, must be established in the United Kingdom.**]**

[F269(3A) An application for a parallel import licence may not be made by—

(a) the holder of the marketing authorisation, within the meaning of the 2001 Directive, or the EU marketing authorisation, in respect of the relevant medicinal product to be imported; or

(b) a company which is in the same group as the holder of that marketing authorisation.**]**

(4) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the authorisation are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

[F270(9) The application must include a statement indicating whether the authorisation or licence sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(10) In this regulation "group" has the same meaning as in Part 15 of the Companies Act 2006 (see section 474(1) of that Act).**]**

Textual Amendments

F260 Words in reg. 49 heading inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 49 heading inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(a)**

F261 Reg. 49(1) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **5** and reg. 49(1) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **5**

F262 Words in reg. 49(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F263 Reg. 49(1A)-(1C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 36(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F264 Words in reg. 49(2) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 49(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(b)**

F265 Reg. 49(3) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **48(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(b)**)

F266 Reg. 49(3)(a) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(a)**

F267 Words in reg. 49(3)(b)(ii) inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(b)**

F268 Words in reg. 49(3)(c) substituted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **4(c)**

F269 Reg. 49(3A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F270 Reg. 49(9)(10) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **48(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 36(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Accompanying material

50.—(1) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide the material specified in Schedule 8 in relation to the product.

[[F271](1A) An applicant for the grant of a parallel import licence for a relevant medicinal product must provide the material specified in Schedule 8A in relation to the product.**]**

[[F272](1A) An applicant for the grant of a UK marketing authorisation for a relevant medicinal product must provide—

(a) in the case of an application under the unfettered access route—

(i) the material specified in Schedule 8C, and

(ii) any material specified in Schedule 8 which is not included in the material specified in Schedule 8C, and

(b) in all other cases, the material specified in Schedule 8,

in relation to the product.**]**

(2) An applicant for the grant of a UK marketing authorisation **[**[F273]or parallel import licence**]** for a radionuclide generator must, in addition, provide—

(a) a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter nucleid preparation; and

(b) qualitative and quantitative particulars of the eluate or the sublimate.

(3) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for dealing with the application.

[[F274](3A) Paragraph (4) does not apply in respect of an application under the unfettered access route.**]**

[[F275](4) If any of the medicinal products to which the application for a UK marketing authorisation relates—

(a) in the case of a UKMA(NI) or a UKMA(UK), is liable to be imported from a country other than an EEA State, or

(b) in the case of a UKMA(GB), is liable to be imported,

the material or information referred to in paragraph (3) may include an undertaking from the manufacturer of the product to comply with the matters set out in Schedule 9.**]**

(5) Material that is submitted under this regulation **[**[F276]for the purposes of a UK marketing authorisation**]** must be submitted in accordance with the applicable provisions of Annex I to the 2001 Directive.

[[F277](5A) The Secretary of State may by regulations in respect of Great Britain amend Schedule 8B (modifications of Annex I) in relation to a UKMA(GB) for the purpose of further modifying Annex I to the 2001 Directive in order to take account of scientific and technical progress.

(5B) The licensing authority may publish, for the purposes of applications made pursuant to this regulation—

(a) guidance on the presentation and content of the material specified in Schedule 8;

(b) scientific guidelines relating to the quality, safety and efficacy of medicinal products; and

(c) guidelines describing the active substance manufacturing process and process controls.

(5C) Unless replaced by guidance or guidelines published under the power conferred by paragraph (5B), the following guidance and guidelines continue to apply as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph) —

(a) the guidance published by the European Commission in the rules governing medicinal products in the European Community, Volume 2B, Notice to Applicants, Medicinal Products for human use, Presentation and content of the dossier, Common Technical Document;

(b) the scientific guidelines relating to the quality, safety and efficacy of medicinal products as adopted by the Committee for Medicinal Products for Human Use and published by the EMA and the other pharmaceutical Community guidelines published by the European Commission in the different volumes of the rules governing medicinal products in the European Community; and

(c) guidelines published by the EMA for the purposes of paragraph 3.2.1.2 of Part I of Annex I to the 2001 Directive.**]**

(6) **[**[F278]Unless the application is for a parallel import licence this**]** regulation is subject to—

[[F279](za) regulation 50A (requirement for certain applications to include results of paediatric investigation plan);

(zb) regulation 50E (application for paediatric use marketing authorisation);

(zc) regulation 50F (other applications including paediatric indications);

(zd) regulation 50G (applications relating to orphan medicinal products);

(ze) regulation 50H (applications relating to advanced therapy medicinal products);

(zf) regulation 50I (applications relating to conditional marketing authorisations);

(zg) regulation 50J (applications relating to medicinal products containing or consisting of genetically modified organisms);**]**

[F280(a) regulation 51 (application for UKMA(NI) relating to generic medicinal products);

(aa) regulation 51A (application for UKMA(GB) relating to generic medicinal products);

(ab) regulation 51B (application for UKMA(UK) relating to generic medicinal products);**]**

[F281(b) regulation 52 (application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc);

(ba) regulation 52A (application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc);

(bb) regulation 52B (application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc);**]**

[F282(c) regulation 53 (application for UKMA(NI) relating to similar biological medicinal products);

(ca) regulation 53A (application for UKMA(GB) relating to similar biological medicinal products);

(cb) regulation 53B (application for UKMA(UK) relating to similar biological medicinal products);**]**

(d) regulation 54 (applications relating to products in well-established medicinal use);

(e) regulation 55 (applications relating to new combinations of active substances);

(f) regulation 56 (applications containing information supplied in relation to another medicinal product with consent); and

(g) Schedule 10 (applications relating to national homoeopathic products).

[F283(7) The licensing authority may make appropriate arrangements with any EEA State or the EMA in order to obtain the information it considers necessary to satisfy itself that a product to be imported under a parallel import licence is essentially similar to a product that has been granted a UK marketing authorisation.

(8) If the licensing authority makes arrangements under paragraph (7), it must publish a list of the EEA States or the organisation with which it has made such arrangements.**]**

Textual Amendments

F271 Reg. 50(1A) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **6(2)** and reg. 50(1A) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **6(2)**

F272 Reg. 50(1A) inserted after subparagraph (1) (31.12.2020) by virtue of S.I. 2019/775, regs. 1, **49(1A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(a)**)

F273 Words in reg. 50(2) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 50(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(c)**

F274 Reg. 50(3A) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **49(1B)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(a)**)

F275 Reg. 50(4) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **49(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(b)**)

F276 Words in reg. 50(5) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **6(4)** and words in reg. 50(5) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **6(4)**

F277 Reg. 50(5A)-(5C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 37(c)(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F278 Words in reg. 50(6) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **6(5)** and words in reg. 50(6) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **6(5)**

F279 Reg. 50(6)(za)-(zg) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F280 Reg. 50(6)(a)-(ab) substituted for reg. 50(6)(a) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(4A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 37(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F281 Reg. 50(6)(b)-(bb) substituted for reg. 50(6)(b) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(4A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 37(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F282 Reg. 50(6)(c)-(cb) substituted for reg. 50(6)(c) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(4A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 37(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F283 Reg. 50(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **49(5)**; 2020 c. 1, Sch. 5 para. 1(1)

[F284Requirement for certain applications to include results of paediatric investigation plan

50A.—(1) This regulation applies in relation to an application—

(a) under regulation 49 for a UKMA(GB) or UKMA(UK) for a relevant medicinal product which is an initial marketing authorisation for the purposes of a global marketing authorisation, as described in regulation 48(5), or

(b) under regulation 49 or 65C for a new indication (including a paediatric indication), a new pharmaceutical form or a new route of administration in relation to a relevant medicinal product which is already the subject of a UKMA(GB) or UKMA(UK).

(2) Paragraph (1)(b) only applies if the medicinal product in relation to which the new indication, new pharmaceutical form or new route of administration is sought is protected in the United Kingdom by a supplementary protection certificate or a patent which qualifies for the granting in the United Kingdom of a supplementary protection certificate.

(3) An applicant making an application to which this regulation applies must, in addition to the material specified in regulation 50, or in Schedule 10A, provide to the licensing authority the results of all studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan.

(4) Where paragraph (1)(b) applies, the material provided pursuant to paragraph (3) must cover both the existing and new indication, pharmaceutical form or route of administration.

(5) Paragraph (3) does not apply–

(a) to the extent that the licensing authority has, in relation to all or part of the paediatric population, granted—

(i) a deferral under regulation 50C of the initiation or completion of some or all of the measures set out in a paediatric investigation plan, or

(ii) a waiver under regulation 50D of the obligation to produce the information referred to in paragraph (3); or

(b) if one of regulations 51 to 54 applies to the application.

(6) The applicant making an application to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

(7) In the case of an application for a UKMA(GB) under the unfettered access route, an agreed paediatric investigation plan in respect of the product's marketing authorisation in Northern Ireland applies also to that application as regards the UK marketing authorisation.

(8) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Agreement and modification of paediatric investigation plan

50B.—(1) Any person may prepare a paediatric investigation plan for the purposes of an application to which regulation 50A applies and submit it to the licensing authority with a request for agreement.

(2) A paediatric investigation plan must—

(a) specify the timing and measures proposed to assess the safety, quality and efficacy of a medicinal product in the paediatric population; and

(b) describe any measures to adapt the formulation of the medicinal product so as to make its use more acceptable, easier, safer or more effective for different subsets of the paediatric population.

(3) A person who requests the agreement of a paediatric investigation plan must submit it to the licensing authority not later than upon completion of the human pharmaco-kinetic studies in adults in relation to the medicinal product to which the plan relates, as specified in section 5.2.3 of Part I of Annex I to the 2001 Directive, unless the licensing authority agrees to accept a later request.

(4) The licensing authority may request the person applying for agreement of a paediatric investigation plan to supply further information in relation to the plan or to submit proposed modifications to it.

(5) The licensing authority must decide whether or not—

(a) the proposed studies will ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or subsets of it; and

(b) the expected therapeutic benefits of the medicinal product justify the studies proposed; and

in doing so must consider whether or not the measures proposed to adapt the formulation of the medicinal product for use in different subsets of the paediatric population are appropriate.

(6) If, following a decision by the licensing authority to agree a paediatric investigation plan, the person carrying out the plan encounters such difficulties with its implementation as to render the plan unworkable or no longer appropriate, that person may propose changes or request a deferral or a waiver, by submitting a request to the licensing authority, explaining the grounds for the request.

(7) Schedule 11 makes provision about advice and representations in relation to proposals to agree, or to refuse to agree, a paediatric investigation plan under paragraph (5) or to grant, or to refuse to grant, a deferral or waiver requested under paragraph (6).

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Deferral of initiation or completion of measures in paediatric investigation plan

50C.—(1) At the same time as the paediatric investigation plan is submitted under regulation 50B(1), the person requesting agreement of it may request the agreement of the licensing authority to a deferral of the initiation or completion of some or all of the measures set out in the plan.

(2) If the licensing authority is satisfied that a deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan can be justified on scientific and technical grounds, or on grounds related to public health, it may—

(a) agree to a request by the applicant to grant a deferral; or

(b) decide of its own motion to grant a deferral.

(3) If the licensing authority is satisfied as set out in paragraph (2), it must decide to grant a deferral where it is satisfied that—

(a) it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population; or

(b) studies in the paediatric population will take longer to conduct than studies in adults.

(4) If the licensing authority grants an application to which regulation 50A applies, it must, if it also grants a deferral in accordance with this regulation—

(a) record that fact in the product's summary of product characteristics, and, if it considers that it would be appropriate to do so, in the package leaflet; and

(b) specify in the document notifying the applicant of the grant of the deferral the time limits for the initiation or completion of the measures to which the deferral relates.

(5) Schedule 11 makes provision about advice and representations in relation to proposals to grant, or to refuse to grant, a deferral under paragraph (2) or (3).

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Waiver of production of information in a paediatric investigation plan

50D.—(1) The applicant making an application to which regulation 50A applies is exempt from the obligation to provide to the licensing authority the results of all studies performed, and details

of all information collected, in compliance with an agreed paediatric investigation plan, if a waiver is granted in accordance with this regulation.

(2) The licensing authority may grant a waiver in accordance with this regulation if it is satisfied that there is evidence showing that—

(a) the medicinal product or class of medicinal products is likely to be ineffective or unsafe in all or part of the paediatric population;

(b) the disease or condition for which the medicinal product or class of medicinal products is intended occurs only in adult populations; or

(c) the medicinal product does not represent a significant therapeutic benefit over existing treatments for patients in the paediatric population.

(3) The licensing authority may grant a waiver in accordance with this regulation—

(a) in respect of the entire paediatric population, or a subset of it;

(b) in respect of all of the therapeutic indications for the medicinal product concerned, or only some of them;

(c) of its own motion, or at the request of the applicant; or

(d) in respect of a specific product or a class of medicinal products.

(4) A person who requests a waiver in accordance with this regulation must submit the request to the licensing authority not later than upon completion of the human pharmaco-kinetic studies in adults in relation to the medicinal product concerned, as specified in section 5.2.3 of Part I of Annex I to the 2001 Directive, unless the licensing authority agrees to accept a later application.

(5) The licensing authority must maintain and publish a list of waivers which are granted under this regulation in respect of a class of medicinal products.

(6) The licensing authority may review a waiver which it has granted under this regulation and may revoke it if it considers it appropriate, having regard to the matters specified in paragraph (2).

(7) If the licensing authority revokes a waiver granted under this regulation, the holder of the UK marketing authorisation to which the waiver relates must, at the end of the period of 36 months beginning with the date of publication of the decision to revoke the waiver, submit the information referred to in regulation 50A(3) to the licensing authority.

(8) If the licensing authority grants an application to which regulation 50A applies, it must, if it also grants a waiver in accordance with this regulation, record that fact in the product's summary of product characteristics, and, if it considers that it would be appropriate to do so, in the package leaflet.

(9) Schedule 11 makes provision about advice and representations in relation to proposals to grant, or to refuse to grant, a waiver in response to a request made in accordance with paragraph (4) and to revoke a waiver under paragraph (6).

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for paediatric use marketing authorisation

50E.—(1) This regulation applies in relation to an application for a UKMA(GB) or UKMA(UK)—

(a) for a relevant medicinal product which is not protected in the United Kingdom by a supplementary protection certificate or by a patent which qualifies for the granting of a supplementary protection certificate; and

(b) which covers exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets of it, including the appropriate strength, pharmaceutical form or route of administration for that product.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority material necessary to establish the quality, safety and efficacy of the product in the paediatric population, including any specific data needed to support an appropriate strength, pharmaceutical form or route of administration for the product, in accordance with an agreed paediatric investigation plan.

(3) An application to which this regulation applies may, in accordance with regulations 51 to 55, refer to material supplied by the holder of a UK marketing authorisation.

(4) The applicant for a UK marketing authorisation to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

(5) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Other applications including paediatric indications

50F.—(1) This regulation applies in relation to an application to which neither regulation 50A nor 50E applies and which is—

(a) an application for a UKMA(GB) for a relevant medicinal product which includes a paediatric indication; or

(b) an application to include a paediatric indication in an existing UKMA(GB).

(2) The applicant making an application to which this regulation applies must include in the application details of the measures intended to ensure the follow up of efficacy and of possible adverse reactions to the paediatric use of the medicinal product.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Applications relating to orphan medicinal products

50G.—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product—

(a) in relation to which the applicant intends to demonstrate that the orphan criteria are met, and

(b) which, in the case of an application for a UKMA(NI) or a UKMA(UK), is not a medicinal product designated as an orphan medicinal product in accordance with the Orphan Regulation.

(2) The orphan criteria are that—

(a) the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition;

(b) either—

(i) the condition referred to in sub-paragraph (a) affects not more than five in 10,000 persons in Great Britain; or

(ii) the medicinal product is unlikely, when marketed, to generate sufficient financial return to justify the necessary investment; and

(c) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in Great Britain, or if such method exists, the medicinal product will be of significant benefit to those affected by the condition.

(3) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority material that demonstrates that the orphan criteria are met.

(4) Schedule 9A makes further provision about the orphan criteria and terms used in regulation 58D.

(5) The Ministers may by regulations amend Schedule 9A.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Applications relating to advanced therapy medicinal products

50H.—(1) This regulation applies in relation to an application for a UKMA(GB) for a relevant medicinal product which is an advanced therapy medicinal product.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority information about the measures the applicant envisages putting in place to ensure the follow up of the efficacy of the product and of any adverse reactions to it.

(3) In relation to an application for a UKMA(GB) for a combined advanced therapy medicinal product, the applicant must, in addition to the material specified in regulation 50 and paragraph (2), provide to the licensing authority evidence of conformity with the requirements of the Medical Devices Regulations 2002, including, where available, the results of the assessment of a notified body in accordance with those Regulations.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Applications relating to conditional marketing authorisations for sale or supply in Great Britain only

50I.—(1) This regulation applies in relation to an application for a UKMA(GB) for a relevant medicinal product which falls within paragraph (2).

(2) A relevant medicinal product falls within this paragraph if it is—

(a) aimed at the treatment, prevention or diagnosis of seriously debilitating or life-threatening diseases; or

(b) to be used in emergency situations, in response to public health threats.

(3) The applicant for a UK marketing authorisation to which this regulation applies may request that the licensing authority grant a conditional marketing authorisation if—

(a) comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied; and

(b) the applicant can demonstrate that—

(i) the positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product,

(ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data,

(iii) unmet medical needs will be fulfilled, and

(iv) the benefit to the public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

(4) In this regulation, "unmet medical needs" means medical needs in relation to a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the United Kingdom, or, even if such method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.

(5) The applicant for a UK marketing authorisation to which this regulation applies must include in the application material which demonstrates that the criteria in paragraph (3)(b) are met.

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Applications in relation to medicinal products containing or consisting of genetically modified organisms

50J.—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product which contains or consists of genetically modified organisms.

(2) The applicant for a UK marketing authorisation to which this regulation applies must, in addition to the material specified in regulation 50, provide to the licensing authority—

(a) a copy of the consent to the deliberate release into the environment of the genetically modified organisms for research and development purposes given pursuant to—

(i) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002,

(ii) regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002,

(iii) regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002, or

(iv) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003;

(b) a complete technical dossier supplying the information specified in Annexes III and IV to Directive 2001/18/EC;

(c) an environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and

(d) the results of any investigations performed for the purposes of research or development.

(3) In this regulation, "genetically modified organism" has the meaning given in Article 2(2) of Directive 2001/18/EC.**]**

Textual Amendments

F284 Regs. 50A-50J inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **53** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 40(a)-(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F285Application for UKMA(NI) relating to generic medicinal products

51.—(1) An applicant for a UKMA(NI) for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UKMA(NI) for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in Northern Ireland before the time at which it may be placed on the market in accordance with Article 10(1) of the 2001 Directive as modified by paragraph (3).

(3) The second subparagraph of Article 10(1) of the 2001 Directive has effect with the exception described in paragraph (4).

(4) Where—

(a) ten years have elapsed since a UK marketing authorisation was granted otherwise than under Chapter 4 of Title III to the 2001 Directive in relation to the reference medicinal product;

(b) in relation to that product there is—

(i) an EU marketing authorisation, or

(ii) a UKMA(NI) which was granted under that Chapter; and

(c) a period of ten years has not elapsed since the authorisation mentioned in sub-paragraph (b) for sale or supply of that product in the European Union,

the product may not be made available for sale or supply in Northern Ireland until the period mentioned in sub-paragraph (c) has elapsed.

Textual Amendments

F285 Regs. 51-51B substituted for reg. 51 (31.12.2020) by S.I. 2019/775, regs. 1, **56** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 41**)

Application for UKMA(GB) relating to generic medicinal products

51A.—(1) An applicant for a UKMA(GB) for a generic medicinal product may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials if the applicant can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for sale or supply in Great Britain which is or has been authorised for not less than eight years—

(a) under regulation 49(1)(a); or

(b) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004.

(2) In the case of an application under this regulation in relation to a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an authorised active substance which differs significantly in properties with regard to safety or efficacy from the active substance in the reference medicinal product, the applicant must supply additional information providing proof of the safety or efficacy of the salt, ester, ether, isomer, mixture of isomers, complex or derivative.

(3) The applicant may omit bioavailability studies from an application under this regulation if the applicant can demonstrate that the generic medicinal product meets the relevant criteria as specified in the guidelines referred to in paragraph (4).

(4) The licensing authority may publish guidelines specifying the criteria to be met by generic medicinal products for the purpose of omitting bioavailability studies from an application in accordance with paragraph (3).

(5) Until replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(2)(b) of the 2001 Directive continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under paragraph (4)).

(6) If the licensing authority grants a UKMA(GB) in relation to the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in Great Britain before the expiry of ten years beginning with the date on which the marketing authorisation for the reference medicinal product entered into force.

(7) Paragraph (8) applies where an EU reference medicinal product which falls within paragraph (b)(ii) of the definition of "reference medicinal product" is used as a reference medicinal product for the purposes of this regulation.

(8) Where this paragraph applies, the terms of the marketing authorisation of the EU reference medicinal product are treated as being the terms of the product's EU marketing authorisation as they stood immediately before IP completion day.

(9) Paragraph (10) applies if—

(a) during the first eight of the ten years referred to in paragraph (6) the marketing authorisation holder for the reference medicinal product obtained a UKMA(GB) or a UKMA(UK) for one or more new therapeutic indications; and

(b) during the scientific evaluation prior to their authorisation, the licensing authority considers the new indications bring a significant clinical benefit in comparison with existing therapies.

(10) Where this paragraph applies, the period of ten years referred to in paragraph (6) is extended to eleven years.

(11) Paragraph (12) applies where—

(a) an application for the grant or variation of a UKMA(GB) is made in relation to a new indication for a well-established substance; and

(b) significant pre-clinical or clinical studies were carried out in relation to the new indication.

(12) Where this paragraph applies, the applicant for a UKMA(GB) under paragraph (1) or regulation 52A or 53A may not refer in its application to the studies mentioned in paragraph (11)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UKMA(GB) in relation to the new indication.

Textual Amendments

F285 Regs. 51-51B substituted for reg. 51 (31.12.2020) by S.I. 2019/775, regs. 1, **56** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 41**)

Application for UKMA(UK) relating to generic medicinal products

51B.—(1) This regulation applies in relation to an application for a UKMA(UK) for a generic medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

(a) a UKMA(UK), the provisions of regulation 51(1) and (2) apply in respect of the application;

(b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) The applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

(a) the period referenced in the applicable Article referred to in regulation 51(1), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 51A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) In the case of an application under paragraph (3) in relation to a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an authorised active substance which differs significantly in properties with regard to safety or efficacy from the active substance in the reference medicinal product, the applicant must supply additional information providing proof of the safety or efficacy of the salt, ester, ether, isomer, mixture of isomers, complex or derivative.

(5) If the licensing authority grants a UK marketing authorisation in relation to the generic medicinal product in accordance with paragraph (3), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in the United Kingdom before the expiry of both—

(a) the period specified in regulation 51(2), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 51A(6) or (where applicable) 51A(10), in relation to the UKMA(GB) for the reference medicinal product.

(6) Paragraph (7) applies where—

(a) an application for the grant or variation of a UKMA(UK) is made in relation to a new indication for a well-established substance; and

(b) significant pre-clinical or clinical studies were carried out in relation to the new indication.

(7) Where this paragraph applies, the applicant for a UKMA(UK) under paragraph (1) or regulation 52B or 53B may not refer in its application to the studies mentioned in paragraph (6)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UKMA(UK) in relation to the new indication.**]**

Textual Amendments

F285 Regs. 51-51B substituted for reg. 51 (31.12.2020) by S.I. 2019/775, regs. 1, **56** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 41**)

[F286Application for UKMA(NI) relating to certain medicinal products that do not qualify as generic etc

52.—(1) This regulation applies where—

(a) an application is made for a UKMA(NI) by reference to another medicinal product as reference medicinal product; and

(b) one or more of the circumstances listed in Article 10(3) of the 2001 Directive applies in respect of the application.

(2) The applicant must provide information in accordance with Article 10(3) and (6) of the 2001 Directive.

(3) Paragraphs (2) to (4) of regulation 51 apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Textual Amendments

F286 Regs. 52-52B substituted for reg. 52 (31.12.2020) by S.I. 2019/775, regs. 1, **57** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 42**)

Application for UKMA(GB) relating to certain medicinal products that do not qualify as generic etc

52A.—(1) This regulation applies where—

(a) an application is made for a UKMA(GB) in respect of a product by reference to another medicinal product as reference medicinal product which is or has been authorised for sale or supply in Great Britain for not less than eight years—

(i) under regulation 49(1)(a); or

(ii) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004; and

(b) one or more of the following circumstances applies in respect of the application—

(i) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,

(ii) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or

(iii) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration.

(2) The applicant—

(a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to the reference medicinal product; but

(b) must provide the results of the appropriate pre-clinical tests or clinical trials relating to the applicable circumstance in paragraph (1)(b).

(3) Paragraphs (2) to (10) of regulation 51A apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Textual Amendments

F286 Regs. 52-52B substituted for reg. 52 (31.12.2020) by S.I. 2019/775, regs. 1, **57** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 42**)

Application for UKMA(UK) relating to certain medicinal products that do not qualify as generic etc

52B.—(1) This regulation applies in relation to an application for a UKMA(UK) in respect of a product by reference to another medicinal product as reference medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

(a) a UKMA(UK), the provisions of regulation 52(1) and (2) apply in respect of the application;

(b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) Subject to paragraph (4), the applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

(a) the period referenced in the applicable Article referred to regulation 52(1), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 52A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) Where one or more of the following circumstances applies in respect of the application—

(a) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,

(b) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or

(c) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration,

the applicant must provide the results of the appropriate pre-clinical tests or clinical trials relating to the applicable circumstance.

(5) Paragraphs (4) and (5) of regulation 51B apply to the application as they apply in relation to an application made in accordance with paragraph (3) of that regulation.**]**

Textual Amendments

F286 Regs. 52-52B substituted for reg. 52 (31.12.2020) by S.I. 2019/775, regs. 1, **57** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 42**)

[F287Application for UKMA(NI) relating to similar biological medicinal products

53.—(1) This regulation applies if an applicant for a UKMA(NI) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of any of the reasons described in Article 10(4) of the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10(4) and (6) of the 2001 Directive.

(3) Paragraphs (2) to (4) of regulation 51 apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Textual Amendments

F287 Regs. 53-53B substituted for reg. 53 (31.12.2020) by S.I. 2019/775, regs. 1, **58** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**)

Application for UKMA(GB) relating to similar biological medicinal products

53A.—(1) This regulation applies if an applicant for a UKMA(GB) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product.

(2) The applicant—

(a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to a reference medicinal product which is or has been authorised for not less than eight years—

(i) under regulation 49(1)(a), or

(ii) if the reference medicinal product is an EU reference medicinal product, under Regulation (EC) No 726/2004; but

(b) must provide the results of appropriate pre-clinical tests or clinical trials relating to the differences referred to in paragraph (1).

(3) The type and quantity of supplementary data to be provided by the applicant under paragraph (2)(b) must comply with the relevant criteria in Annex I to the 2001 Directive and in the related detailed guidelines published by the licensing authority under paragraph (4), or (as the case may be) as mentioned in paragraph (5).

(4) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (2)(b).

(5) Unless replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(4) of the 2001 Directive continue to apply on and after IP completion

day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(6) Paragraphs (4) to (12) of regulation 51A apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Textual Amendments

F287 Regs. 53-53B substituted for reg. 53 (31.12.2020) by S.I. 2019/775, regs. 1, **58** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**)

Application for UKMA(UK) relating to similar biological medicinal products

53B.—(1) This regulation applies in relation to an application for a UKMA(UK) for a biological medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

(a) a UKMA(UK), the provisions of regulation 53 apply in respect of the application;

(b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) Subject to paragraph (4), the applicant may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials only after the expiry of both—

(a) the period referenced in the applicable Article referred to regulation 53(1), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 53A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) Where the applicant for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product, the applicant must provide the results of the appropriate pre-clinical tests or clinical trials relating to the differences.

(5) The type and quantity of supplementary data to be provided by the applicant under paragraph (4) must comply with the relevant criteria in Annex I to the 2001 Directive and in the related detailed guidelines published by the licensing authority under paragraph (6), or (as the case may be) as mentioned in paragraph (7).

(6) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (4).

(7) Unless replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(4) of the 2001 Directive continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(8) Paragraphs (4) and (5) of regulation 51B apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.**]**

Textual Amendments

F287 Regs. 53-53B substituted for reg. 53 (31.12.2020) by S.I. 2019/775, regs. 1, **58** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**)

Applications relating to products in well-established medicinal use

54.—(1) This regulation applies if an applicant for a UK marketing authorisation for a relevant medicinal product is able to demonstrate that the active substances of the product have been in well-established medicinal use within the **[**F288United Kingdom or the**]** European Union for at least 10 years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I to the 2001 Directive.

[F289(2) The applicant may, by way of derogation from paragraph 10 of Schedule 8, replace the results of pre-clinical tests or clinical trials with appropriate scientific literature.**]**

Textual Amendments

F288 Words in reg. 54(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **59(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F289 Reg. 54(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **59(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Applications relating to new combinations of active substances

[F290**55.**—(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product that contains active substances, provided those active substances—

(a) have not been used in that combination for therapeutic purposes; and

(b) where the application is for—

(i) a UKMA(NI), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004;

(ii) a UKMA(GB), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations; or

(iii) a UKMA(UK), have been used in medicinal products that have been the subject of—

(aa) a UKMA(UK) under these Regulations; or

(bb) a relevant Northern Ireland authorisation.

(2) The applicant must provide the results of new pre-clinical tests or new clinical trials relating to that combination in accordance with paragraph 10 of Schedule 8, but does not need to provide scientific references relating to each individual active substance.

(3) In paragraph (1), "relevant Northern Ireland authorisation" means—

(a) a UKMA(NI) under these Regulations;

(b) a marketing authorisation under the 2001 Directive; or

(c) an EU marketing authorisation,

which authorises the sale or supply of a medicinal product in Northern Ireland.**]**

Textual Amendments

F290 Reg. 55 substituted (31.12.2020) by S.I. 2019/775, **reg. 60** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 44**)

Applications containing information supplied in relation to another product with consent

56.—(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product where—

(a) the product that is the subject of the application ("product A") has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as a product ("product B");

(b) product B is the subject of a UK marketing authorisation; and

(c) the holder of the marketing authorisation for product B has allowed use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on product B with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

(2) The documentation referred to in paragraph (1)(c) in relation to product B may be used in relation to the application in relation to product A [F291]...

Textual Amendments

F291 Words in reg. 56(2) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **61**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation to update information supplied in connection with application

57.—(1) The applicant for a UK marketing authorisation must update information supplied in accordance with paragraphs 18 to 21 of Schedule 8 (material to accompany an application for a UK marketing authorisation) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.

[F292Obligation to update information supplied in connection with parallel import licence application

57A.—(1) The applicant for a parallel import licence must update information supplied in accordance with Schedule 8A (material to accompany an application for a parallel import licence) in connection with the application.

(2) The applicant must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(3) Updated information within paragraphs (1) or (2) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.]

Textual Amendments

F292 Reg. 57A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **7** and reg. 57A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **7**

Consideration of application

Consideration of application

58.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a UK marketing authorisation before the end of 210 days beginning immediately after the day on which the application for the authorisation is submitted in accordance with regulations 49 to 55.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the information or material is provided.

(3) If the licensing authority requests the applicant to give an oral or written explanation of the application, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the explanation is provided.

(4) The licensing authority may grant the application only if, having considered the application and the accompanying material, the authority thinks that—

(a) the applicant has established the therapeutic efficacy of the product to which the application relates;

(b) the positive therapeutic effects of the product outweigh the risks to the health of patients or of the public associated with the product;

(c) the application and the accompanying material complies with regulations 49 to 55; and

(d) the product's qualitative and quantitative composition is as described in the application and the accompanying material.

[F293(4A) When considering an application for a UK marketing authorisation, the licensing authority may, if it considers it appropriate, have regard to—

(a) an opinion of the Committee for Medicinal Products for Human Use; or

(b) the results of an assessment of an application for a marketing authorisation by the appropriate authority for the licensing of medicinal products of a country other than the United Kingdom,

in respect of the medicinal product to which the application relates.

(4B) The licensing authority may under paragraph (4A)—

(a) decide to have regard to the opinions and assessments described in that paragraph in relation to certain types of medicinal products only;

(b) determine and publish a list of the countries other than the United Kingdom whose assessments of applications for a marketing authorisation are relevant for the purposes of paragraph (4A)(b); and

(c) decide to have regard to the assessments described in paragraph (4A)(b) in relation to medicinal products that have been authorised by way of certain procedures only.

(4C) When considering an application for a UK marketing authorisation (other than an application under the unfettered access route), the licensing authority may, if it considers it appropriate and without undertaking further consideration, rely on a decision by the European Commission to authorise the medicinal product to which the application relates to establish that any or all of the conditions in paragraph (4)(a), (b) or (d) have been met.**]**

(5) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a UK marketing authorisation.

F294(6) . . . . . .

F295(7) . . . . . .

[F296(8) In the case of an application under the unfettered access route, the licensing authority may grant a UKMA(GB) (notwithstanding paragraph (4)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 50 will continue to be met.

(9) The licencing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.**]**

Textual Amendments

F293 Regs. 58(4A)-(4C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **62(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 45(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F294 Reg. 58(6) omitted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **62(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F295 Reg. 58(7) omitted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **62(3)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F296 Reg. 58(8)(9) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **62(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 45(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F297**Paediatric rewards**

58A.—(1) Paragraph (2) applies if—

(a) an application—

(i) to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or

(ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,

is granted by the licensing authority; and

(b) the licensing authority is satisfied that the material provided by the applicant pursuant to—

(i) regulation 50A(3), where paragraph (1)(a)(i) applies; or

(ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,

demonstrates compliance with the agreed paediatric investigation plan.

(2) Where this paragraph applies, the licensing authority must—

(a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and

(b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.

(3) Where—

(a) paragraph (2) applies; or

(b) an application to which Article 7 or 8 of the Paediatric Regulation applies—

(i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or

(ii) confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,

the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).

(4) Paragraph (3) does not apply if the grant of the application referred to in paragraph (1)(a)—

(a) relates to a new paediatric indication; and

(b) the holder of the UK marketing authorisation is entitled to a one year extension of the ten year period referred to in regulation 51A(6), under regulation 51A(12).

(4A) Paragraph (3) does not apply where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is not in force in the same part of the United Kingdom as the supplementary protection certificate.

(4B) Where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is in force in in Great Britain only or in Northern Ireland only,

the extension provided for in paragraph (3) only applies in relation to Great Britain only or Northern Ireland only (as appropriate).

(5) If the UK marketing authorisation to which this regulation applies is an orphan marketing authorisation, paragraph (3) does not apply and regulation 58D(5) (orphan rewards) applies.

(6) Paragraphs (7) and (8) apply if the licensing authority grants a UK marketing authorisation in response to an application to which regulation 50E (paediatric use marketing authorisation) applies.

(7) Where this paragraph applies, the medicinal product to which the paediatric use marketing authorisation relates may retain the name of any medicinal product which contains the same active substance and in respect of which the holder of the paediatric use marketing authorisation has been granted a UK marketing authorisation for use in adults.

(8) Where this paragraph applies, the holder of the paediatric use marketing authorisation is entitled to benefit from the periods of data and marketing exclusivity referred to in regulation 51A(1) and (6) in relation to the material supplied pursuant to regulation 50E(2).

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Publication of information relating to paediatric marketing authorisations

58B.—(1) The licensing authority must publish a register of UK marketing authorisations—

(a) which include a paediatric indication following completion of an agreed paediatric investigation plan; and

(b) in relation to which the medicinal product was placed on the market for other indications before the holder obtained that paediatric indication.

(2) The register referred to in paragraph (1) must include the date by which the product must be placed on the market taking account of the paediatric indication in accordance with regulation 78A(4) (post-authorisation requirements in relation to UK marketing authorisations to which paediatric specific provisions apply).

(3) The licensing authority must publish a list of the marketing authorisation holders which have—

(a) benefitted from any of the rewards in regulation 58A; or

(b) failed to comply with any of the obligations in regulation 78A.

(4) The licensing authority must publish decisions made under—

(a) regulation 50B(5) or (7) (agreement and modification of paediatric investigation plan);

(b) regulation 50C(2) (deferral of the initiation or completion of measures in a paediatric investigation plan); and

(c) regulation 50D(2) (waiver of production of information in a paediatric investigation plan) in relation to a specific medicinal product.

(5) The decisions referred to in paragraph (4) must be published, with the omission of information of a commercially confidential nature, as soon as reasonably practicable after the decision has been made.

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Consideration of applications relating to orphan medicinal products

58C.—(1) If the licensing authority is satisfied in relation to an application for a UK marketing authorisation (including an application under the unfettered access route)—

(a) the orphan criteria are met in relation to all of the therapeutic indications to which the application relates; and

(b) it is otherwise appropriate to grant a UK marketing authorisation in respect of the application under regulation 49(1)(a),

it may grant a UK marketing authorisation which is known as an orphan marketing authorisation.

(2) The licensing authority must publish and keep up to date a list of orphan marketing authorisations.

(3) Schedule 11 makes provision about advice and representations in relation to proposals to grant a UK marketing authorisation in respect of which the applicant intended to demonstrate that the orphan criteria were met, in cases where the licensing authority considers that those criteria are not met.

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Orphan rewards

58D.—(1) Subject to the following provisions of this regulation, for the period of ten years beginning with the date on which the licensing authority grants an orphan marketing authorisation, the licensing authority must not—

(a) grant an application for a UK marketing authorisation; or

(b) grant an application to vary a UK marketing authorisation;

in relation to a medicinal product which is similar to the medicinal product to which the orphan marketing authorisation relates and in respect of the therapeutic indications which are covered by the orphan marketing authorisation.

(4) The period of ten years referred to in paragraph (1) may be reduced to six years if, at the end of the fifth year beginning on the date referred to in paragraph (1), the licensing authority is satisfied that the orphan criteria are no longer met in relation to the medicinal product.

(5) The period of ten years referred to in paragraph (1) is extended to twelve years if regulation 58A(2) (paediatric rewards) applies to the orphan marketing authorisation.

(6) Paragraph (1) does not apply if—

(a) the holder of the orphan marketing authorisation consents to the grant or variation of a UK marketing authorisation in relation to a similar medicinal product;

(b) the licensing authority is satisfied that the holder of the orphan marketing authorisation is unable to supply sufficient quantities of the medicinal product to which the orphan marketing authorisation relates; or

(c) a subsequent applicant can establish to the satisfaction of the licensing authority that the medicinal product to which the application relates, although similar to the medicinal product to which the orphan marketing authorisation relates, is safer or more effective than, or clinically superior to, that product.

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Consideration of applications relating to combined advanced therapy medicinal products

58E.—(1) When determining an application to which regulation 50H(3) (applications relating to combined advance therapy medicinal products) applies, the licensing authority must—

(a) assess the entire combined advanced therapy medicinal product in accordance with these Regulations; and

(b) recognise the results of the assessment of the notified body, if supplied.

(2) The licensing authority may request the notified body, if relevant, to provide it with information related to the results of the assessment.

(3) Paragraph (4) applies if an application to which regulation 50H(3) applies does not include the results of the assessment of a notified body, or if the notified body fails to supply information related to the results of the assessment when requested by the licensing authority.

(4) Where this paragraph applies, the licensing authority must seek an opinion on the conformity of the device part in accordance with the Medical Devices Regulations 2002 from a notified body identified in conjunction with the applicant, unless the licensing authority decides that the involvement of a notified body is not required.

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Consideration of applications relating to conditional marketing authorisations

58F.—(1) If the licensing authority is satisfied in relation to an application to which regulation 50I (applications relating to conditional marketing authorisations) applies that—

(a) the criteria in regulation 50I(3)(b) are met; and

(b) it is otherwise appropriate to grant a UKMA(GB) in respect of the application in accordance with regulation 49(1)(a),

it may grant a UK marketing authorisation which is known as a conditional marketing authorisation.

(2) Where regulation 50I(2)(b) (applications relating to conditional marketing authorisations) applies, the licensing authority may grant a conditional marketing authorisation if, in addition to comprehensive clinical data, comprehensive pre-clinical or pharmaceutical data have not been supplied.

(3) The licensing authority may, of its own motion, propose that a conditional marketing authorisation be granted if, having consulted the applicant for a UK marketing authorisation, it considers that the criteria in regulation 50I(3)(b) are met.

(4) If the licensing authority grants a conditional marketing authorisation in relation to a medicinal product, it may at any time decide that it is appropriate to grant a UK marketing authorisation in relation to that product which is not a conditional marketing authorisation.

(5) If the licensing authority grants a conditional marketing authorisation, the product's summary of product characteristics and package leaflet must include a statement to that effect, and the summary of product characteristics must include the date on which the conditional marketing authorisation is due for renewal.

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Consideration of applications in relation to medicinal products containing or consisting of genetically modified organisms

58G.—(1) When determining an application for a UK marketing authorisation in relation to which regulation 50J (applications relating to medicinal products containing or consisting of genetically modified organisms) applies, the licensing authority must be satisfied that the application respects the environmental safety requirements laid down by Directive 2001/18/EC.

(2) In reaching its view under paragraph (1), the licensing authority must consult the bodies responsible for the giving of consent pursuant to the legislation referred to in regulation 50J(2)(a).**]**

Textual Amendments

F297 Regs. 58A-58G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **64** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 47**); 2020 c. 1, **Sch. 5 para. 1(1)**

Conditions of UK marketing authorisation [F298or parallel import licence]: general

59.—(1) **[**F299Unless paragraph (1A) applies the licensing authority**]** may—

(a) grant a UK marketing authorisation subject to one or more of the conditions in paragraph (2); or

(b) vary or remove a condition in paragraph (2) to which the UK marketing authorisation is subject.

[F300(1A) Where the application concerns a parallel import licence, the licensing authority may—

(a) grant a parallel import licence subject to one or more of the conditions in paragraph (2)(a), (c), (d) or (e); or

(b) vary or remove a condition in paragraph (2)(a), (c), (d) or (e) to which the parallel import licence is subject.**]**

(2) Those conditions are—

(a) to take certain measures for ensuring the safe use of the medicinal product and include them in the risk management plan;

(b) to conduct post-authorisation safety studies;

(c) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Part 11;

(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;

(e) the existence of an adequate pharmacovigilance system; and

(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed.

(3) **[**F301In relation to a UKMA(NI) or UKMA(UK), an obligation**]** to conduct such studies as are referred to in paragraph (2)(f) must be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive, while taking into account the scientific guidance referred to in Article 108a of the 2001 Directive.

[F302(3A) In relation to a UKMA(GB), an obligation to conduct such studies as are referred to in paragraph (2)(f) must—

(a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and

(b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.

(3B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the condition referred to in paragraph (2)(f).

(3C) Paragraph (3A)(a) ceases to apply on the coming into force of regulations made under paragraph (3B).**]**

(4) The **[**F303UK**]** marketing authorisation **[**F304or parallel import licence**]** must lay down deadlines for the fulfilment of the conditions in paragraph (2) **[**F305where relevant and necessary**]**.

[F306(4A) Where the application is one to which regulation 50A, 50E or 50F (applications to which paediatric-specific provisions apply) applies, the licensing authority must, if it considers that there is a particular cause for concern, grant the UK marketing authorisation subject to a condition that—

(a) a risk management system be set up comprising a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of those interventions; or

(b) specific post-marketing studies be performed and submitted for review.

(4B) The licensing authority may request the holder to submit, in addition to the assessment required to be submitted pursuant to Part 9 of Schedule 12A (post-authorisation safety studies), a report assessing the effectiveness of any risk management system, and the results of any studies performed, in compliance with a condition imposed under paragraph (4A).

(4C) If the licensing authority grants a conditional marketing authorisation—

(a) it must impose, as a condition of the conditional marketing authorisation, an obligation on the holder of the authorisation to complete ongoing studies, or to conduct new studies, with a view to confirming the that the positive therapeutic effects of the product outweigh the risks to the health of patients or the public associated with the product, and to provide the additional data referred to in regulation 50I(3)(a);

(b) it may impose, as a condition of the conditional marketing authorisation, an obligation on the holder of that authorisation in relation to collection of pharmacovigilance data.

(4D) If the licensing authority grants a UK marketing authorisation in relation to an advanced therapy medicinal product, it must, if it considers that there is a particular cause for concern, grant the UK marketing authorisation subject to a condition that—

(a) a risk management system be set up which is designed to identify, characterise, prevent or minimise risks related to advanced therapy medicinal products, including an evaluation of the effectiveness of that system; or

(b) that specific post-marketing studies be carried out and submitted for review by the licensing authority.

(4E) The licensing authority may request the holder to submit, in addition to the assessment required to be submitted pursuant to Part 9 of Schedule 12A, a report assessing the effectiveness

of any risk management system, and the results of any studies performed, in compliance with a condition imposed under paragraph (4D).**]**

(5) The licensing authority must notify the EMA of any **[**[F307]UKMA(NI) or UKMA(UK)**]** that it has granted subject to a condition included in accordance with this regulation.

(6) The holder of the authorisation must incorporate any condition included in a marketing authorisation **[**[F308]or parallel import licence**]** in accordance with this regulation into the risk management system for the product.

(7) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject.

Textual Amendments

F298 Words in reg. 59 heading inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 59 heading inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(d)**

F299 Words in reg. 59(1) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **8(2)** and words in reg. 59(1) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **8(2)**

F300 Reg. 59(1A) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **8(3)** and reg. 59(1A) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **8(3)**

F301 Words in reg. 59(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 65(1A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 48(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F302 Reg. 59(3A)-(3C) inserted (31.12.2020) by S.I. 2019/775, **reg. 65(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 48(c)**)

F303 Word in reg. 59(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **65(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F304 Words in reg. 59(4) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 59(4) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(e)**

F305 Words in reg. 59(4) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **8(4)** and words in reg. 59(4) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **8(4)**

F306 Reg. 59(4A)-(4E) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **65(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F307 Words in reg. 59(5) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 65(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 48(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F308 Words in reg. 59(6) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 59(6) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(e)**

Conditions of UK marketing authorisation [F309or parallel import licence]: exceptional circumstances

60.—(1) The licensing authority may—

(a) grant a UK marketing authorisation **[**[F309]or parallel import licence**]** subject to conditions in accordance with the following paragraphs of this regulation; or

(b) vary or remove such a condition to which the UK marketing authorisation **[**F309or parallel import licence**]** is subject.

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the authorisation **[**F310or licence**]** or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation **[**F311or licence**]** subject to conditions may be exercised only—

(a) in exceptional circumstances; and

(b) when the applicant can show that the applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the authorisation **[**F310or licence**]** relates.

(6) The conditions may, in particular, require that, where there is a serious adverse reaction relating to the use of the product—

(a) the reaction must be reported to the licensing authority; and

(b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

(a) the conditions under this regulation to which a UK marketing authorisation **[**F309or parallel import licence**]** is subject; and

(b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

(a) at the end of the period of one year beginning with the date on which the authorisation **[**F310or licence**]** was granted; and

(b) at the end of each subsequent period of one year.

[F312(9) The licensing authority must notify the EMA of any UKMA(NI) or UKMA(UK) that it has granted subject to a condition included in accordance with this regulation.**]**

(10) The holder of the authorisation **[**F310or licence**]** must incorporate any condition included in a marketing authorisation **[**F313or licence**]** in accordance with this regulation into the risk management system for the product.

(11) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation **[**F309or parallel import licence**]** is subject.

Textual Amendments

F309 Words in reg. 60 inserted (31.12.2020) by S.I. 2019/775, **reg. 66(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**)

F310 Words in reg. 60 inserted (31.12.2020) by S.I. 2019/775, **reg. 66(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**)

F311 Words in reg. 60(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 66(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**)

F312 Reg. 60(9) substituted (31.12.2020) by S.I. 2019/775, **reg. 66(d)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**)

F313 Words in reg. 60(10) inserted (31.12.2020) by S.I. 2019/775, **reg. 66(e)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**)

[F314Condition as to the submitting of samples and other information to the appropriate authority

60A.—(1) In this regulation—

"the appropriate authority" is to be construed in accordance with section 57(7) of the Health and Social Care Act 2012;

"appropriate documentation", in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing condition or pursuant to a notification under paragraph (12), means—

(a) any certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products that relates to the sample of the batch submitted to the appropriate authority with that certificate; and

(b) such other documentation as the appropriate authority notifies the holder of the UK marketing authorisation to which the sample relates that it requires;

"approved country list for batch testing and certification of biological medicinal products" means the list described in paragraph (5), and "approved country for batch testing and certification of biological medicinal products" means a country included in that list;

"the batch testing condition", in respect of a UK marketing authorisation, is a condition to the effect that, unless the batch testing exemption applies, the holder of the UK marketing authorisation—

(a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and

(b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in the United Kingdom until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the batch is in conformity with the approved specifications in the UK marketing authorisation; and

"the batch testing exemption" means that—

(a) in the case of a medicinal product for sale or supply in Northern Ireland only—

(i) a certificate has been issued by a laboratory in an EEA State, and

(ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or

(b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and

(iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority's own examination of a sample from the batch, the appropriate documentation or both.

(2) The licensing authority may impose the batch testing condition in respect of a UK marketing authorisation for a medicinal product that is—

(a) a live vaccine;

(b) an immunological product used in the primary immunisation of infants or other groups at risk;

(c) an immunological product used in public health immunisation programmes;

(d) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or

(e) derived from human blood or human plasma.

(3) If the licensing authority imposes a condition in respect of a UK marketing authorisation for a medicinal product of a kind mentioned in paragraph (2)(d), it must, in imposing that condition, specify a period of time for the duration of the condition.

(4) The appropriate authority must complete its examination of the sample for testing, the appropriate documentation or both (as the case may be) within the period of 60 days, beginning with the date on which the appropriate authority is in receipt of both the sample for testing, and the appropriate documentation.

(5) The appropriate authority must publish a list, to be known as the approved country list for batch testing and certification of biological medicinal products, specifying the countries that are approved for the purposes of the appropriate authority's assessment under paragraph (6) and regulation 60B(5).

(6) Where a holder of a UK marketing authorisation, in order to comply with the batch testing condition, submits appropriate documentation that includes a certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products in respect of the batch, the appropriate authority must, in addition to any other factors it considers relevant, take that into account in determining whether the appropriate authority needs to undertake any further testing of the medicinal product submitted to it.

(7) In order to determine whether a country should be included in the approved country list for batch testing and certification of biological medicinal products, the appropriate authority may, in particular, take into account whether the relevant certification process in that country is based on testing performed under a quality assurance system that undergoes regular external assessment to ensure it meets an appropriate standard of competence for testing biological medicines.

(8) The appropriate authority must—

(a) review the countries it has included in the approved country list for batch testing and certification of biological medicinal products to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

(b) undertake that review at least every three years beginning with the date on which that country is included in the list.

(9) The appropriate authority must—

(a) publish a list of countries, or organisations, with whom the United Kingdom has an agreement for the purposes of the application of the batch testing exemption under this regulation or regulation 60B;

(b) include in that list any conditions or restrictions in that agreement that affect the applicability of the batch testing exemption under this regulation or regulation 60B; and

(c) update that list as soon as reasonably practicable if—

(i) the United Kingdom no longer has an agreement with a country or organisation included in the list,

(ii) any such agreement is amended, or

(iii) the United Kingdom enters in to a new agreement with a country or organisation.

(10) Where a holder of a UK marketing authorisation relies on the batch testing exemption in relation to a batch of a medicinal product, that holder must submit the certificate in respect of that batch to the licensing authority and the appropriate authority, and such other documentation as those authorities may notify that holder they require, before it sells or supplies, or offers to sell or supply, a medicinal product that forms part of that batch in the United Kingdom.

(11) Paragraph (12) applies where the appropriate authority considers that there are public health concerns in respect of a batch of a medicinal product ("the relevant batch") in relation to which the batch testing exemption would otherwise apply.

(12) Where this paragraph applies, the appropriate authority must, subject to paragraph (13), notify the holder of the UK marketing authorisation in respect of the relevant batch that it nevertheless requires that holder—

(a) to submit a sample from the relevant batch to the appropriate authority, together with appropriate documentation; and

(b) not to sell or supply, or to offer to sell or supply, a medicinal product that forms part of that batch in the United Kingdom until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the relevant batch is in conformity with the approved specifications in the UK marketing authorisation.

(13) The appropriate authority may only exercise its powers under paragraph (12) if the agreement made between the country in which the certificate was issued, and the United Kingdom (whether the agreement is solely with that country, a group of countries or an organisation of which that country is a part) provides for the relevant batch to be re-examined by the appropriate authority in the circumstances described in paragraph (11).

(14) The appropriate authority may, in any particular case, apply this regulation to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this regulation to—

(a) a UK marketing authorisation should be read as a reference to a parallel import licence for a medicinal product,

(b) the holder of a UK marketing authorisation should be read as a reference to the holder of a parallel import licence, and

(c) the approved specifications in a UK marketing authorisation should be read as a reference to the approved specifications in the UK reference product specified for the purposes of the parallel import licence in accordance with paragraph 4 of Schedule 8A.

(15) Where, pursuant to paragraph (14), this regulation is applied to a medicinal product imported into the United Kingdom pursuant to a parallel import licence, sub-paragraph (a) of the definition of "the batch testing exemption" does not apply.

(16) In the application of this regulation to a medicinal product for sale or supply in Northern Ireland only to which Article 114 of the 2001 Directive applies, a reference in this regulation to a laboratory is to an Official Medicines Control Laboratory or a laboratory referred to in that Article.**]**

Textual Amendments

F314 Regs. 60A, 60B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **67** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 50**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F314Submitting of samples and other information: EU marketing authorisations

60B.—(1) In this regulation—

"the appropriate authority" is to be construed in accordance with section 57(7) of the Health and Social Care Act 2012;

"appropriate documentation", in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing requirement or pursuant to a notification under paragraph (8), means such documentation as the appropriate authority notifies the holder of the EU marketing authorisation to which the sample relates that it requires;

"approved country list for batch testing and certification of biological medicinal products" means the list described in regulation 60A(5), and "approved country for batch testing and certification of biological medicinal products" means a country included in that list;

"the batch testing exemption" means that—

(a) (i) a certificate has been issued by a laboratory in an EEA State, and

(ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or

(b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and

(iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority's own examination of a sample from the batch, the appropriate documentation or both;

"the batch testing requirement", in respect of an EU marketing authorisation, is a requirement that, unless the batch testing exemption applies, the holder of the EU marketing authorisation—

(a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and

(b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the batch is in conformity with the approved specifications in the EU marketing authorisation.

(2) The licensing authority may impose the batch testing requirement on the holder of an EU marketing authorisation for a medicinal product—

(a) that is—

(i) a live vaccine;

(ii) an immunological product used in the primary immunisation of infants or other groups at risk;

(iii) an immunological product used in public health immunisation programmes;

(iv) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or

(v) derived from human blood or human plasma, and

(b) which is intended for sale or supply in Northern Ireland.

(3) If the licensing authority imposes the batch testing requirement in respect of an EU marketing authorisation for a medicinal product of a kind mentioned in paragraph (2)(a)(iv), it must, in imposing that requirement, specify a period of time for the duration of the requirement.

(4) The appropriate authority must complete its examination of the sample for testing, the appropriate documentation or both (as the case may be) within the period of 60 days, beginning with the date on which the appropriate authority is in receipt of both the sample for testing, and the appropriate documentation.

(5) Where a holder of an EU marketing authorisation, in order to comply with the batch testing requirement, submits appropriate documentation that includes a certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products in respect of the batch, the appropriate authority must, in addition to any other factors it considers relevant, take that into account in determining whether the appropriate authority needs to undertake any further testing of the medicinal product submitted to it.

(6) Where a holder of an EU marketing authorisation relies on the batch testing exemption in relation to a batch of a medicinal product, that holder must submit the certificate in respect of that batch to the licensing authority and the appropriate authority, and such other documentation as those authorities may notify that holder they require, before it sells or supplies, or offers to sell or supply, a medicinal product that forms part of that batch in Northern Ireland.

(7) Paragraph (8) applies where the appropriate authority considers that there are public health concerns in respect of a batch of a medicinal product ("the relevant batch") in relation to which the batch testing exemption would otherwise apply.

(8) Where this paragraph applies, the appropriate authority must, subject to paragraph (9), notify the holder of the EU marketing authorisation in respect of the relevant batch that it nevertheless requires that holder—

(a) to submit a sample from the relevant batch to the appropriate authority, together with appropriate documentation; and

(b) not to sell or supply, or to offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the relevant batch is in conformity with the approved specifications in the EU marketing authorisation.

(9) The appropriate authority may only exercise its powers under paragraph (8) if the agreement made between the country in which the certificate was issued, and the United Kingdom (whether the agreement is solely with that country, a group of countries or an organisation of which that country is a part) provides for the relevant batch to be re-examined by the appropriate authority in the circumstances described in paragraph (7).

(10) A reference in this regulation to a laboratory (other than in paragraph (b) of the definition of "the batch testing exemption" in paragraph (1)) is to an Official Medicines Control Laboratory or a laboratory referred to in Article 114 of the 2001 Directive.**]**

Textual Amendments

F314 Regs. 60A, 60B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **67** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 50**); 2020 c. 1, **Sch. 5 para. 1(1)**

Conditions of UK marketing authorisation: new obligations post-authorisation

61.—(1) After the granting of a UK marketing authorisation, the licensing authority may impose an obligation on the holder of the authorisation in accordance with either or both of —

(a) paragraph (4), in a case where paragraph (2) applies; or

(b) paragraph (5), in a case where paragraph (3) applies.

(2) This paragraph applies if there are concerns about the risks of a medicinal product that is the subject of a marketing authorisation.

(3) This paragraph applies if the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly.

[F315(4) The obligation in this paragraph is—

(a) to conduct a post-authorisation safety study; or

(b) in relation to a UKMA(GB), to comply with such other conditions or restrictions as the licensing authority considers essential for the safe and effective use of the medicinal product.**]**

(5) The obligation in this paragraph is to conduct a post-authorisation efficacy study.

(6) If concerns as described in paragraph (2) apply to more than one medicinal product **[**F316authorised by a UKMA(NI) or UKMA(UK)**]**, the licensing authority shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study.

[F317(6A) If concerns as described in paragraph (2) apply to more than one medicinal product authorised by a UKMA(GB), the licensing authority—

(a) must, where the obligation is to conduct a post-authorisation safety study, encourage the UK marketing authorisation holders concerned to conduct a joint study, and

(b) may, where the obligation is to comply with any other conditions or restrictions, encourage the UK marketing authorisation holders concerned to take co-ordinated action to comply with the conditions or restrictions.**]**

(7) **[**F318In relation to a UKMA(NI) or UKMA(UK), the obligation under paragraph (5) must**]** be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive while taking account of the scientific guidance referred to in Article 108a of the 2001 Directive.

[F319(7A) In relation to a UKMA(GB), the obligation under paragraph (5) must—

(a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and

(b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.

(7B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the obligation under paragraph (5).

(7C) Paragraph (7A)(a) ceases to apply on the coming into force of regulations made under paragraph (7B).**]**

(8) Where the licensing authority imposes an obligation under paragraph (4) or (5), it must without delay give written notice to the holder of —

(a) the imposition of the obligation;

(b) the justification for the imposition;

(c) the objectives and timeframe for submission and conduct of the study; and

(d) the opportunity to present written observations in accordance with paragraph (9) and the time limit specified for doing so.

(9) Where the holder so requests within the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (8), the licensing authority must provide the holder of the authorisation with an opportunity to present written observations in response to the imposition of the obligation within the time limit specified by the licensing authority in the notice.

(10) Where the holder presents written observations under paragraph (9), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (4) or (5) on the basis of the written observations as soon as is reasonably practicable.

(11) Paragraph (12) applies where the licensing authority—

(a) imposes an obligation under paragraph (4) or (5) and the holder does not present written representations under paragraph (9); or

(b) confirms the imposition of an obligation under paragraph (10).

(12) Where this paragraph applies, the licensing authority must vary the marketing authorisation to include the obligation as a condition of the marketing authorisation as if it were a condition imposed under regulation 59 (conditions of UK marketing authorisations: general).

(13) The licensing authority must notify the EMA **[**[F320], in relation to a UKMA(NI) or UKMA(UK),**]** that the marketing authorisation is subject to a condition included in accordance with paragraph (12).

(14) The holder of the authorisation must incorporate any condition included in a marketing authorisation in accordance with paragraph (12) into the risk management system for the product.

(15) Schedule 11, which makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject, shall apply in relation to the variation or removal of a condition included in a marketing authorisation in accordance with paragraph (12).

Textual Amendments

F315 Reg. 61(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **68(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 51(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F316 Words in reg. 61(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 68(2A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 51(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F317 Reg. 61(6A) inserted (31.12.2020) by S.I. 2019/775, **reg. 68(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(c)**)

F318 Words in reg. 61(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) (S.I. 2019/775), reg. 68(3A) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 51(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F319 Reg. 61(7A)-(7C) inserted (31.12.2020) by S.I. 2019/775, **reg. 68(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(e)**)

F320 Words in reg. 61(13) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) (S.I. 2019/775), reg. 68(5) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 51(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Classification of UK marketing authorisation [F321or parallel import licence]

62.—(1) A UK marketing authorisation **[**F322or parallel import licence**]** must include a term that the product to which the authorisation relates is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(2) In making a determination under paragraph (1), the licensing authority must have regard to the following in relation to the product—

(a) the maximum single dose;

(b) the maximum daily dose;

(c) the strength of the product;

(d) its pharmaceutical form;

(e) its packaging; and

(f) such other circumstances relating to its use as the licensing authority considers relevant.

(3) A UK marketing authorisation **[**F323or parallel import licence**]** must be granted subject to a condition that the product to which the authorisation relates is to be available only on prescription if the licensing authority considers that the product—

(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;

(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;

(c) contains substances, or preparations of substances, of which the activity requires, or the side effects require, further investigation; or

(d) is normally prescribed by a doctor or dentist for parenteral administration.

(4) In deciding whether paragraph (3) applies to a product, the licensing authority must take into account whether the product—

(a) contains a substance listed in any of Schedules I, II or IV to the Narcotics Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention);

(b) contains a substance listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention);

(c) is likely, if incorrectly used—

(i) to present a substantial risk of medicinal abuse,

(ii) to lead to addiction, or

(iii) to be used for illegal purposes;

(d) contains a substance that, by reason of its novelty or properties, might fall within paragraph (c), but as to which there is insufficient information available to determine whether it does so fall;

(e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments that can only be followed in a hospital;

(f) is used in the treatment of conditions that must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or

(g) is intended for outpatients but may produce very serious side effects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(5) A UK marketing authorisation **[**[F324]or parallel import licence**]** may include a term that the product to which the authorisation relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Textual Amendments

F321 Words in reg. 62 heading inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 62 heading inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(f)**

F322 Words in reg. 62(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 62(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(g)**

F323 Words in reg. 62(3) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 62(3) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(g)**

F324 Words in reg. 62(5) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 62(5) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(g)**

Frequency of periodic safety update reports

63.—(1) The licensing authority must, if paragraph (2) applies, include in a UK marketing authorisation a term that specifies the frequency, calculated from the date on which the authorisation is granted, with which the holder of the authorisation must submit periodic safety update reports in accordance with regulation 191(8) (obligation on holder to submit periodic safety update reports: general requirements).

(2) This paragraph applies in the case of a medicinal product in relation to which regulation 191(8) applies by virtue of regulation 191(1).

Duties of licensing authority in connection with determination

64.—(1) This regulation applies if the licensing authority grants a UK marketing authorisation.

(2) The licensing authority must inform the holder of the authorisation of the summary of the product characteristics as approved by the authority.

(3) The licensing authority must ensure that the summary of the product characteristics continues to match the version it has approved, subject to any changes it approves.

(4) As soon as is reasonably practicable after granting the marketing authorisation, the licensing authority must make available publicly—

(a) the marketing authorisation;

(b) the package leaflet;

(c) the summary of the product characteristics;

[[F325](d) any conditions—

(i) in the case of a UKMA(NI) or UKMA(UK), established in accordance with Articles 21a, 22 and 22a of the 2001 Directive;

(ii) in the case of UKMA(GB), imposed under regulations 59 to 61; and**]**

(e) any deadlines for the fulfilment of those conditions.

(5) The licensing authority must draw up an assessment report and make comments on the file as regards—

(a) the results of the pharmaceutical and pre-clinical tests, the clinical trials, the risk management system and the pharmacovigilance system of the product to which the authorisation relates; or

(b) in the case of a national homoeopathic medicinal product within the meaning of Schedule 10, the information submitted under paragraphs 3 to 5 of that Schedule.

(6) The licensing authority must—

(a) revise the assessment report whenever new information becomes available that is of importance for the evaluation of the quality, safety or efficacy of the medicinal product;

(b) make the assessment report publicly available (with the omission of information of a commercially confidential nature) as soon as is reasonably practicable after it has been prepared or revised; and

(c) include in the assessment report a summary, written in a manner that is understandable to the public, that contains, in particular, a section relating to the conditions of use of the medicinal product.

(7) The assessment must be provided separately for each indication that is authorised.

Textual Amendments

F325 Reg. 64(4)(d) substituted (31.12.2020) by S.I. 2019/775, **reg. 69** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 52**)

[[F326]**Obligation of licensing authority in case of change of classification**

64A.—(1) In this regulation, "classification", in relation to a medicinal product, means the term of the product's UK marketing authorisation which determines the way in which the product is to be made available, as described in regulation 62(1).

(2) This regulation applies where—

(a) the licensing authority grants or varies—

(i) a UK marketing authorisation;

(ii) an Article 126a authorisation;

(iii) a traditional herbal registration; or

(iv) a certificate of registration of a homoeopathic medicinal product;

(b) the grant or variation of the UK marketing authorisation involves a change of the classification of the medicinal product to which the authorisation relates; and

(c) the application for the UK marketing authorisation or variation was supported by the results of significant pre-clinical tests or clinical trials relating to the proposed classification.

(3) Where this regulation applies, the licensing authority may not, for the period of one year beginning with the date on which the UK marketing authorisation was granted or varied, refer to the results of the tests or trials referred to in paragraph (2)(c) when examining an application by another applicant or UK marketing authorisation holder for a change of classification of the same kind as that to which the tests or trials relate.**]**

Textual Amendments

F326 Reg. 64A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **70** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 53**); 2020 c. 1, **Sch. 5 para. 1(1)**

Validity of UK marketing authorisation

Validity of UK marketing authorisation

65.—(1) Subject to the following paragraphs, a UK marketing authorisation remains in force—

(a) for an initial period of five years beginning with the date on which it is granted; and

(b) if the authorisation is renewed in accordance with regulation 66, for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of an authorisation, determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event the authorisation remains in force—

(a) for a further period of five years beginning with the date on which it is first renewed; and

(b) if the authorisation is further renewed under regulation 66, for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of an authorisation is made in accordance with regulation 66 the authorisation remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

[F327(za) regulation 65B;**]**

(a) regulation 67 (failure to place on the market etc); and

(b) regulation 68 (revocation etc of marketing authorisations).

Textual Amendments

F327 Reg. 65(5)(za) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **71**; 2020 c. 1, Sch. 5 para. 1(1)

[F328Validity of parallel import licence

65A.—(1) Unless paragraph (2) applies, a parallel import licence remains in force for a period of 5 years from the date it is granted or renewed.

(2) A parallel import licence will cease to be valid if—

(a) the information supplied in the application for a licence no longer matches the information currently approved for the reference product by the licensing authority;

(b) details about the product imported under the licence are not consistent with the details supplied in the application; or

(c) the patient information leaflet supplied with the product is not consistent with latest version of the leaflet that is required to be issued with the product by the licensing authority, and

an application to vary the licence to update any details in relation to sub-paragraph (a) to (c) has not been granted by the licensing authority because the condition in regulation 68(11) has not been met.**]**

Textual Amendments

F328 Reg. 65A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **9** and reg. 65A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **9**

[F329Validity of conditional marketing authorisation

65B.—(1) A conditional marketing authorisation remains in force—

(a) for an initial period of one year beginning with the date on which it is granted; and

(b) if it is renewed in accordance with regulation 66B, for further periods of one year beginning with the date on which the renewal is granted.

(2) If an application for the renewal or further renewal of a conditional marketing authorisation is made in accordance with regulation 66B the authorisation remains in force until the licensing authority notifies the applicant of its decision on the application.

Textual Amendments

F329 Regs. 65B, 65C inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **72** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 54**); 2020 c. 1, **Sch. 5 para. 1(1)**

Variation of a UKMA(GB)

65C.—(1) A UKMA(GB) holder may apply to vary the authorisation.

(2) Any such application must be made in accordance with Schedule 10A.

(3) Schedule 10A does not apply to the transfer of a UKMA(GB) from one person to another.

(4) The licensing authority may publish guidance on the details of the various categories of variations, on the operation of the procedures laid down in Schedule 10A, and on the documentation to be submitted pursuant to those procedures.

(5) Any guidance referred to in paragraph (4) must be regularly reviewed and, when necessary, updated.

(6) Unless replaced by guidelines published under paragraph (4), the guidelines published by the Commission under Article 4 of Regulation (EC) No 1234/2008 which applied immediately before IP completion day, insofar only as they concern applications under Chapter IIa of that Regulation, continue to apply to—

(a) applications made under regulation 65C on or after IP completion day; or

(b) applications made before IP completion day to which regulation 65C and Schedule 10A apply by virtue of Parts 3 and 5 of Schedule 33A.

(7) The Ministers may by regulations amend Schedule 10A.**]**

Textual Amendments

F329 Regs. 65B, 65C inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **72** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 54**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for renewal of authorisation

66.—(1) The licensing authority may renew a UK marketing authorisation in response to an application made in accordance with this regulation.

[[F330](2) The applicant, where it is applying for renewal of—

(a) a UKMA(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a UKMA(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a UKMA(UK), must be established in the United Kingdom.**]**

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (as the case may be) (3)(a) of regulation 65 (initial and further period of validity).

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy, including—

(a) the evaluation of data contained in suspected adverse reaction reports and periodic safety update reports submitted in accordance with Part 11; and

(b) all amendments made since the authorisation was granted.

(7) The licensing authority may renew a UK marketing authorisation only if, having considered the application and the material accompanying it, the authority thinks that the positive therapeutic effects of the product to which the authorisation relates outweigh the risks of the product to the health of patients or of the public.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a UK marketing authorisation.

Textual Amendments

F330 Reg. 66(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 74** (as amended by (S.I. 2020/1488), reg. 1, Sch. 2 para. 55); 2020 c. 1, **Sch. 5 para. 1(1)**

[F331Application for renewal of a parallel import licence

66A.—(1) The licensing authority may renew a parallel import licence in response to an application made in accordance with this regulation.

(2) The applicant must be established in the **[**F332United Kingdom**]**.

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority within three months of the end of a period expiring 5 years after the date of grant or (as the case may be) latest renewal of the licence.**]**

Textual Amendments

F331 Reg. 66A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **10** and reg. 66A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **10**

F332 Words in reg. 66A(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **75**; 2020 c. 1, Sch. 5 para. 1(1)

[F333Renewal of conditional marketing authorisation

66B.—(1) The licensing authority may renew a conditional marketing authorisation in relation to an application made to it by the holder of the authorisation.

(2) The application must be made at least six months before the date on which the conditional marketing authorisation is due to expire.

(3) The application must include an interim report on the fulfilment of the obligations to which the conditional marketing authorisation is subject.

(4) When considering an application under paragraph (1), the licensing authority must consider whether—

(a) the positive therapeutic effects of the product continue to outweigh the risks to the health of patients and the public associated with the product; and

(b) the obligations referred to in regulation 59(4C) and any time limits for their fulfilment remain appropriate, modifying or removing them if necessary.

(5) The provisions of regulation 66(2), (3), (4), (6) and (8) apply to an application for renewal of a conditional marketing authorisation.**]**

Textual Amendments

F333 Reg. 66B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **76**; 2020 c. 1, Sch. 5 para. 1(1)

Failure to place on the market etc

67.—(1) A UK marketing authorisation ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom **[**F334(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)**]** during the period of three years beginning immediately after the day on which it was granted.

(2) A UK marketing authorisation for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom **[**F335(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)**]** for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

(a) in response to an application in writing by the holder of the UK marketing authorisation; or

(b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

(a) in exceptional circumstances; and

(b) on public health grounds.

(6) An exemption—

(a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and

(b) may be renewed or further renewed.

Textual Amendments

F334 Words in reg. 67(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 76A(2)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 56**)

F335 Words in reg. 67(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 76A(3)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 56**)

Revocation, variation and suspension of marketing authorisation

Revocation, variation and suspension of UK marketing authorisation [F336or parallel import licence]

68.—(1) The licensing authority may revoke, vary or suspend a UK marketing authorisation **[**F337or parallel import licence**]** if any of the following conditions is met.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the authorisation relates is harmful;

(b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;

(c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or

(d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.

[F338(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation or licence;

(b) in the case of a UK marketing authorisation, a requirement imposed by Part 13 (packaging and leaflets); or

(c) in the case of a parallel import licence, a requirement in relation to packaging and leaflets imposed by the licensing authority.**]**

[F339(5) Condition D is that the licensing authority thinks that a condition to which—

(a) the UK marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of UK marketing authorisations or parallel import licence: general); or

(b) the UK marketing authorisation is subject by virtue of regulations 60 (conditions of UK marketing authorisations: exceptional circumstances) **[**F340, regulation 60A (conditions as to testing of samples by the appropriate authority)**]** or 61 (conditions of UK marketing authorisations: new obligations post-authorisation),

has not been fulfilled.**]**

(6) Condition E is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the authorisation **[**F341or licence**]** has ceased to be **[**F342established in—

(a) the United Kingdom; or

(b) in relation to a UKMA(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.**]**

(8) Condition G is that—

(a) the product to which the authorisation relates is manufactured in the United Kingdom; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from **[**F343countries other than approved countries for import**]**), 39

(further requirements for manufacturer's licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).

(9) Condition H is that—

(a) the product to which the authorisation relates is manufactured in a member State [F344]...; and

(b) the licensing authority thinks that the licensee under the manufacturer's licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.

(10) Condition I is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—

(a) may suspend the **[**[F345]authorisation or licence.**]**

[F346](b) . . . . . .

(11) Condition J is that—

(a) the holder applies to vary the authorisation **[**[F347]or licence**]**; and

(b) the licensing authority thinks that the application should be granted.

[[F348](11A) Condition K is that the manufacture of the product to which the authorisation relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 8.**]**

[[F349](11B) Condition L is that the licensing authority thinks that the term of the authorisation which specifies the way in which the product is to be made available, as described in regulation 62(1), is incorrect.

(11C) Condition M is that, in respect of a parallel import licence, the UK marketing authorisation in respect of the medicinal product that was specified in the application for that licence under paragraph 4 of Schedule 8A, has been varied, suspended or revoked by the licensing authority under this regulation.

(11D) Condition N is that, in respect of a parallel import licence, the licensing authority is no longer satisfied that the product is essentially similar to a product that has been granted a UK marketing authorisation.

(11E) The licensing authority may not exercise its powers under paragraph (1) by virtue of the condition in paragraph (11D)—

(a) before the end of the period of one year beginning with IP completion day; and

(b) in any event, in a way that prevents the import of any medicinal product in respect of which a qualified person undertook the certification referred to in Article 51(3) of the 2001 Directive before IP completion day.

(11F) Condition O is that the licensing authority thinks that a variation of a UK marketing authorisation is necessary as a result of the submission of the results of a study by the holder of that authorisation under regulation 78A(14).

(11G) Condition P is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.**]**

(12) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a UK marketing authorisation **[**[F350]or parallel import licence**]**, other than a proposal to vary an authorisation **[**[F351]or licence**]** on the application of its holder.

[F352](13) . . . . . .

Textual Amendments

F336 Words in reg. 68 heading inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 68 heading inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(h)**

F337 Words in reg. 68(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 68(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(i)**

F338 Reg. 68(4) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **11(2)** and reg. 68(4) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **11(2)**

F339 Reg. 68(5) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **11(3)** and reg. 68(5) substituted (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **11(3)**

F340 Words in reg. 68(5) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F341 Words in reg. 68(7) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F342 Reg. 68(7)(a)(b) and words substituted for words (31.12.2020) by S.I. 2019/775, **reg. 77(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(a)**)

F343 Words in reg. 68(8)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F344 Words in reg. 68(9)(a) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 77(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(b)**)

F345 Words in reg. 68(10)(a) substituted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F346 Reg. 68(10)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F347 Words in reg. 68(11)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(7)**; 2020 c. 1, Sch. 5 para. 1(1)

F348 Reg. 68(11A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **17**

F349 Reg. 68(11B)-(11G) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(8)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 57(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F350 Words in reg. 68(12) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F351 Words in reg. 68(12) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F352 Reg. 68(13) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **77(10)**; 2020 c. 1, Sch. 5 para. 1(1)

Suspension of use etc of relevant medicinal product

69.—(1) The licensing authority may, if any of the following conditions are met, suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a UK marketing authorisation **[**[F353]or parallel import licence**]** relates.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the authorisation relates is harmful;

(b) the positive therapeutic effects of the product do not outweigh the risks of the product to the health of patients or of the public;

(c) the product lacks therapeutic efficacy, in that therapeutic results cannot be obtained from the product; or

(d) the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the holder of the authorisation has not complied with regulation 75(7) (requirements to provide proof of controls on manufacturing process).

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the authorisation; or

(b) a requirement imposed by Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 26 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product to which the authorisation relates.

(6) A suspension under this regulation may relate to batches of the product.

(7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the UK marketing authorisation **[**[F354]or parallel import licence**]**.

(8) The licensing authority must provide in the notice that the suspension—

(a) is to take effect immediately or from a date specified in the notice; and

(b) is to apply for the period specified in the notice.

(9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—

(a) in exceptional circumstances; and

(b) for such a transitional period as the licensing authority may determine,

allow the supply of the medicinal product to patients who are already being treated with the medicinal product.

[F355](10) . . . . . .

Textual Amendments

F353 Words in reg. 69(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 69(1)(7) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(j)**

F354 Words in reg. 69(7) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 69(1)(7) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(j)**

F355 Reg. 69(10) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **78**; 2020 c. 1, Sch. 5 para. 1(1)

Authorisations granted under Chapter 4 of Title III of the 2001 Directive

[F356]**70.** . . . . . .

Textual Amendments

F356 Reg. 70 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **79**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of medicinal product from the market

71.—(1) This regulation applies if—

[[F357](a) under regulation 68 the licensing authority revokes or suspends a UK marketing authorisation or parallel import licence; or**]**

[[F358](b) under—

(i) regulation 69 the licensing authority suspends the use, sale, supply or offer for sale or supply within Great Britain of a product to which a UKMA(GB) relates; or

(ii) regulation 69 or Article 20(4) of Regulation (EC) No 726/2004 the licensing authority suspends the use, sale, supply or offer for sale or supply within Northern Ireland of a product to which a UKMA(NI) or UKMA(UK) relates.**]**

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the authorisation **[**[F359]or related parallel import licence**]** requiring that person to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the authorisation relates of—

(a) the revocation or suspension;

(b) the reasons for the revocation or suspension; and

(c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

Textual Amendments

F357 Reg. 71(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **80(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F358 Reg. 71(1)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 80(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 58**)

F359 Words in reg. 71(2) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **13** and words in reg. 71(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **13**

Sale etc of suspended medicinal product

72.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a medicinal product is suspended in accordance with

[F360(a) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), regulation 69;

(b) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or UKMA(UK), regulation 69 or Article 20(4) of Regulation (EC) No 726/2004**]**.

(2) A person must not—

(a) sell, supply or offer to sell or supply the product; or

(b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Textual Amendments

F360 Reg. 72(1)(a)(b) substituted for words in reg. 72(1) (31.12.2020) by S.I. 2019/775, **reg. 81** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 59**)

Obligations of holder of marketing authorisation

Obligation to notify placing on the market etc

73.—(1) The holder of a UK marketing authorisation must notify the licensing authority of the date on which the product to which the authorisation relates is placed on the market in the United Kingdom, taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a UK marketing authorisation must notify the licensing authority if the product to which the authorisation relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

[F361(5A) The holder of a UK marketing authorisation must notify the licensing authority forthwith if the holder takes action to—

(a) request the cancellation of the authorisation;

(b) not apply for the renewal of the authorisation; or

(c) withdraw the product to which the authorisation relates from the market in a **[**F362country other than the United Kingdom**]** (whether temporarily or permanently) and the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5B) A notification under paragraph (3) or (5A) must include the reasons for the action, in particular declaring if the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5C) The holder of a **[**F363UKMA(NI) or UKMA(UK)**]** must also notify the EMA forthwith where the action which is the subject of a notification by the holder under paragraph (3) or (5A) is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.**]**

(6) The licensing authority may require the holder of a UK marketing authorisation to provide—

(a) information relating to the volume of sales in the United Kingdom of the product to which the authorisation relates; or

(b) information of which the holder is aware relating to the volume of prescriptions in the United Kingdom for the product.

(7) The holder of a UK marketing authorisation must provide the licensing authority with information that it requires under paragraph (6)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F361 Reg. 73(5A)-(5C) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **3**

F362 Words in reg. 73(5A)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **82(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F363 Words in reg. 73(5C) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 82(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 60**)

Obligation to take account of scientific and technical progress

74.—(1) The holder of a UK marketing authorisation must keep under review the methods of manufacture and control of the product to which the authorisation relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the marketing authorisation to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation to provide information relating to safety etc

75.—(1) The holder of a UK marketing authorisation **[**F364or parallel import licence**]** must provide the licensing authority with any new information that might entail the variation of the authorisation.

(2) The holder **[**F365of a UK marketing authorisation**]** must, in particular, provide the licensing authority with the following information—

(a) information about any prohibition or restriction imposed in relation to the product to which the authorisation relates by the competent authority of any country in which the product is on the market;

(b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation;

(c) data on the use of the medicinal product where such use is outside the terms of the marketing authorisation; and

(d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

[F366(2A) The holder of a parallel import licence must, in particular, provide the licensing authority with—

(a) information about any prohibition or restriction imposed in relation to the product to which the licence relates by the competent authority of any country in which the product is on the market; and

(b) other information that the holder considers might influence the evaluation of the benefits and risks of the product.**]**

(3) Information within paragraph (1) **[**F367to (2A)**]** must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a UK marketing authorisation to provide the authority with information that—

(a) is specified by the licensing authority; and

(b) demonstrates that the positive therapeutic effects of the product to which the authorisation relates continue to outweigh the risks of the product to the health of patients or of the public.

[F368(4A) The licensing authority may require the holder of a parallel import licence to provide further information specified by the licensing authority.**]**

(5) The information that may be required under paragraph (4) **[**F369or (4A)**]** includes information arising from use of the product—

[F370(a) in a country other than the United Kingdom;**]**

(b) outside the terms of the **[**F371UK**]** marketing authorisation,

including use in clinical trials.

(6) If the information supplied under paragraph (1), (2)**[**F372, (4) or (4A)**]** entails the variation of the UK marketing authorisation **[**F373or parallel import licence**]**, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a UK marketing authorisation to provide the authority with proof of the control methods employed by the manufacturer of the product to which the authorisation relates.

(8) The holder of a UK marketing authorisation **[**F374or parallel import licence**]** must provide the licensing authority with information it requests under paragraphs **[**F375(4), (4A) or**]** (7)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F364 Words in reg. 75(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 75(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(l)**

F365 Words in reg. 75(2) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(2)** and words in reg. 75(2) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(2)**

F366 Reg. 75(2A) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(3)** and reg. 75(2A) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(3)**

F367 Words in reg. 75(3) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(4)** and words in reg. 75(3) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(4)**

F368 Reg. 75(4A) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(5)** and reg. 75(4A) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(5)**

F369 Words in reg. 75(5) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(6)** and words in reg. 75(5) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(6)**

F370 Reg. 75(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **83(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F371 Word in reg. 75(5)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **83(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F372 Words in reg. 75(6) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(7)** and words in reg. 75(6) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(7)**

F373 Words in reg. 75(6) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 75(6) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(l)**

F374 Words in reg. 75(8) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 75(8) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(l)**

F375 Words in reg. 75(8) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **14(8)** and words in reg. 75(8) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **14(8)**

Obligation in relation to product information

76.—(1) The holder of a UK marketing authorisation **[**[F376]or parallel import licence**]** for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

[[F377](2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product authorised for sale or supply by a UKMA(NI) or a UKMA(UK)—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product authorised for sale or supply by a UKMA(GB), the UK web-portal established in accordance with regulation 203(1).**]**

Textual Amendments

F376 Words in reg. 76(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 76(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(m)**

F377 Reg. 76(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 84** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 61**)

Record-keeping obligations

77. The holder of a marketing authorisation **[**[F378]or parallel import licence**]** must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of any product to which the authorisation relates.

Textual Amendments

F378 Words in reg. 77 inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 77 inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(n)**

Obligation to ensure appropriate and continued supplies

78. The holder of a marketing authorisation must take all reasonable steps to ensure appropriate and continued supplies of the product to which the authorisation relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

[[F379]Post authorisation requirements in relation to UK marketing authorisations to which paediatric specific provisions apply

78A.—(1) Paragraph (2) applies where—

(a) a holder of a UK marketing authorisation intends to discontinue supply of the product to which that authorisation relates;

(b) the holder of the authorisation benefited from a reward or incentive under regulation 58A(3) or (8) or 58D(5) in relation to the product; and

(c) the period of protection provided pursuant to those regulations has expired.

(2) Where this paragraph applies, the holder of the UK marketing authorisation must—

(a) either—

(i) transfer the UK marketing authorisation to another person who has declared an intention to continue to supply the product; or

(ii) allow such a person to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product in accordance with regulation 56; and

(b) notify the licensing authority of its intention to cease to supply the product before the beginning of the period of six months ending immediately before the day on which the holder does so.

(3) Paragraph (4) applies to the holder of a UK marketing authorisation if—

(a) that authorisation includes a paediatric indication following completion of an agreed paediatric investigation plan; and

(b) the product was placed on the market for other indications before that holder obtained that paediatric indication.

(4) Where this paragraph applies, the holder of the UK marketing authorisation must place the product on the market taking account of the paediatric indication before the end of the period of two years beginning immediately after the day on which the paediatric indication is authorised.

(5) Paragraph (6) applies if—

(a) a decision by the licensing authority in respect of a paediatric investigation plan is addressed to a person ("PIP sponsor"); and

(b) the plan refers to clinical trials carried out in a country other than the United Kingdom ("non-UK clinical trials").

(6) Where this paragraph applies, the PIP sponsor must send to the licensing authority the details set out in Article 11 of the Clinical Trials Directive in relation to the non-UK clinical trials within whichever is the later of—

(a) the period of one month beginning after the day on which the decision was received; or

(b) the period of one month beginning after the day on which the necessary permission to conduct the clinical trial was received from the competent authorities in the country where the clinical trial is to take place.

(7) Where paragraph (6) applies, the PIP sponsor must submit the results of those clinical trials to the licensing authority within the period of twelve months beginning with the day on which the last of those trials ended, subject to paragraph (8).

(8) Paragraph (7) does not apply in the case of a clinical trial which forms part of a paediatric study to which paragraph (12) applies.

(9) Paragraph (10) applies in relation to the sponsor of a paediatric clinical trial in the United Kingdom in respect of a medicinal product if—

(a) the product has a UK marketing authorisation but the sponsor is not the holder of the authorisation; or

(b) the product does not have a UK marketing authorisation.

(10) Where this paragraph applies, the sponsor of the clinical trial must submit the results of the trial to the licensing authority within the period of twelve months beginning with the day on which the trial ended.

(11) Paragraph (12) applies in relation to the holder of a UK marketing authorisation who sponsors a paediatric clinical trial in respect of the medicinal product to which that authorisation relates.

(12) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the trial to the licensing authority within the period of six months beginning with the day on which the trial ended.

(13) Paragraph (14) applies in relation to the holder of a UK marketing authorisation who sponsors a study which involves the use in the paediatric population of a medicinal product to which that UK marketing authorisation relates, irrespective of whether or not—

(a) the studies are conducted in accordance with an agreed paediatric investigation plan; or

(b) the marketing authorisation holder intends to apply for a marketing authorisation for a paediatric indication in relation to the product.

(14) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the study to the licensing authority within the period of six months beginning with the day on which the study ended.

(15) Where the licensing authority has granted a deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan, in accordance with regulation 50C, the person to whom that decision was addressed must submit to the licensing authority an annual report providing an update on progress with the paediatric studies to which the deferral relates.

(16) The first report referred to in paragraph (15) must be submitted within the period of twelve months beginning with the date on which the licensing authority granted the deferral.

Textual Amendments

F379 Regs. 78A, 78B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **87** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 64**); 2020 c. 1, **Sch. 5 para. 1(1)**

Post authorisation requirements in relation to UKMA(GB) for advanced therapy medicinal products

78B.—(1) The holder of a UKMA(GB) in respect of an advanced therapy medicinal product must—

(a) establish and maintain a system ensuring that the individual product and its starting raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used;

(b) where the product contains human tissues or cells, ensure that the traceability system is complementary to and compatible with requirements imposed pursuant to—

(i) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990,

(ii) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005, and

(iii) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007;

(c) keep the data referred to in paragraph (a) for a minimum of 30 years after the expiry of the date of the product, or longer if required by the licensing authority as a term of the UKMA(GB); and

(d) in the event of the UKMA(GB) holder's bankruptcy or liquidation occurring within the period of time for which that holder is required to keep the data referred to in paragraph (a), transfer that data to another person or the licensing authority.

(2) The holder of a UKMA(GB) who is subject to the obligations in paragraph (1) remains subject to them even if the UKMA(GB) is suspended or revoked.**]**

Textual Amendments

F379 Regs. 78A, 78B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **87** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 64**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences relating to specific requirements

Failure to provide information on marketing authorisations to EMA

79.—(1) The holder of **[**[F380]a UKMA(NI) or UKMA(UK)**]** is guilty of an offence if the holder—

(a) has not submitted information to the EMA as required by Article 57(2)(b) of Regulation (EC) No 726/2004 (information on all existing medicinal products for human use

authorised or registered in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted before 2nd July 2012; and

(b) fails to do so as soon as is reasonably practicable after the coming into force of these Regulations.

(2) The holder of **[**F381UKMA(NI) or UKMA(UK)**]** is guilty of an offence if the holder fails to submit information to the EMA as required by Article 57(2)(c) of Regulation (EC) No 726/2004 (information on any new or varied authorisations granted in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted on or after 2nd July 2012 as soon as is reasonably practicable after the grant of the authorisation.

Textual Amendments

F380 Words in reg. 79(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 88(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 65**)

F381 Words in reg. 79(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 88(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 65**)

Urgent safety restrictions

80. The holder of a **[**F382UK**]** marketing authorisation is guilty of an offence if the holder —

[F383(a) fails—

(i) in respect of a UKMA(GB) or UKMA(UK), to inform the licensing authority in accordance with paragraph 14(1) of Schedule 10A, or

(ii) in respect of a UKMA(NI), UKMA(UK) or EU marketing authorisation, to inform the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008,

that the holder has taken urgent safety restrictions on the holder's own initiative;**]**

[F384(b) fails—

(i) in respect of a UKMA(GB), to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with paragraph 14(3) of Schedule 10A, or

(ii) in respect of a UKMA(NI) or UKMA(UK), to implement an urgent safety restriction imposed on the holder by the European Commission under Article 22(2) of Regulation (EC) No 1234/2008; or**]**

(c) fails **[**F385in respect of a UKMA(NI)**]** to submit an application for variation of the marketing authorisation to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—

(i) the taking under Article 22(1) or, as the case may be,

(ii) the imposition under Article 22(2),

of that Regulation of an urgent safety restriction.

[F386(d) fails in respect of a UKMA(GB) to submit an application for variation of the UK marketing authorisation to the licensing authority in accordance with paragraph 14(4) of Schedule 10A before the end of the period of fifteen days beginning with the day after—

(i) the taking under paragraph 14(1) of Schedule 10A or, as the case may be,

(ii) the imposition under paragraph 14(3) of that Schedule,

of an urgent safety restriction.**]**

Textual Amendments

F382 Word in reg. 80 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **89(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F383 Reg. 80(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 89(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(a)**)

F384 Reg. 80(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 89(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(b)**)

F385 Words in reg. 80(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 89(4A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(c)**)

F386 Reg. 80(d) inserted (31.12.2020) by S.I. 2019/775, **reg. 89(5)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(d)(ii)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F387Urgent safety restrictions: parallel import licences

80A. The holder of a parallel import licence is guilty of an offence if the holder—

(a) fails to inform the licensing authority that the holder has taken urgent safety restrictions on the holder's own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority; or

(c) fails to submit an application for variation of the parallel import licence to the licensing authority before the end of a period of fifteen days beginning on the day after—

(i) the taking of urgent safety restrictions under paragraph (a) or, as the case may be,

(ii) the imposition of urgent safety restrictions under paragraph (b).**]**

Textual Amendments

F387 Reg. 80A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **15** and reg. 80A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **15**

Offences relating to EU marketing authorisations

[F388Application of regulations 81 to 94

A81. Regulations 81 to 94 apply in relation to medicinal products for sale or supply in Northern Ireland **[**F389(that are not in Northern Ireland by virtue of regulation 167A)**].]**

Textual Amendments

F388 Reg. A81 inserted (31.12.2020) by S.I. 2019/775, regs. 1, **90** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**)

F389 Words in reg. A81 inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **13**

Obligation to update information supplied in connection with EU application

81. An applicant for an EU marketing authorisation is guilty of an offence if that person fails to supply updated information to the EMA in accordance with Article 8(3) of the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004.

EU marketing authorisations: failure to notify placing on market etc

82.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to notify the EMA in accordance with—

(a) the first paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify date of placing of product on the market); F390...

(b) the second paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify that product is to be withdrawn from the **[**F391market); or**]**

[F392(c) Article 14b of Regulation (EC) No 726/2004 (requirement to notify suspending of marketing of the product etc).**]**

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requires under the third paragraph of Article 13(4) of Regulation (EC) No 726/2004 (information as to sales and prescriptions)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the EMA, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F390 Word in reg. 82(1)(a) omitted (11.11.2013) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(2)**

F391 Words in reg. 82(1)(b) substituted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(3)**

F392 Reg. 82(1)(c) added (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(4)**

EU marketing authorisations: failure to take account of technical and scientific progress

83. The holder of an EU marketing authorisation is guilty of an offence if the holder fails to apply to vary the marketing authorisation as required by Article 16(1) of Regulation (EC) No 726/2004 (obligation to take account of scientific and technical progress).

EU marketing authorisations: failure to provide information as to safety etc

84.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide information to the EMA, the Commission or the licensing authority as required by Article 16(2) of Regulation (EC) No 726/2004 (new information which might entail amendment of particulars or documents) as soon as is reasonably practicable after becoming aware of the information.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requests as required by the first paragraph of Article **[**[F393]16(3a)**]** of Regulation (EC) No 726/2004 (data on risk-benefit balance).

Textual Amendments

F393 Word in reg. 84(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **18**

EU marketing authorisations: failure to update product information

85.—(1) The holder of an EU marketing authorisation for a medicinal product is guilty of an offence if the holder fails to ensure that the product information relating to the product is kept up to date with current scientific knowledge, as required by Article 16(3) of Regulation (EC) No 726/2004.

(2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

EU marketing authorisations: breach of pharmacovigilance condition etc

86.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to comply with—

(a) any obligation to which the marketing authorisation is subject by virtue of Articles 10a(1) or 14(7); or

(b) any condition to which the authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to incorporate into the risk management system for the product as required by Article 14a of Regulation (EC) No 726/2004—

(a) any recommendation referred to in Article 9(4)(c), (ca), (cb) or (cc);

(b) any obligation to which the authorisation is subject by virtue of Articles 10a(1) or 14(7) ; or

(c) any condition to which the marketing authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.

Offences relating to advanced therapy medicinal products

Offences in connection with risk management systems and traceability systems

87.—(1) The holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the holder fails to—

(a) submit an additional report evaluating the effectiveness of a risk management system and the results of studies within the period of 21 days beginning on the day following receipt of a request made under the second sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, or such longer period as the EMA may specify; or

(b) include in any periodic safety update report referred to in Article 28(2) of Regulation (EC) No 726/2004 an evaluation of the effectiveness of a risk management system or of the results of any study performed pursuant to the first sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, as required by the third sub-paragraph of Article 14(2).

(2) A person who is, or who immediately before its revocation or withdrawal was, the holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) establish and maintain a traceability system in accordance with the requirements set out in Article 15(1) of Regulation (EC) No 1394/2007;

(b) where the product contains human cells or tissues, to ensure that the traceability system is complementary to and compatible with the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC, as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC, as regards blood cells; or

(c) to keep the data to which the traceability system relates in accordance with the requirements of Article 15(4) of Regulation (EC) No 1394/2007.

Offence concerning data for advanced therapy medicinal products

88.—(1) A person who is, or immediately before its revocation or suspension was, the holder of an EU marketing authorisation relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) keep the data referred to in Article 15(1) of Regulation (EC) No 1394/2007 in accordance with the requirements of Article 15(4) of that Regulation; or

(b) transfer the data referred to in Article 15(1) to the EMA in the event of that person's bankruptcy or liquidation in accordance with Article 15(5),

but this is subject to paragraph (2).

(2) Paragraph (1)(b) does not apply if—

(a) the person is bankrupt or in liquidation and has transferred the data to another person; or

(b) the period for which the person was required to keep the data in accordance with the requirements of Article 15(4) mentioned in paragraph (1)(a) has expired.

Offences relating to the Paediatric Regulation

Offences in connection with withdrawal of product from the market

89.—(1) This regulation applies to a person ("H") if—

(a) H is the holder of a UK marketing authorisation;

(b) H has benefited from one or more rewards or incentives under **[**[F394]Article 37 or 38**]** of the Paediatric Regulation in relation to the product to which the authorisation relates, and

(c) all of the periods of protection provided pursuant to those Articles have expired in relation to H.

(2) H is guilty of an offence if H ceases to supply the product without previously in accordance with Article 35 of the Paediatric Regulation —

(a) transferring the UK marketing authorisation to another person who has declared an intention to continue to supply the product; or

(b) allowing such a person to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product as provided for in regulation 56.

(3) H is guilty of an offence if H—

(a) ceases to supply the product; and

(b) does not in accordance with Article 35 of the Paediatric Regulation inform the EMA of H's intention to do so before the beginning of the period of six months ending immediately before the day on which H does so.

Textual Amendments

F394 Words in reg. 89(1)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 90A** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**)

Failure to place on the market taking account of paediatric indication

90.—(1) A person ("P") is guilty of an offence if—

(a) P is the holder of a UK marketing authorisation;

(b) P obtains a paediatric indication in respect of the product to which the authorisation relates following completion of an agreed paediatric investigation plan;

(c) the product was placed on the market for other indications before P obtained that paediatric indication; and

(d) P fails to place the product on the market taking account of the paediatric indication in accordance with Article 33 of the Paediatric Regulation before the end of the period of two years beginning immediately after the day on which the paediatric indication is authorised.

(2) In this regulation "paediatric indication" means a term of the marketing authorisation enabling the product to which it relates to be used by or administered to persons under the age of 18 years.

Failure to notify results of third country clinical trials

F395 91. . . . . . .

Textual Amendments

F395 Reg. 91 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 90B** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**)

Failure of sponsor of UK paediatric clinical trial to notify results of trial

92.—(1) This regulation applies to the sponsor ("S") of a paediatric clinical trial in the United Kingdom in respect of a medicinal product if—

(a) the product has a UK marketing authorisation but S is not the holder of the authorisation; or

(b) the product does not have a marketing authorisation.

(2) S is guilty of an offence if S does not submit the results of the clinical trial to the EMA in accordance with Article 41(2) of the Paediatric Regulation within the period of twelve months beginning with the day on which the trial ended.

Failure to notify results of paediatric study

93.—(1) This regulation applies to a person ("H") if—

(a) H is the holder of a UK marketing authorisation; and

(b) H sponsors a paediatric study in respect of the product to which the authorisation relates.

(2) H is guilty of an offence if H does not submit the results of the study to the licensing authority in accordance with Article 46(1) of the Paediatric Regulation within the period of six months beginning with the day on which the study ended.

(3) H is guilty of an offence if H does not submit the results of any clinical trial that forms part of that study to the EMA in accordance with Article 41(2) of the Paediatric Regulation within the period of six months beginning with the day on which the trial ended.

Failure to submit report to EMA

94. The holder of a marketing authorisation is guilty of an offence if the holder fails to submit an annual report to the EMA as required by Article 34(4) of the Paediatric Regulation.

[F396Offences relating to the safety features appearing on the packaging of medicinal products

Textual Amendments

F396 Reg. 94A and cross-heading inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **8** and reg. 94A and cross-heading inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **8**

Offences relating to Commission Regulation 2016/161

94A.—[F397(1) A person who is—

(a) the holder of a UKMA(NI), UKMA(UK) or parallel import licence, or

(b) a parallel distributor,

is guilty of an offence if the holder fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).**]**

(2) The provisions mentioned in paragraph (1) are—

(a) Article 33 (uploading of information in the repositories system);

(b) Article 40 (products recalled, withdrawn or stolen);

(c) Article 41 (products to be supplied as free samples); and

(d) Article 42 (removal of unique identifiers from the repositories system).

[F398(3) In this regulation "parallel distributor" means a person who imports into Northern Ireland from an EEA state a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004 and in relation to which that person is not the holder of a UKMA(NI), UKMA(UK), Article 126a authorisation, COR(NI), COR(UK), THR(NI) or THR(UK).**]]**

Textual Amendments

F397 Reg. 94A(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 91(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 68**)

F398 Reg. 94A(3) substituted (31.12.2020) by S.I. 2019/775, **reg. 91(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 68**)

General provisions relating to offences

Offences in connection with application

95. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a marketing authorisation for a relevant medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product;

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular;

(c) **[**F399, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,**]** fails to provide the EMA with any information that is relevant to the evaluation of the safety, quality or efficacy of the product as required by paragraph (7) or (11) in the "Introduction and general principles" of Annex 1 to the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004; or

(d) **[**F400, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,**]** provides to the EMA any information of the kind described in sub-paragraph (c) that is false or misleading in a material particular.

Textual Amendments

F399 Words in reg. 95(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 92(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 69**)

F400 Words in reg. 95(d) inserted (31.12.2020) by S.I. 2019/775, **reg. 92(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 69**)

[F401**Offences in connection with parallel import licence application**

95A. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular.**]**

Textual Amendments

F401 Reg. 95A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **16** and reg. 95A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **16**

Provision of false or misleading information

96.—(1) The holder of a marketing authorisation **[**F402or parallel import licence**]** is guilty of an offence if the holder provides any information to which paragraph (2) applies that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product but that is false or misleading in a material particular to—

(a) the licensing authority;

(b) the EMA; or

(c) the competent authorities of other EEA States.

(2) This paragraph applies to information about the product that is supplied pursuant to the obligations in—

(a) these Regulations; or

(b) Regulation (EC) No 726/2004.

(3) This regulation is without prejudice to the operation of regulation 95.

Textual Amendments

F402 Words in reg. 96(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 96(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(o)**

Breach of pharmacovigilance condition

[[F403]**97.**—(1) The holder of a marketing authorisation or a parallel import licence is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of a UK marketing authorisation or parallel import licence: general).

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation is subject by virtue of regulation 60 (conditions of a UK marketing authorisation: exceptional circumstances) **[**[F404], regulation 60A (condition as to the testing of samples by the appropriate authority)**]** or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).**]**

Textual Amendments

F403 Reg. 97 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **17** and reg. 97 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **17**

F404 Words in reg. 97(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **94(3)**; 2020 c. 1, Sch. 5 para. 1(1)

General offence of breach of provision of this Part

98.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

(a) failure by the holder of a marketing authorisation **[**[F405]or parallel import licence**]** to comply with any requirement or obligation in this Part:

(b) contravention by any person of any prohibition in this Part; or

(c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Textual Amendments

F405 Words in reg. 98(2)(a) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 98(2)(a) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(p)**

Penalties

99.—(1) A person guilty of an offence under this Part, other than a breach of regulation 79 (failure to provide information on marketing authorisations to EMA), is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

(2) A person guilty of a breach of regulation 79 is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine.

Persons liable

100. If a breach of regulation 95 (offences in connection with application) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

101.—(1) Paragraph (2) applies if the holder of a marketing authorisation **[**F406or parallel import licence**]** is charged with an offence under this Part in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

(a) the holder communicated the terms of the authorisation to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulations 73(3) or 78, or an offence under any of regulations 88 to 93, 95 and 96, to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Textual Amendments

F406 Words in reg. 101(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 101(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(q)**

PART 6

Certification of homoeopathic medicinal products

Application of Part

Application of Part

102.—(1) This Part applies to a homoeopathic medicinal product (a "registrable homoeopathic medicinal product") that meets the following conditions.

(2) Condition A is that the product is administered orally or externally.

(3) Condition B is that no specific therapeutic indication appears—

(a) on the labelling of the product; or

(b) in any information supplied with the product.

(4) Condition C is that—

(a) the product contains no more than one part per 10,000 of the mother tincture; and

(b) in a case where the product's active substance is a relevant allopathic substance, the product contains no more than 1/100th of the smallest concentration of that substance used in allopathy.

(5) In this regulation "relevant allopathic substance" means an active substance whose presence in an allopathic medicinal product means that the product is only available on prescription.

(6) For this purpose—

(a) "allopathic medicinal product" means a medicinal product other than a homoeopathic medicinal product; and

(b) "allopathy" means treatment using an allopathic medicinal product.

[[F407](7) The Secretary of State may make regulations in respect of Great Britain to amend paragraphs (4) to (6).

(8) The Secretary of State may only exercise the power in paragraph (7) if the Secretary of State considers that it is necessary to do so because of new scientific evidence.**]**

Textual Amendments

F407 Reg. 102(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **98** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 75**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application for certificate of registration and consideration of application

Application for certificate of registration

103.—(1) The licensing authority may, subject to regulation 104, grant an application for a certificate of registration for a registrable homoeopathic medicinal product in response to an application made in accordance with this Part.

[[F408](1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a COR(GB) only where—

(a) there is already in place, or will be at the time the COR(GB) is granted, a certificate of registration in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in paragraph (5B), and

(c) the registrable homoeopathic medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A certificate of registration must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that certificate of registration being "in force" is limited to that territory.**]**

(2) A certificate granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The application may relate to two or more homoeopathic medicinal products derived from the same homoeopathic stock or the same combination of homoeopathic stocks.

(4) The applicant **[**[F409]where it is applying for—

(a) a COR(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a COR(UK), must be established in the United Kingdom.**]**

(5) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

[[F410](5A) The application must include a statement indicating whether the certificate sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.

(5B) The applicant for the grant of a COR(GB) under the unfettered access route must provide—

(a) the application form submitted in connection with the granting of the COR(NI) which authorises the sale or supply of the product in Northern Ireland;

(b) a copy of all material submitted in support of the application for the COR(NI) which authorises the sale or supply of the product in Northern Ireland; and

(c) a copy of the COR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in paragraph (8) which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.**]**

(6) An application is treated as signed for the purposes of paragraph (5)(b) if it is signed with an electronic signature.

(7) The application and any accompanying material must be in English.

(8) The applicant must provide each of the following for each product to which the application relates—

(a) a statement of the scientific name, or other name given in a pharmacopoeia, of the homoeopathic stock or stocks from which the product is derived;

(b) a statement of the routes of administration, pharmaceutical forms and degree of dilution of the product;

(c) a dossier describing how the homoeopathic stock or stocks are obtained and controlled and justifying their homoeopathic use on the basis of an adequate bibliography;

(d) a manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation of the product;

(e) evidence that each manufacturer of the medicinal product is authorised to manufacture it (which, in the case of a product manufactured in the United Kingdom [F411]..., means the manufacturer's licence or (as the case may be) its equivalent in **[**[F412]a country other than the United Kingdom**]**);

(f) where an authorisation to place the product on the market has been granted by **[**[F413]a country other than the United Kingdom**]**, a copy of the authorisation;

(g) a mock-up of the outer and immediate packaging of the product; and

(h) data concerning the stability of the product.

(9) This material, taken as a whole, must be such as to demonstrate the pharmaceutical quality and batch to batch homogeneity of each product to which the application relates.

(10) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

Textual Amendments

F408 Reg. 103(1A)(1B) inserted (31.12.2020) by S.I. 2019/775, **reg. 99(1A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(a)**)

F409 Reg. 103(4)(a)-(c) substituted for words in reg. 103(4) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 99(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 76(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F410 Reg. 103(5A)(5B) inserted (31.12.2020) by S.I. 2019/775, **reg. 99(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(c)**)

F411 Words in reg. 103(8)(e) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F412 Words in reg. 103(8)(e) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F413 Words in reg. 103(8)(f) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **99(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Consideration of application

104.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration before the end of the period of 210 days beginning immediately after the day on which an application for the certificate is submitted in accordance with regulation 103.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the information or material is provided.

(3) The licensing authority may grant a certificate only if, having considered the application and the accompanying material, the authority thinks that—

(a) the risks to the health of patients or of the public associated with the product do not outweigh any beneficial effects of the homoeopathic medicinal product in question;

(b) the application and the accompanying material complies with regulation 103; and

(c) the product's qualitative or quantitative composition is as described in the application and the accompanying material.

(4) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a certificate of registration.

(5) This regulation does not apply to an application that—

(a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or

(b) has been referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(6) An application to which paragraph (5) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

[[F414](7) In the case of an application under the unfettered access route, the licensing authority may grant a COR(GB) (notwithstanding paragraph (3)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 103(1A) will continue to be met.

(8) The licensing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.**]**

Textual Amendments

F414 Reg. 104(7)(8) inserted (31.12.20200 by S.I. 2019/775, **reg. 100(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 77**)

Conditions of certificate of registration

105.—(1) The licensing authority may—

(a) grant a certificate of registration subject to conditions; or

(b) vary or remove a condition to which the certificate of registration is subject.

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the certificate or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—

(a) in exceptional circumstances; and

(b) when the applicant can show that the applicant is unable to provide comprehensive data on the safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the certificate relates.

(6) The conditions may, in particular, require that, where there is an incident relating to the use of the product—

(a) the incident must be reported to the licensing authority; and

(b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

(a) the conditions to which a certificate of registration is subject; and

(b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

(a) at the end of the period of one year beginning with the date on which the certificate was granted; and

(b) at the end of each subsequent period of one year.

(9) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a certificate of registration is subject.

Classification of certificate of registration

106.—(1) A certificate of registration must include a term that the product to which the certificate relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

(2) A certificate of registration may include a term that the product to which the certificate relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Validity of certificate of registration

107.—(1) Subject to the following paragraphs, a certificate of registration remains in force—

(a) for an initial period of five years beginning with the date on which it is granted; and

(b) if the authorisation is renewed under regulation 108 for an unlimited period after its renewal.

(2) The licensing authority may, on the first application for renewal of a certificate, determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the certificate remains in force—

(a) for a further period of five years beginning with the date on which it is first renewed; and

(b) if the authorisation is further renewed under regulation 108 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a certificate is made in accordance with regulation 108 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

(a) regulation 109 (failure to place on the market etc); and

(b) regulation 110 (revocation etc of certificate of registration).

Application for renewal of certificate

108.—(1) An application for the renewal of a certificate of registration must be made to the licensing authority.

(2) The applicant **[**F415, where it is applying for renewal of—

(a) a COR(NI) and originally granted—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB) and originally granted—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) in the whole United Kingdom, must be established in the United Kingdom.**]**

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (as the case may be) (3)(a) of regulation 107 (initial and further period of validity).

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy (including all amendments made since the authorisation was granted).

(7) The licensing authority may renew a certificate only if, having considered the application and the material accompanying it, the authority thinks that the risks to the health of patients or of the public associated with the homoeopathic medicinal product to which the certificate relates do not outweigh any beneficial effects of the product.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a certificate of registration.

Textual Amendments

F415 Reg. 108(2)(a)-(c) substituted for words in reg. 108(2) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 101** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 78**); 2020 c. 1, **Sch. 5 para. 1(1)**

Failure to place on the market etc

109.—(1) A certificate of registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom **[**[F416](or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)**]** during the period of three years beginning immediately after the day on which it was granted.

(2) A certificate of registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom **[**[F417](or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)**]** for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

(a) in response to an application in writing by the holder of the certificate of registration; or

(b) by the licensing authority of its own motion.

(5) An exemption may be granted only—

(a) in exceptional circumstances; and

(b) on public health grounds.

(6) An exemption—

(a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and

(b) may be renewed or further renewed.

Textual Amendments

F416 Words in reg. 109(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 101A(2)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**)

F417 Words in reg. 109(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 101A(3)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**)

Revocation, variation and suspension of certificate of registration

Revocation, variation and suspension of certificate of registration

110.—(1) The licensing authority may revoke, vary or suspend a certificate of registration if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the certificate relates is harmful;

(b) the risks of the product to the health of patients or of the public outweigh any beneficial effects of the product; or

(c) the product's qualitative or quantitative composition is not as described in the application for the certificate or the material supplied with it.

(3) Condition B is that the licensing authority thinks that the application or the material accompanying it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the certificate; or

(b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that a condition to which the certificate is subject by virtue of regulation 105 (conditions of certificate or registration) has not been fulfilled.

(6) Condition E is that the licensing authority thinks that the holder of the certificate has not complied with regulation 115(1) to (3) (requirements to provide information).

(7) Condition F is that the holder of the certificate has ceased to be **[**[F418]established in—

(a) the United Kingdom; or

(b) in relation to a COR(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.**]**

(8) Condition G is that—

(a) the holder applies to vary the certificate; and

(b) the licensing authority thinks that the application should be granted.

[[F419](8A) Condition H is that the manufacture and control of the product to which the certificate relates is not in compliance with the particulars provided under regulation 103(8)(c) and (d).**]**

[[F420](8B) Condition I is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.**]**

(9) Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a certificate of registration, other than a proposal to vary a certificate on the application of its holder.

(10) This regulation is subject to regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive).

Textual Amendments

F418 Reg. 110(7)(a)(b) substituted for words in reg. 110(7) (31.12.2020) by S.I. 2019/775, **reg. 102(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(a)**)

F419 Reg. 110(8A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **19**

F420 Reg. 110(8B) inserted (31.12.20200 by S.I. 2019/775, **reg. 102(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(b)**)

Certificates granted under Chapter 4 of Title III of the 2001 Directive

[[F421]**111.** . . . . . .

Textual Amendments

F421 Reg. 111 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **103**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of homoeopathic medicinal product from the market

112.—(1) This regulation applies if under regulation 110 [F422]... the licensing authority revokes or suspends a certificate of registration.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the certificate requiring the holder to comply with the following requirement.

(3) That requirement is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product to which the certificate relates; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

(4) The notice must specify the grounds for giving the notice.

Textual Amendments

F422 Words in reg. 112(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **104**; 2020 c. 1, Sch. 5 para. 1(1)

Obligations of holder of certificate of registration

Obligation to notify placing on the market etc

113.—(1) The holder of a certificate of registration must notify the licensing authority of the date on which the product to which the certificate relates is placed on the market in the United Kingdom taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a certificate of registration must notify the licensing authority if the product to which the certificate relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

[[F423](3A) A notification under paragraph (3) must include the reasons for the withdrawal [F424]....**]**

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

(6) The licensing authority may require the holder of a certificate of registration to provide information relating to the volume of sales in the United Kingdom of the product to which the certificate relates.

(7) The holder of a certificate of registration must provide the licensing authority with information that it requires under paragraph (6)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F423 Reg. 113(3A) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **5**

F424 Words in reg. 113(3A) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **105**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation to take account of scientific and technical progress

114.—(1) The holder of a certificate of registration must keep under review the methods of manufacture and control of the product to which the certificate relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the certificate of registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

Obligation to provide information relating to safety etc

115.—(1) The holder of a certificate of registration must provide the licensing authority with any new information that might entail the variation of the certificate.

(2) The holder must, in particular, provide the licensing authority with the following information—

(a) information about any prohibition or restriction imposed in relation to the product to which the certificate relates by the competent authority of any country in which the product is on the market;

(b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the certificate of registration;

(c) data on the use of the product where such use is outside the terms of the certificate of registration; and

(d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a certificate of registration to provide the authority with information that—

(a) is specified by the licensing authority; and

(b) demonstrates that the risks of the product to the health of patients or of the public do not outweigh any beneficial effects of the product to which the certificate relates.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

(a) in a country **[**F425other than the United Kingdom**]**; or

(b) outside the terms of the certificate of registration.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the certificate of registration, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a certificate of registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the certificate relates.

(8) The licensing authority may notify the holder of a certificate of registration that it requires the holder to provide to the licensing authority information of any description specified in the notice, within the period specified in the notice, subject to paragraph (9).

(9) A notice under paragraph (8) must not be served unless it appears to the licensing authority, or it is represented to the licensing authority by the Commission or by an expert committee appointed by the licensing authority—

(a) that circumstances exist by reason of which it is necessary to consider whether the certificate of registration should be varied, suspended or revoked; and

(b) that the information required by the notice is needed to consider that question.

(10) The holder of a certificate of registration must provide the licensing authority with information that it requires under paragraphs (4) or (7)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F425 Words in reg. 115(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **106**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation in relation to product information

116.—(1) The holder of the certificate of registration for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

[[F426](2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product authorised by a COR(NI) or COR(UK)—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product authorised by a COR(GB), the UK web-portal established in accordance with regulation 203(1).**]**

Textual Amendments

F426 Reg. 116(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 107** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 81**)

Record-keeping obligation

117. The holder of a certificate of registration must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of the product to which the certificate relates.

Obligation to ensure appropriate and continued supplies

118. The holder of a certificate of registration must take all reasonable steps to ensure appropriate and continued supplies of the product to which the certificate relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

Provisions relating to offences

Offences in connection with applications

119. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a certificate of registration for a registrable homoeopathic medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to an evaluation of the quality of the product; or

(b) provides to the licensing authority any information that is relevant to an evaluation of the quality of the product that is false or misleading in a material particular.

Provision of false or misleading information

120.—(1) The holder of a certificate of registration for a medicinal product is guilty of an offence if the person provides the licensing authority with any information that is relevant to the quality of the product but that is false or misleading in a material particular.

(2) Paragraph (1) is without prejudice to the operation of regulation 119.

General offence of breach of provision of this Part

121.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

(a) failure by the holder of a certificate of registration to comply with any requirement or obligation in this Part;

(b) contravention by any person of any prohibition in this Part; or

(c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

122. A person guilty of an offence under this Part is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

Persons liable

123. If an offence under regulation 119 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

124.—(1) Paragraph (2) applies if the holder of a certificate of registration is charged with an offence under this Part in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the certificate.

(2) It is a defence for the holder to prove that—

(a) the holder communicated the terms of the certificate to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulation 113(3) or 118 or an offence under regulation 119 or 120 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 7

Traditional herbal registrations

[F427 Interpretation and application of Part]

Textual Amendments

F427 Pt. 7 cross-heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **108**; 2020 c. 1, Sch. 5 para. 1(1)

[F428 Interpretation of this Part

124A. In this Part, "relevant list" means—

(a) the list referred to in Article 16f(1) of the 2001 Directive, as that list may be amended from time to time; or

(b) if the licensing authority publishes a list under regulation 126A(1), that list.**]**

Textual Amendments

F428 Reg. 124A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **109**; 2020 c. 1, Sch. 5 para. 1(1)

Traditional herbal medicinal products

125.—(1) This Part applies to a herbal medicinal product (a "traditional herbal medicinal product") if the following conditions are met.

(2) Condition A is met if by virtue of its composition and indications the product is appropriate for use without the need for a medical practitioner to—

(a) diagnose the condition to be treated by the product;

(b) prescribe the product; or

(c) monitor the product's use.

(3) Condition B is met if the product is intended to be administered at a particular strength and in accordance with a particular posology.

(4) Condition C is met if the product is intended to be administered externally, orally or by inhalation.

(5) Condition D is met if—

(a) the product has been in medicinal use for a continuous period of at least 30 years, and

[[F429](b) in relation to—

(i) a THR(NI) or THR(UK), the product has been in medicinal use in the European Union for a continuous period of at least 15 years;

(ii) a THR(GB), the product has been in medicinal use in the United Kingdom or a country included in the list published under regulation 125A(1) for a continuous period of at least 15 years.**]**

(6) It is immaterial for the purposes of condition D whether or not during a period mentioned in that condition—

(a) the sale or supply of the product has been based on a specific authorisation; or

(b) the number or quantity of the ingredients (or any of them) has been reduced.

(7) Condition E is met if there is sufficient information about the use of the product as mentioned in condition D (referred to in this Part as its "traditional use"), so that (in particular)—

(a) it has been established that the traditional use of the product is not harmful; and

(b) the pharmacological effects or efficacy of the product are plausible on the basis of long-standing use and experience.

Textual Amendments

F429 Reg. 125(5)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 110** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 82**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F430List of approved countries for traditional use of a herbal medicinal product

125A.—(1) The licensing authority may publish a list of countries for the purposes of regulation 125(5)(b) (condition D).

(2) In establishing the list under paragraph (1), the licensing authority may only include a country in that list if it is satisfied that—

(a) continuous use evidence in respect of that country can be sufficiently validated by the licensing authority; and

(b) the country has a level of pharmacovigilance that is equivalent to that in the United Kingdom to ensure that any safety issues in respect of the herbal medicinal product have been properly identified.

(3) The licensing authority must—

(a) review any list it publishes under paragraph (1) to determine if a country still satisfies the criteria for inclusion in the list specified in paragraph (2), and if it is not so satisfied, remove that country from the list; and

(b) undertake such a review at least every three years beginning with the date on which the country is included in that list.**]**

Textual Amendments

F430 Reg. 125A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **111**; 2020 c. 1, Sch. 5 para. 1(1)

Addition of vitamins or minerals

126. The addition to a traditional herbal medicinal product of a vitamin or mineral does not prevent a traditional herbal registration from being granted for the product if—

(a) there is well-documented evidence of the safety of the vitamin or mineral; and

(b) the action of the vitamin or mineral is ancillary to the action of the product's active herbal ingredients in connection with the use authorised by the traditional herbal registration.

[F431List of herbal substances, preparations and combinations for use in traditional herbal medicinal products

Textual Amendments

F431 Reg. 126A and cross-heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **112** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 83**); 2020 c. 1, **Sch. 5 para. 1(1)**

Licensing authority list as to herbal substances, preparations and combinations for use in traditional herbal medicinal products

126A.—(1) The licensing authority may establish, and publish a list of, herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products for which a THR(GB) may be granted.

(2) A list established under paragraph (1) must contain, with regard to each herbal substance—

(a) the indication;

(b) the specified strength and posology;

(c) the route of administration; and

(d) any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

(3) The licensing authority may review and amend any list it publishes under paragraph (1) at such intervals as it considers appropriate.**]**

Application for traditional herbal registration

Application for grant of traditional herbal registration

127.—(1) The licensing authority may, subject to regulation 130, grant an application for a traditional herbal registration for a traditional herbal medicinal product in response to an application made in accordance with this Part.

[F432(1A) The licensing authority may accept an application meeting reduced or alternative requirements specified in this Part ("under the unfettered access route") and grant a THR(GB) only where—

(a) there is already in place, or will be at the time the THR(GB) is granted, a traditional herbal registration in respect of the product authorising sale or supply in Northern Ireland,

(b) the applicant complies with the requirements in regulation 128(1A), and

(c) the traditional herbal medicinal product satisfies the definition of qualifying Northern Ireland goods.

(1B) A traditional herbal registration must state whether it is in force in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only,

and in these Regulations the meaning of a reference to that traditional herbal registration being "in force" is limited to that territory.**]**

(2) A registration granted under paragraph (1) shall contain terms approved by the licensing authority.

(3) The applicant **[**F433, where it is applying for—

(a) a THR(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a THR (GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a THR(UK), must be established in the United Kingdom.**]**

(4) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

[F434(4A) The application must include a statement indicating whether the traditional herbal registration sought is for sale or supply of the product in—

(a) the whole United Kingdom;

(b) Great Britain only; or

(c) Northern Ireland only.**]**

(5) An application is treated as signed for the purposes of paragraph (4)(b) if it is signed with an electronic signature.

(6) The application and any accompanying material must be in English.

(7) The application must include a statement indicating whether the product to which the application relates should be available—

(a) only from a pharmacy; or

(b) on general sale.

(8) The application must include a statement indicating—

(a) whether any terms of the registration are proposed relating to the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product); and

(b) if so, what terms are proposed.

Textual Amendments

F432 Reg. 127(1A)(1B) inserted (31.12.2020) by S.I. 2019/775, **reg. 113(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

F433 Reg. 127(3)(a)-(c) substituted for words in reg. 127(3) (31.12.2020) by S.I. 2019/775, **reg. 113(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

F434 Reg. 127(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 113(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**)

Accompanying material

128.—**[**[F435](1) The applicant for the grant of a traditional herbal registration other than a THR(GB) under the unfettered access route must provide the material specified in Schedule 12 in relation to the product.

(1A) The applicant for the grant of a THR(GB) under the unfettered access route must provide—

(a) the application form submitted in connection with the granting of the THR(NI) which authorises the sale or supply of the product in Northern Ireland;

(b) a copy of all material submitted in support of the application for the THR(NI) which authorises the sale or supply of the product in Northern Ireland; and

(c) a copy of the THR(NI) which authorises the sale or supply of the medicinal product in Northern Ireland,

together with any material specified in Schedule 12 which is not included in the material specified in sub-paragraphs (a) to (c) in relation to the product.**]**

(2) The applicant must also, if requested by the licensing authority to do so, provide the licensing authority with material or information that the licensing authority reasonably considers necessary for considering the application.

(3) If the application relates to a product that is contained in the list referred to in Article 16f(1) of the 2001 Directive **[**[F436]where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB)**]**—

(a) the applicant does not need to provide the material referred to in paragraphs 16 to 20 of Part 1 of Schedule 12; and

(b) paragraph (2) of this regulation does not apply.

(4) Material that is submitted under this regulation must be submitted in accordance with Annex I to the 2001 Directive, so far as applicable to traditional herbal medicinal products.

Textual Amendments

F435 Reg. 128(1)(1A) substituted for reg. 128(1) (31.12.2020) by S.I. 2019/775, **reg. 114(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 85**)

F436 Words in reg. 128(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 114(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 85**)

Obligation to update information supplied in connection with application

129.—(1) The applicant for a traditional herbal registration must update information supplied in connection with the application to include any further information that is relevant to the evaluation of the safety, quality or efficacy of the product concerned.

(2) Updated information within paragraph (1) must be provided as soon as is reasonably practicable after the applicant becomes aware of it.

Consideration of application

Consideration of application

130.—(1) The licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration before the end of the period of 210 days beginning immediately after the day on which an application for the registration is submitted in accordance with regulation 128.

(2) If the licensing authority requests the applicant to provide any further information or material, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the information or material is provided.

(3) If the licensing authority requests the applicant to give an oral or written explanation of the application, the period referred to in paragraph (1) is suspended for the period—

(a) beginning with the date on which the request is made; and

(b) ending with the date on which the explanation is provided.

(4) The licensing authority may grant the application only if, having considered the application and the accompanying material, the authority thinks that—

(a) the product complies with conditions A to E of regulation 125 (conditions for a product to be a traditional herbal medicinal product);

(b) the product to which the application relates is not harmful under normal conditions of use;

(c) the application and the accompanying material complies with the requirements of this Part;

(d) the product's qualitative and quantitative composition is as described in the application and the accompanying material; and

(e) the product's pharmaceutical quality has been satisfactorily demonstrated.

(5) The licensing authority need not take into account any updated information supplied in connection with the application under regulation 129 (obligation to update information supplied in

connection with application), unless it thinks that the information is unfavourable in respect of the safety, quality or efficacy of the product concerned

(6) The licensing authority may refuse the application on the ground that it is more appropriate to consider whether to authorise the placing of the product on the market in response to an application for a **[**F437UK**]** marketing authorisation or certificate of registration for the product.

(7) Paragraph (4)(a)

[F438(a) where the application is for a THR(NI) or THR(UK), is subject to Article 16c(4) of the 2001 Directive (procedure where product has been used in the European Union for less than 15 years);

(b) where the application is for a THR(GB), is subject to regulation 130A.**]**

(8) If the application relates to a herbal medicinal product that is contained in the list referred to Article 16f(1) of the 2001 Directive **[**F439where the application is for a THR(NI) or THR(UK), or the list established under regulation 126A where the application is for a THR(GB)**]**—

(a) paragraph (4)(a) applies as if it referred to conditions A to D of regulation 125; and

(b) paragraph (4)(b) does not apply.

(9) Where **[**F440, in relation to an application for a THR(NI) or THR(UK),**]** Article 16d(1) of the 2001 Directive (products to which the mutual recognition procedure and decentralised procedure apply) does not apply to the product, the licensing authority must, in considering the application, take into account any registrations granted by other member States in accordance with Chapter 2a of Title III of the 2001 Directive.

(10) The licensing authority must take into account—

(a) any herbal monograph of the kind referred to **[**F441—

(i) in Article 16h(3) of the 2001 Directive, where the application is for a THR(NI) or THR(UK);

(ii) in regulation 143A, where the application is for a THR(GB),

that the authority thinks relevant to the application; or**]**

(b) if no relevant monograph within sub-paragraph (a) has been established, such other monographs, publications or data as the authority thinks relevant.

(11) Schedule 11 makes provision about advice and representations in relation to an application for the grant of a traditional herbal registration.

(12) This regulation does not apply where **[**F442, in relation to an application for a THR(NI) or THR(UK),**]** Article 16d(1) applies to the product and the application—

(a) has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive; or

(b) has been referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

(13) An application to which paragraph (12) applies is to be determined by the licensing authority in accordance with Chapter 4 of Title III of the 2001 Directive.

[F443(14) In the case of an application under the unfettered access route, the licensing authority may grant a THR(GB) (notwithstanding paragraph (4)) where the licensing authority—

(a) has considered the application under the unfettered access route and the accompanying material,

(b) is satisfied that the applicant has complied with the application requirements, and

(c) is satisfied that the conditions in regulation 127(1A) will continue to be met.

(15) The licencing authority may refuse to grant an application under the unfettered access route where it is of the opinion that it would represent a risk to public health to do so.**]**

Textual Amendments

F437 Word in reg. 130(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **116(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F438 Reg. 130(7)(a)(b) substituted for words in reg. 130(7) (31.12.2020) by S.I. 2019/775, **reg. 116(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F439 Words in reg. 130(8) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(b)**) 2020 c. 1, **Sch. 5 para. 1(1)**

F440 Words in reg. 130(9) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(c)**)

F441 Reg. 130(10)(a)(i)(ii) substituted for words in reg. 130(10)(a) (31.12.2020) by S.I. 2019/775, **reg. 116(6)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F442 Words in reg. 130(12) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(7)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(e)**)

F443 Reg. 130(14)(15) inserted (31.12.2020) by S.I. 2019/775, **reg. 116(8)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(f)**)

[F444Procedure where less than 15 years use of traditional herbal medicinal product

130A.—(1) Where an application for a THR(GB) (other than an application under the unfettered access route) has been made and the licensing authority considers that—

(a) the traditional herbal medicinal product does not satisfy regulation 125(5)(b) (Condition D); but

(b) otherwise satisfies the conditions in regulation 125,

the licensing authority may refer the matter to the appropriate committee for relevant advice, and the procedure in Part 3 of Schedule 11 applies (referral to the appropriate committee for traditional herbal registrations).

(2) In this regulation—

"appropriate committee" has the same meaning as in paragraph 2(4) of Schedule 11;

"relevant advice" means advice as to whether—

(a) the conditions in regulation 125, other than condition D, are met in relation to the application; and

(b) the licensing authority should exercise its powers under regulation 143A to establish a herbal monograph.**]**

Textual Amendments

F444 Reg. 130A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **117** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 88**); 2020 c. 1, **Sch. 5 para. 1(1)**

Classification of traditional herbal registration

131.—(1) A traditional herbal registration must include a term that the product to which the registration relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

(2) A traditional herbal registration may include a term that the product to which the registration relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

Validity of traditional herbal registration

Validity of traditional herbal registration

132.—(1) Subject to the following paragraphs, a traditional herbal registration remains in force—

(a) for an initial period of five years beginning with the date on which it is granted; and

(b) if the registration is renewed under regulation 133 for an unlimited period after its renewal.

(2) The licensing authority may on the first application for renewal of a registration determine on grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, that it should be necessary for the holder to make one further application for renewal.

(3) In that event, the registration remains in force—

(a) for a further period of five years beginning with the date on which it is first renewed; and

(b) if the registration is further renewed under regulation 133 for an unlimited period after its further renewal.

(4) If an application for the renewal or further renewal of a registration is made in accordance with regulation 133 the certificate remains in force until the licensing authority notifies the applicant of its decision on the application.

(5) This regulation is subject to—

(a) regulation 134 (failure to place on the market); and

(b) regulation 135 (revocation etc of traditional herbal registration).

Application for renewal of registration

133.—(1) An application for the renewal of a traditional herbal registration must be made to the licensing authority.

(2) The applicant **[**[F445], where it is applying for renewal of—

(a) a THR(NI)—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a THR(GB)—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) a THR(UK), must be established in the United Kingdom.**]**

(3) The application must be—

(a) made in writing;

(b) signed by or on behalf of the applicant; and

(c) unless the licensing authority directs otherwise, accompanied by any fee payable in connection with the application.

(4) An application is treated as signed for the purposes of paragraph (3)(b) if it is signed with an electronic signature.

(5) The application must be made so that it is received by the licensing authority before the beginning of the period of nine months ending with the expiry of the period mentioned in paragraph (1)(a) or (3)(a) of regulation 132 (initial and further period of validity), as the case may be.

(6) The holder must provide a consolidated version of the file in respect of quality, safety and efficacy including—

(a) the evaluation of data contained in suspected adverse reaction reports and periodic safety update reports submitted in accordance with Part 11; and

(b) all variations introduced since the traditional herbal registration was granted.

(7) The licensing authority may renew a traditional herbal registration only if, having considered the application and the material accompanying it, the authority thinks that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(8) Schedule 11 makes provision about advice and representations in relation to an application for the renewal of a traditional herbal registration.

Textual Amendments

F445 Reg. 133(2)(a)-(c) substituted for words in reg. 133(2) (31.12.2020) by S.I. 2019/775, **reg. 18** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 89**); 2020 c. 1, **Sch. 5 para. 1(1)**

Failure to place on the market etc

134.—(1) A traditional herbal registration ceases to be in force if the product to which it relates is not placed on the market in the United Kingdom **[**[F446](or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)**]** during the period of three years beginning immediately after the day on which it was granted.

(2) A traditional herbal registration for a product which has been placed on the market ceases to be in force if the product to which it relates is not sold or supplied in the United Kingdom **[**[F447](or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)**]** for a period of three years.

(3) This regulation does not apply if the licensing authority grants an exemption from its operation.

(4) An exemption may be granted—

(a) in response to an application in writing by the holder of the traditional herbal registration; or

(b) by the licensing authority of its own motion.

(5) An exemption may only be granted only—

(a) in exceptional circumstances; and

(b) on public health grounds.

(6) An exemption—

(a) has effect for the period determined by the licensing authority, which may not exceed three years beginning with the day on which it is granted; and

(b) may be renewed or further renewed.

Textual Amendments

F446 Words in reg. 134(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 118A(2)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 90**)

F447 Words in reg. 134(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 118A(3)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 90**)

Revocation, variation and suspension of traditional herbal registration

Revocation, variation and suspension of traditional herbal registration

135.—(1) The licensing authority may revoke, vary or suspend a traditional herbal registration if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

(a) the product to which the registration relates is harmful;

(b) the pharmacological effects or efficacy of the product are no longer plausible; or

(c) the product's qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.

(3) Condition B is that the licensing authority thinks that the application or the material supplied with it is incorrect.

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the registration; or

(b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that the holder of the registration has not complied with regulation 145(1) to (3) (requirement to provide information that may entail amendment of authorisation).

[[F448](6) Condition E is that the holder of the registration has ceased to be established in—

(a) the United Kingdom; or

(b) in relation to a THR(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.**]**

(7) Condition F is that—

(a) the product to which the registration relates is manufactured in the United Kingdom; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with regulations 37 (manufacturing and assembly), 38 (imports from states other than EEA States **[**[F449]/ countries other than approved countries for import**]**), 39 (further requirements for manufacturer's licence), 40 (obligation to provide information relating to control methods) or 41 (requirements as to qualified persons).

(8) Condition G is that—

(a) the product to which the registration relates is manufactured in an EEA State [F450]...; and

(b) the licensing authority thinks that the holder of the manufacturer's licence for the product has failed to comply in relation to the product with provision giving effect to Article 41 of the 2001 Directive (requirements relating to manufacturing authorisations) in that member State.

(9) Condition H is that the licensing authority thinks that urgent action to protect public health is necessary, in which case it—

(a) may suspend the registration; and

(b) **[**[F451]in the case of a THR(NI) or THR(UK),**]** must notify the suspension to the EMA, the European Commission, and all other member States by the end of the next working day following the day on which the suspension comes into force.

(10) Condition I is that—

(a) the holder applies to vary the registration; and

(b) the licensing authority thinks that the application should be granted.

[[F452](10A) Condition J is that the manufacture of the product to which registration relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 12.**]**

[[F453](10B) Condition K is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.**]**

[F454](11) . . . . . .

Textual Amendments

F448 Reg. 135(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 119(1A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(a)**)

F449 Words in reg. 135(7)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F450 Words in reg. 135(8)(a) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 119(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(c)**)

F451 Words in reg. 135(9)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F452 Reg. 135(10A) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **20**

F453 Reg. 135(10B) inserted (31.12.2020) by S.I. 2019/775, **reg. 119(4A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(e)**)

F454 Reg. 135(11) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **119(5)**; 2020 c. 1, Sch. 5 para. 1(1)

Revocation by licensing authority: further provisions

136.—(1) The licensing authority must revoke a traditional herbal registration if—

(a) the application for the registration was submitted in accordance with regulation 128(3) on the basis that the herbal medicinal product to which it relates was contained in

[F455(i) the list referred to in Article 16f(1) of the 2001 Directive, in the case of a THR(NI) or THR(UK);

(ii) the list established under regulation 126A where the application is for a THR(GB); and**]**

(b) the product ceases to be contained in that list.

(2) Paragraph (1) does not apply if within the period of three months beginning immediately after the day on which product ceases to be contained on the list the holder—

(a) submits to the licensing authority the material specified in Schedule 12 (including that referred to in paragraphs 16 to 20 of Part 1 of that Schedule) in relation to the product; and

(b) provides the licensing authority with any material or information that the licensing authority reasonably considers necessary for considering the application and requests the holder to provide.

F456(3) . . . . . .

Textual Amendments

F455 Reg. 136(1)(a)(i)(ii) substituted for words in reg. 136(1)(a) (31.12.2020) by S.I. 2019/775, **reg. 120(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 92**); 2020 c. 1, **Sch. 5 para. 1(1)**

F456 Reg. 136(3) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **120(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Procedures for revocation, variation or suspension

137. Schedule 11 makes provision about advice and representations in relation to a proposal to revoke, vary or suspend a traditional herbal registration, other than a proposal to vary a registration on the application of its holder.

Suspension of use etc of traditional herbal medicinal product

138.—(1) The licensing authority may suspend the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates if any of the following conditions are met.

(2) Condition A is that the licensing authority thinks that—

(a) the product is harmful;

(b) the pharmacological effects or efficacy of the product are no longer plausible; or

(c) the product's qualitative or quantitative composition is not as described in the application for the registration or the material accompanying it.

(3) Condition B is that the licensing authority thinks that the holder has not complied with regulation 145(7) (requirements to provide proof of controls on manufacturing process).

(4) Condition C is that the licensing authority thinks that there has been a breach of—

(a) a term of the registration; or

(b) a requirement imposed by Chapter 1 of Part 13 (packaging and leaflets).

(5) Condition D is that the licensing authority thinks that paragraph (4) or (5) of regulation 23 (power to revoke, suspend or vary manufacturers' licences) applies in relation to the manufacturer's licence for the product.

(6) A suspension under this regulation may relate to batches of the product.

(7) The licensing authority must give notice in writing of a suspension under this regulation to the holder of the registration.

(8) The licensing authority must provide in the notice that the suspension—

(a) is to take effect immediately or from a date specified in the notice; and

(b) is to apply for the period specified in the notice.

(9) Where a medicinal product is the subject of a suspension under this regulation, the licensing authority may—

(a) in exceptional circumstances; and

(b) for such a transitional period as the licensing authority may determine,

allow the supply of the medicinal product to patients who are already being treated with the medicinal product.

F457(10) . . . . . .

Textual Amendments

F457 Reg. 138(10) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **121**; 2020 c. 1, Sch. 5 para. 1(1)

Registrations granted under Chapter 4 of Title III of the 2001 Directive

F458**139.** . . . . . .

Textual Amendments

F458 Reg. 139 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **122**; 2020 c. 1, Sch. 5 para. 1(1)

Withdrawal of traditional herbal medicinal product from the market

140.—(1) This regulation applies if—

[F459(a) under—

(i) regulation 135 or 136, in the case of a THR(GB);

(ii) regulation 135 or 136 or Article 34(3) of the 2001 Directive, in the case of a THR(NI) or THR(UK),

the licensing authority revokes or suspends the registration; or**]**

(b) under regulation 138 the licensing authority suspends the use, sale, supply or offer for sale or supply within the United Kingdom of a product to which a traditional herbal registration relates.

(2) The licensing authority may give written notice to the person who is, or immediately before its revocation was, the holder of the registration requiring the holder to comply with both of the following requirements.

(3) Requirement A is to take all reasonably practicable steps to inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of the product to which the registration relates of—

(a) the revocation or suspension;

(b) the reasons for the revocation or suspension; and

(c) any action to be taken to restrict or prevent further use, sale, supply or offer for sale or supply of the product.

(4) Requirement B is to take all reasonably practicable steps to withdraw from the market in the United Kingdom and recover possession of—

(a) the product; or

(b) the batches of the product specified in the notice,

within the time and for the period specified in the notice.

Textual Amendments

F459 Reg. 140(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 123** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 93**); 2020 c. 1, **Sch. 5 para. 1(1)**

Sale etc of suspended traditional herbal medicinal product

141.—(1) This regulation applies if the use, sale, supply or offer for sale or supply of a traditional herbal medicinal product is suspended in accordance with regulation 138 [F460]....

(2) A person must not—

(a) sell, supply or offer to sell or supply the product; or

(b) procure the sale, supply or offer for sale or supply of the product,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

Textual Amendments

F460 Words in reg. 141(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **124**; 2020 c. 1, Sch. 5 para. 1(1)

Obligations of holder of traditional herbal registration

Obligation to notify placing on the market etc

142.—(1) The holder of a traditional herbal registration must notify the licensing authority of the date on which the product to which the registration relates is placed on the market in the United Kingdom taking account of the various presentations authorised.

(2) A notification under paragraph (1) must be given before the end of the period of two months beginning with the date on which the product is placed on the market.

(3) The holder of a traditional herbal registration must notify the licensing authority if the product to which the registration relates is to be withdrawn from the market in the United Kingdom (whether temporarily or permanently).

(4) A notification under paragraph (3) must be given before the beginning of the period of two months ending with the date on which the product is to be withdrawn from the market unless it is not reasonably practicable to do so.

(5) In that event, the notification must be given as far as is reasonably practicable in advance of the date on which the product is withdrawn from the market.

[[F461](5A) The holder of a traditional herbal registration must notify the licensing authority forthwith if the holder takes action to—

(a) request the cancellation of the registration;

(b) not apply for the renewal of the registration; or

(c) withdraw the product to which the registration relates from the market in a third country (whether temporarily or permanently) and the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5B) A notification under paragraph (3) or (5A) must include the reasons for the action, in particular declaring if the action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.

(5C) The holder of a **[**[F462]THR(NI) or THR(UK)**]** must notify the EMA forthwith where the action which is the subject of a notification by the holder under paragraph (3) or (5A) is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive.**]**

(6) The licensing authority may require the holder of a traditional herbal registration to provide information relating to the volume of sales in the United Kingdom of the product to which the registration relates.

(7) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (6)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F461 Reg. 142(5A)-(5C) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **6**

F462 Words in reg. 142(5C) substituted (31.12.2020) by S.I. 2019/775, **reg. 125** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 94**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligation to take account of scientific and technical progress

143.—(1) The holder of a traditional herbal registration must keep under review the methods of manufacture and control of the product to which the registration relates, taking account of scientific and technical progress.

(2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the traditional herbal registration to make any changes to those methods that are required to ensure they are generally accepted scientific methods.

[[F463]Establishment of herbal monographs

143A.—(1) The licensing authority may establish herbal monographs for herbal medicinal products and traditional herbal medicinal products to be placed on the market in Great Britain.

(2) Subject to paragraph (3), the licensing authority must—

(a) consult the appropriate committee, within the meaning of paragraph 2(4) of Schedule 11, on a proposal to establish herbal monographs under paragraph (1); and

(b) take the advice of the appropriate committee into account in determining whether to proceed with that proposal.

(3) Where an application for a traditional herbal registration has been referred to the appropriate committee by the licensing authority under regulation 130A, the licensing authority must consider whether to exercise its powers under paragraph (1), taking into account any relevant advice of the appropriate committee given under Part 3 of Schedule 11 in relation to that application.

(4) The licensing authority must publish a list of any herbal monographs established under this regulation.

(5) Until the licensing authority exercises the power under paragraph (1), the Community herbal monographs published from time to time under Article 16h(3) of the 2001 Directive continue to apply, and holders of a traditional herbal registration and the licensing authority must continue to take them into account in exercising any function or in relation to any obligation to which they are relevant under this Part.**]**

Textual Amendments

F463 Reg. 143A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **126** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 95**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligation following new herbal monograph

[[F464]**144.**—(1) Paragraph (2) applies where a new herbal monograph of the kind referred to—

(a) in the case of a THR (NI) or THR (UK), in Article 16h(3) of the 2001 Directive, or

(b) in the case of a THR (GB), in regulation 143A,

is established.

(2) Where this paragraph applies, the holder of the THR(GB), THR(NI) or THR(UK) to which the monograph relates must as soon as is reasonably practicable—

(a) consider whether to modify the registration dossier; and

(b) notify any modification to the licensing authority.**]**

Textual Amendments

F464 Reg. 144 substituted (31.12.2020) by S.I. 2019/775, **reg. 127** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 96**)

Obligation to provide information relating to safety etc

145.—(1) The holder of a traditional herbal registration must provide the licensing authority with any new information that might entail the variation of the registration.

(2) The holder must, in particular, provide the licensing authority with the following information—

(a) information about any prohibition or restriction imposed in relation to the product to which the registration relates by the competent authority of any country in which the product is on the market;

(b) positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the traditional herbal registration;

(c) data on the use of the product where such use is outside the terms of the traditional herbal registration; and

(d) any other information that the holder considers might influence the evaluation of the benefits and risks of the product.

(3) Information within paragraph (1) or (2) must be provided as soon as is reasonably practicable after the holder becomes aware of it.

(4) The licensing authority may require the holder of a traditional herbal registration to provide the authority with information that—

(a) is specified by the licensing authority; and

(b) demonstrates that the positive therapeutic effects of the product to which the registration relates outweigh the risks of the product to the health of patients or of the public.

(5) The information that may be required under paragraph (4) includes information arising from use of the product—

(a) in a country **[**F465other than the United Kingdom**]**; or

(b) outside the terms of the traditional herbal registration,

including use in clinical trials.

(6) If the information supplied under paragraph (1), (2) or (4) entails the variation of the traditional herbal registration, the holder must make an application to the licensing authority to that effect as soon as is reasonably practicable after becoming aware of the information.

(7) The licensing authority may require the holder of a traditional herbal registration to provide the authority with proof of the control methods employed by the manufacturer of the product to which the registration relates.

(8) The holder of a traditional herbal registration must provide the licensing authority with information that it requires under paragraph (4) or (7)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the licensing authority, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

Textual Amendments

F465 Words in reg. 145(5)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **128**; 2020 c. 1, Sch. 5 para. 1(1)

Obligation in relation to product information

146.—(1) The holder of the traditional herbal registration for a medicinal product must ensure that the product information relating to the product is kept up to date with current scientific knowledge.

[F466(2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of—

(a) in the case of a medicinal product for sale or supply in Northern Ireland—

(i) the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004, and

(ii) the UK web-portal established in accordance with regulation 203(1);

(b) in the case of a medicinal product for sale or supply in Great Britain only, the UK web-portal established in accordance with regulation 203(1).**]**

Textual Amendments

F466 Reg. 146(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 129** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 97**)

Record-keeping obligations

147. The holder of a traditional herbal registration must keep any documents or information that will facilitate the withdrawal or recall from sale or supply of any product to which the registration relates.

Obligation to ensure appropriate and continued supplies

148. The holder of a traditional herbal registration must take all reasonable steps to ensure appropriate and continued supplies of the product to which the registration relates to pharmacies and persons authorised to supply the product so that the needs of patients in the United Kingdom are met.

[F467Urgent safety restrictions

148A.—(1) Where, in the event of a risk to public health, the holder of a traditional herbal registration takes urgent safety restrictions on its own initiative, it must inform the licensing authority immediately.

(2) If the licensing authority has not raised objections within 24 hours following receipt of that information, the urgent safety restrictions are deemed to be accepted by the licensing authority.

(3) In the event of a risk to public health, the licensing authority may impose urgent safety restrictions.

(4) Where an urgent safety restriction is taken by the holder of a traditional herbal registration, or imposed by the licensing authority, the holder must submit an application for variation of that registration in relation to that restriction within 15 days beginning with the date of the initiation of that restriction.**]**

Textual Amendments

F467 Reg. 148A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **130**; 2020 c. 1, Sch. 5 para. 1(1)

Offences relating to traditional herbal registrations

Urgent safety restrictions

[F468149.—(1) The holder of a THR(NI) or a THR(UK) is guilty of an offence if the holder—

(a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008 that the holder has taken urgent safety restrictions on the holder's own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or

(c) fails to submit an application for variation of the traditional herbal registration to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—

(i) the taking under Article 22(1) or, as the case may be,

(ii) the imposition under Article 22(2),

of that Regulation of an urgent safety restriction;

(2) The holder of a THR(GB) is guilty of an offence if the holder—

(a) fails to inform the licensing authority in accordance with regulation 148A(1) that the holder has taken urgent safety restrictions on the holder's own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority in accordance with regulation 148A(2); or

(c) fails to submit an application for variation of the traditional herbal registration to the licensing authority in accordance with regulation 148A(4) before the end of the period of 15 days beginning with the day after—

(i) the taking under regulation 148A(1), or

(ii) the imposition under regulation 148A(2),

of an urgent safety restriction.**]**

Textual Amendments

F468 Reg. 149 substituted (31.12.2020) by S.I. 2019/775, **reg. 131** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 98**)

Offences in connection with applications

150. A person is guilty of an offence if in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal medicinal product the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product that is false or misleading in a material particular.

Provision of false or misleading information

151.—(1) The holder of a traditional herbal registration is guilty of an offence if the holder provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a traditional herbal medicinal product but that is false or misleading in a material particular.

(2) Paragraph (1) is without prejudice to regulation 150.

General offence of breach of provision of this Part

152.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

(a) failure by the holder of a traditional herbal registration to comply with any requirement or obligation in this Part;

(b) contravention by any person of any prohibition in this Part; or

(c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Penalties

153. A person guilty of an offence under this Part is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

Persons liable

154. If an offence under regulation 150 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

155.—(1) Paragraph (2) applies if the holder of a traditional herbal registration is charged with an offence under this Part in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

(a) the holder communicated the terms of the registration to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulation 142(3) or 148 or an offence under regulation 150 or 151 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 8

Article 126a authorisations

Article 126a authorisations

156.—(1) The licensing authority may grant an Article 126a authorisation for **[**F469sale or supply of**]** a medicinal product **[**F470in Northern Ireland only,**]** if the following conditions are met.

(2) Condition A is that no United Kingdom marketing authorisation, certificate of registration or traditional herbal registration is in force **[**F471in Northern Ireland**]** for the product.

(3) Condition B is that no application is pending in the United Kingdom for a marketing authorisation, certificate of registration or traditional herbal registration **[**F472to be in force in Northern Ireland**]** for the product.

(4) Condition C is that the licensing authority considers that the placing of the product on the market in **[**[F473]Northern Ireland**]** is justified for public health reasons.

(5) Condition D is that the product is imported from **[**[F474]an EU member State**]** that has, in accordance with the 2001 Directive, authorised the placing on the market of the product in that member State.

(6) Condition E is that the person to whom the authorisation is granted is established in the European Union.

(7) Before granting an Article 126a authorisation, the licensing authority must notify the authorisation holder in the member State mentioned in paragraph (5) of the proposal to grant the Article 126a authorisation.

(8) Before granting an Article 126a authorisation, the licensing authority may request the competent authority in the member State mentioned in paragraph (5) to provide in accordance with Article 126a(3)(b) of the 2001 Directive a copy of—

(a) the assessment report for that product as mentioned in Article 21(4) of the 2001 Directive; and

(b) the authorisation in force for that product.

(9) An Article 126a authorisation remains in force for the period specified in it unless revoked before the end of that period.

(10) That period may be specified by reference to the occurrence or non-occurrence of a particular event or events.

Textual Amendments

F469 Words in reg. 156(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 132(a)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F470 Words in reg. 156(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 132(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F471 Words in reg. 156(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 132(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F472 Words in reg. 156(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 132(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F473 Words in reg. 156(4) substituted (31.12.2020) by S.I. 2019/775, **reg. 132(d)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F474 Words in reg. 156(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 132(e)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

Requests from [F475EU member States]

157.—(1) Paragraph (2) applies where the licensing authority **[**[F476], in relation to a UKMA(NI),**]** is requested by the competent authority of **[**[F477]a member State**]** to provide in accordance with Article 126a(3)(b) of the 2001 Directive a copy of—

(a) the assessment report for a medicinal product as mentioned in regulation 64(5) (duties of licensing authority in connection with determination); and

(b) the marketing authorisation in force for that product.

(2) The licensing authority must supply those documents to the competent authority before the end of the period of thirty days beginning on the day after the request is received.

Textual Amendments

F475 Words in reg. 157 heading substituted (31.12.2020) by S.I. 2019/775, **reg. 132A(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F476 Words in reg. 157(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 132A(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

F477 Words in reg. 157(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 132A(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**)

Application of these Regulations

158. The following provisions of Part 5 (marketing authorisations) apply to an Article 126a authorisation as they apply to a marketing authorisation—

(a) regulation 62 (classification of marketing authorisation);

(b) regulation 63 (frequency of periodic safety update reports);

(c) regulation 68 (revocation etc of marketing authorisation) and Schedule 11 (advice and representations in connection with revocations etc) so far as relating to that regulation;

(d) regulation 69 (suspension of use etc of medicinal product);

(e) regulation 71 (withdrawal of medicinal products from the market);

(f) regulation 72 (sale etc of suspended medicinal product);

(g) regulation 80 (urgent safety restrictions); and

(h) regulations 98 (general offence of breach of provision of this Part), 99 (penalties) and 101(1) and (2) (defences), so far as relating to the regulations mentioned in sub-paragraphs (a) and (e) to (f).

PART 9

Borderline products

Provisional determination

159.—(1) This regulation applies if the licensing authority thinks that a product without a **[**[F478]UK**]** marketing authorisation, traditional herbal registration, certificate of registration or **[**[F479], only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,**]** is a medicinal product.

(2) The licensing authority may give a notice in writing (a "provisional determination notice") to any person (the "recipient")—

(a) who has sold or supplied the product, or has offered to sell or supply it; or

(b) whom the licensing authority thinks may sell or supply the product.

(3) The provisional determination notice must—

(a) advise the recipient that the licensing authority has made a provisional determination that the product is a medicinal product;

(b) give reasons for the provisional determination;

(c) advise the recipient of the recipient's rights to challenge the provisional determination in accordance with regulation 160 and

(d) specify a period of at least six weeks beginning immediately after the date on which the provisional determination notice is given to the recipient (in this Part "the determination date") within which any written representations in accordance with regulation 160(2)(a) must be made to the licensing authority.

Textual Amendments

F478 Word in reg. 159(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **133(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F479 Words in reg. 159(1) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 133(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 100**)

Challenge to provisional determination

160.—(1) A recipient of a provisional determination notice may, within the period of four weeks beginning immediately after the determination date, give notice in writing to the licensing authority requesting the authority to submit the provisional determination to review.

(2) If the recipient gives such notice the recipient must—

(a) within the period specified in the provisional determination notice, make written representations to the licensing authority explaining why the recipient thinks the product is not a medicinal product; or

(b) within the period of four weeks beginning immediately after the determination date, inform the licensing authority in writing that the recipient wants to make oral representations explaining why the recipient thinks the product is not a medicinal product.

(3) If—

(a) the recipient has informed the licensing authority that the recipient wants to make written representations in accordance with paragraph (2)(a); and

(b) the licensing authority thinks that, because of exceptional circumstances or the nature or complexity of the issues involved, additional time is needed for the preparation of written representations,

the licensing authority may alter the period for making written representations.

(4) The licensing authority must inform the recipient in writing of an alteration under paragraph (3) and of the reasons for it.

Written representations procedure

161.—(1) If a recipient makes written representations in accordance with regulation 160(2)(a) the licensing authority must appoint a panel of at least two persons ("the reviewers") to advise on the provisional determination.

(2) The licensing authority must provide the reviewers with—

(a) the recipient's written representations; and

(b) any written representations of the licensing authority.

(3) The reviewers must advise the licensing authority on the authority's provisional determination taking account of—

(a) the written representations; and

(b) any other evidence submitted to them.

(4) The licensing authority must take into account the reviewers' advice and make a final determination as to whether the product is a medicinal product.

(5) The licensing authority must—

(a) inform the recipient in writing of its final determination and of the reasons for it; and

(b) if the licensing authority disagrees with the reviewers' advice, inform the recipient in writing of the reasons for that disagreement.

Oral representations procedure

162.—(1) If a recipient informs the licensing authority in accordance with regulation 160(2)(b) that the recipient wants to make oral representations, the licensing authority must—

(a) appoint a panel of at least two persons ("the reviewers") to conduct the review; and

(b) after consultation with the recipient set a date for the hearing.

(2) The licensing authority may alter the date of the hearing at the request of the recipient or of its own motion if it thinks that because of exceptional circumstances or the nature or complexity of the issues involved additional time is needed for preparation for the hearing.

(3) The licensing authority must inform the recipient in writing of any alteration under paragraph (2) and of the reasons for it.

(4) The recipient and the licensing authority may make oral representations at the hearing.

(5) The reviewers must advise the licensing authority on the authority's provisional determination, taking account of—

(a) the oral representations made and any other evidence submitted by the recipient at the hearing;

(b) any oral representations made or other evidence submitted by the licensing authority at the hearing; and

(c) any other evidence heard by the review panel.

(6) The licensing authority must take into account the reviewers' advice and make a final determination as to whether the product is a medicinal product.

(7) The licensing authority must—

(a) inform the recipient in writing of its final determination and of the reasons for it; and

(b) if the licensing authority disagrees with the reviewers' advice, inform the recipient in writing of the reasons for that disagreement.

Final determination without representations

163.—(1) This regulation applies if the recipient—

(a) does not give notification to the licensing authority that the recipient wishes to challenge its provisional determination within the period of four weeks beginning immediately after the determination date;

(b) gives such notification, but fails to make written representations to the licensing authority within the period for making those representations; or

(c) gives such notification, but fails to make oral representations at a hearing before the reviewers appointed for the purposes of advising on the provisional determination.

(2) The licensing authority must—

(a) make a final determination as to whether the product is a medicinal product; and

(b) inform the recipient in writing of its final determination and of the reasons for it.

Effect of final determination

164.—(1) If the licensing authority makes a final determination that a product is a medicinal product, it may give a notice to any person—

(a) who has sold or supplied the product, or has offered to sell or supply it; or

(b) whom the licensing authority thinks may sell or supply the product.

(2) The notice must require the person—

(a) to cease to sell, supply or offer to sell or supply the product from the date specified in the notice until a **[**[F480]UK**]** marketing authorisation, traditional herbal registration, certificate of registration or **[**[F481], only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,**]** is granted in respect of the product; or

(b) not to sell, supply or offer to sell or supply the product unless a **[**[F482]UK**]** marketing authorisation, traditional herbal registration, certificate of registration or **[**[F483], only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,**]** is granted in respect of the product.

Textual Amendments

F480 Word in reg. 164(2)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **134(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F481 Words in reg. 164(2)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 134(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 101**)

F482 Word in reg. 164(2)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **134(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F483 Words in reg. 164(2)(b) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 134(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 101**)

Determination in other cases

165. Nothing in this Part prevents the licensing authority from determining that a product is a medicinal product **[**[F484]in relation to these Regulations**]** without following the procedures in this Part when it thinks it appropriate.

Textual Amendments

F484 Words in reg. 165 inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **3** and words in reg. 165 inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **3**

Offences relating to borderline products

166.—(1) A person is guilty of an offence if that person sells or supplies, or offers to sell or supply a product in breach of a notice under regulation 164(1) imposing a requirement under—

(a) regulation 164(2)(a); or

(b) regulation 164(2)(b).

(2) A person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

Supply to fulfil special patient needs

167.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product (a "special medicinal product") if—

(a) the medicinal product is supplied in response to an unsolicited order;

(b) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;

(c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and

(d) the following conditions are met.

(2) Condition A is that the medicinal product is supplied—

(a) to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber; or

(b) for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre.

(3) Condition B is that no advertisement relating to the medicinal product is published by any person.

(4) Condition C is that—

(a) the manufacture and assembly of the medicinal product are carried out under such supervision; and

(b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the licensing authority or to the enforcement authority on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the United Kingdom **[**[F485], imported into Northern Ireland from a country other than an EEA State or Great Britain, or imported into Great Britain from a country other than an approved country for import or Northern Ireland**]**—

(a) it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or

(b) it is manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorisation granted by the licensing authority for the purposes of regulation 36 of the Clinical Trials Regulations.

(7) Condition F is that if the product is **[**[F486]imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import**]**—

[[F487](a) it is manufactured or assembled in that State or country (as appropriate) by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, the provisions of the 2001 Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, in accordance with the provisions applicable in that country; or**]**

[[F488](b) it is manufactured or assembled as an investigational medicinal product in that State or country (as appropriate) by the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, Article 13 of the Clinical Trials Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, regulations 13 and 43 of the Clinical Trials Regulations,**]**

[[F489]and it is imported by the holder of a wholesale dealer's licence in relation to the product in question.**]**

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person ("P"), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6)(a) or (7)(a), P must be the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Textual Amendments

F485 Words in reg. 167(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F486 Words in reg. 167(7) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(i)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F487 Reg. 167(7)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(ii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F488 Reg. 167(7)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(iii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F489 Words in reg. 167(7)(b) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **5(2)(b)** and words in reg. 167(7)(b) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **5(2)(b)**

[F490NIMAR supply to Northern Ireland

167A.—(1) If the following conditions are met—

(a) the prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product sold or supplied, or offered for sale or supply, in Northern Ireland, and

(b) that product is classified in Northern Ireland as a prescription only medicine.

(2) Condition A is that a UK marketing authorisation of a following type is in force for the product—

(a) a UKMA(UK);

(b) a UKMA(GB).

(3) Condition B is that the product is classified as a prescription only medicine in accordance with regulation 5(3) for the purposes of sale and supply in Great Britain.

(4) Condition C is that the product is a listed NIMAR product.

(5) Condition D is that if the product is to be distributed by wholesale dealing by a person ("P") in Northern Ireland, P must be a holder of a wholesale dealer's licence.

(6) Condition E is that if the product is manufactured or assembled in Great Britain, it is supplied to Northern Ireland—

(a) by the holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

(7) Condition F is that if the product is manufactured outside of the UK and imported into Great Britain, it is supplied to Northern Ireland—

(a) by a holder of a manufacturer's licence in respect of that product; or

(b) by the holder of a wholesale dealer's licence.

Textual Amendments

F490 Regs. 167A, 167B inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **14**

List of NIMAR products

167B.—(1) The licensing authority must maintain a list for the purposes of regulation 167A(4).

(2) In relation to each listed NIMAR product, the list must specify the date the NIMAR product was added to the list.

(3) The licensing authority must publish the list and keep it up to date.

(4) A product may only be included on the list if the following conditions are satisfied—

(a) Condition A is that the Secretary of State has in relation to Northern Ireland been provided with at least one of the following—

(i) information requested under regulation 28 (provision of information about availability of health service medicines) of the 2018 Regulations;

(ii) information under regulation 29 (requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines) of the 2018 Regulations;

(b) Condition B is that the holder of a UK marketing authorisation, has notified the Secretary of State that—

(i) in relation to a medicinal product to which a UKMA(UK) relates, the qualified person who is at the disposal of the holder of a manufacturer's licence is unable to secure the matters mentioned in paragraph 12A of Schedule 7 for the purpose of supplying the product into Northern Ireland from Great Britain; or

(ii) in relation to a medicinal product to which a UKMA(GB) relates, the inability of a qualified person who is at the disposal of the holder of a manufacturer's licence to secure the matters mentioned in paragraph 12A of Schedule 7 prevents the holder of the UKMA(GB) from converting it into a UKMA(UK);

(c) Condition C is that the licensing authority considers that clinical needs in Northern Ireland for the product may be unmet.

(5) The licensing authority must remove a product from the list if the licensing authority considers that medicinal products, not including listed NIMAR products, available in Northern Ireland are capable of meeting clinical need.**]**

Textual Amendments

F490 Regs. 167A, 167B inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **14**

[F491Early Access to Medicines Scheme: establishment and licensing authority functions

167C.—(1) The licensing authority must establish and operate a scheme, to be known as the Early Access to Medicines Scheme—

(a) the purpose of which is to give patients with life threatening or seriously debilitating conditions access to medicinal products that may be used for preventing, diagnosing or treating those conditions but which are either not authorised or not authorised for that use; and

(b) which is to include arrangements to support the collection of data about EAMS medicinal products.

(2) The licensing authority has the following functions with regard to the Early Access to Medicines Scheme—

(a) issuing, where appropriate, a designation ("Promising Innovative Medicines designation") in respect of a product under consideration for inclusion in the Scheme to the person who is or may in due course be responsible for placing the product on the market, after concluding based on early clinical and non-clinical data that the medicinal product may be eligible for inclusion in the Scheme because—

(i) there is a life threatening or seriously debilitating condition and a high unmet need,

(ii) the medicinal product is likely to offer a major advantage over methods of preventing, diagnosing or treating the condition already in use in the United Kingdom, and

(iii) the potential adverse effects of the medicinal product are likely to be outweighed by the potential benefits, allowing for a reasonable expectation of a positive risk-benefit balance;

(b) issuing, where appropriate, an opinion ("EAMS scientific opinion") to a holder of a Promising Innovative Medicines designation to the effect that the holder is able—

(i) to demonstrate that there is a life threatening or seriously debilitating condition and a high unmet need,

(ii) to demonstrate that the medicinal product offers a major advantage over methods of preventing, diagnosing or treating the condition already in use in the United Kingdom,

(iii) to demonstrate that the potential adverse effects of the medicinal product are outweighed by the potential benefits, allowing for a reasonable expectation of a positive risk-benefit balance,

(iv) to supply the product to or within the United Kingdom (or a part thereof) for use as part of the Scheme, and

(v) to manufacture, or secure the manufacturing of, the product to a consistent quality standard and in compliance with good manufacturing practice,

as a consequence of which the product is included in and may be supplied as part of the Scheme;

(c) where it issues an opinion under sub-paragraph (b), attaching where appropriate conditions, which may be varied from time to time, to the access to the Scheme that the opinion gives (which may include conditions that are equivalent to requirements of Part 13);

(d) revoking, pursuant to paragraph (3), opinions issued in accordance with sub-paragraph (b); and

(e) renewing opinions issued in accordance with sub-paragraph (b) that would otherwise cease to have effect in accordance with regulation 167D(1).

(3) The licensing authority may, if it is reasonable to do so, revoke an EAMS scientific opinion at any time (as a consequence of which, subject to regulation 167D(2), the product can no longer be supplied as part of the Scheme) if—

(a) there is a breach of the conditions referred to in paragraph (2)(c);

(b) there is a breach of regulation 167E to 167G; or

(c) sufficient grounds no longer exist for inclusion of the product within the Scheme.

(4) For the purposes of this regulation and regulations 167E and 167G, "authorised" has the meaning given in regulation 3(15), and (including the purposes of regulation 43(6)(aa)) "unauthorised" is to be construed accordingly.

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS scientific opinions ceasing to have effect

167D.—(1) Subject to paragraph (2), an EAMS scientific opinion ceases to have effect—

(a) at the end of a period of one year beginning with the date on which it is issued;

(b) on the granting of a marketing authorisation in respect of the product to which the opinion relates (but if the marketing authorisation is to apply in Great Britain only, the opinion can continue to have effect in Northern Ireland and vice versa);

(c) on a variation of an existing marketing authorisation to take account of the advantage, identified in the opinion, because of which the product was included in the Early Access to Medicines Scheme (but if the variation is of a marketing authorisation that applies in Great Britain only, the opinion can continue to have effect in Northern Ireland and vice versa); or

(d) if it is revoked by the licensing authority pursuant to regulation 167C(3).

(2) The licensing authority may provide, in conditions attached in accordance with regulation 167C(2)(c), for a winding down period during which an EAMS scientific opinion is to continue to have effect in specified circumstances or for specified purposes (or both), notwithstanding that it has otherwise ceased to have effect by virtue of paragraph (1).

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS medicinal products: manufacture, assembly, importation, distribution and supply

167E.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an EAMS medicinal product if—

(a) the medicinal product is supplied in response to an unsolicited order;

(b) the medicinal product is manufactured and assembled in accordance with the specification (of the EAMS medicinal product) of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;

(c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient that relate to the advantage identified in the EAMS scientific opinion in respect of the product;

(d) the EAMS scientific opinion issued in respect of the product and has not ceased to have effect in respect of it in accordance with regulation 167D; and

(e) the conditions in paragraphs (2) to (4) are met.

(2) If the EAMS medicinal product is—

(a) manufactured or assembled (wholly or partly) in the United Kingdom, that manufacture or assembly must be—

(i) by the holder of a manufacturer's licence (which need not relate specifically to the manufacture of special medicinal products) or, if the licensing authority agrees, a manufacturing authorisation (within the meaning given in regulation 36(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004) that relates to the manufacture or assembly of investigational medicinal products, and

(ii) a function permitted by that manufacturer's licence or manufacturing authorisation;

(b) manufactured or assembled (wholly or partly) in an EEA State and imported into Northern Ireland (whether it is for sale or supply in Northern Ireland or Great Britain), that manufacture or assembly must be—

(i) by a holder of a relevant authorisation in relation to the manufacture or assembly of medicinal products that has effect in accordance with the provisions of the 2001 Directive as implemented in that State, or

(ii) if the medicinal product was manufactured or assembled as an investigational medicinal product in that State, by the holder of a relevant authorisation in relation to the manufacture or assembly of investigational medicinal products that has effect in accordance with the provisions of the EU Clinical Trials Regulation;

(c) manufactured or assembled (wholly or partly) in an approved country for import and imported into Great Britain, that manufacture or assembly must be—

(i) by a holder of a relevant authorisation in relation to the manufacture or assembly of medicinal products that has effect in accordance with the provisions applicable in that country, or

(ii) if the medicinal product was manufactured or assembled as an investigational medicinal product in that country, by the holder of a relevant authorisation in relation to the manufacture or assembly of investigational medicinal products that has effect in accordance with the provisions applicable in that country,

and that importation must be by the holder of a wholesale dealer's licence that permits importation into Great Britain of the product in question; or

(d) manufactured or assembled (wholly or partly) outside the United Kingdom but sub-paragraph (b) or (c) does not apply to the importation of that product, the importation of that product must be—

(i) by the holder of a manufacturer's licence that relates to the importation of special medicinal products or, if the licensing authority agrees, investigational medicinal products, and

(ii) a function permitted by that licence.

(3) Written records of the manufacture or assembly of the EAMS medicinal product must be maintained by the manufacturer or assembler and be available to the licensing authority or to the enforcement authority on request.

(4) If the EAMS medicinal product is distributed by way of wholesale dealing by a person ("P"), who has not, as the case may be, manufactured, assembled or imported the product as mentioned in paragraph (2), P must be the holder of a wholesale dealer's licence that permits distribution of the product in question.

(5) Where, with the agreement of the licensing authority, to ensure the ongoing availability of an EAMS medicinal product, an authorised product is assembled as that EAMS medicinal product and is supplied as part of the Scheme—

(a) that authorised product is to be treated—

(i) as an unauthorised product for the purposes of Part 13, and

(ii) as that EAMS product for the purposes regulations 167G and 167H and Part 11; and

(b) in any circumstances where that supply would not be an off label supply to which the prohibitions in regulation 46(2) did not apply (by operation of the common law), that supply is to be treated as an off label supply to which those prohibitions do not apply.

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

Advertising of EAMS medicinal products

167F.—(1) No advertisement relating to an EAMS medicinal product may be published by any person in respect of an advantage identified in the EAMS scientific opinion in respect of the product (although this does not preclude a person promoting the Early Access to Medicine Scheme itself).

(2) In this regulation, "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

EAMS medicinal products: pharmacovigilance

167G.—(1) The EAMS scientific opinion holder must comply with the following pharmacovigilance requirements in respect of an EAMS medicinal product—

(a) a risk management system must be agreed with the licensing authority and operated by the EAMS scientific opinion holder in accordance with the risk management plan;

(b) the EAMS scientific opinion holder must record and maintain adverse reaction reports in respect of the EAMS medicinal product and must ensure that these reports are accessible (electronically or physically) at a single point within the United Kingdom;

(c) the EAMS scientific opinion holder must submit electronically to the licensing authority—

(i) a report on all serious suspected adverse reactions that occur within 15 days of receipt, and

(ii) a report on all non-serious suspected adverse reactions that occur in the United Kingdom within 90 days of receipt,

and must ensure that the reports referred to in sub-paragraphs (i) and (ii) are in the format and content specified by Part 6 of Schedule 12A;

(d) the EAMS scientific opinion holder must—

(i) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports, and

(ii) collect follow-up information on reports submitted under sub-paragraphs (c)(i) and (c)(ii) and submit it electronically to the licensing authority by way of an update to the original report within the specified time period;

(e) the EAMS scientific opinion holder must submit periodic reports, in the manner specified in conditions attached under regulation 167C(2)(c), on the use of the EAMS medicinal product to the licensing authority, and where reasonably practicable, these reports must contain—

(i) details of any suspected adverse drug reaction to the medicinal product,

(ii) a summary of any significant new data on the quality, safety or efficacy of the medicinal product concerned,

(iii) any proposed updates to the medicinal product information,

(iv) all data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product in the United Kingdom, and

(v) a scientific evaluation of the risk-benefit balance of the medicinal product;

(f) the EAMS scientific opinion holder must notify the licensing authority without delay if it detects any relevant changes in relation to the EAMS medicinal product, and for these purposes, "relevant changes" means—

(i) new risks,

(ii) risks that have changed, and

(iii) changes to the risk-benefit balance; and

(g) the EAMS scientific opinion holder must—

(i) record all pharmacovigilance information required under this regulation,

(ii) maintain those records for at least five years beginning on the date on which the EAMS scientific opinion ceases to have effect in accordance with regulation 167D(1) (subject to any winding down period provided for in accordance with regulation 167D(2)), and

(iii) make those records available to the licensing authority or to the enforcement authority on request.

(2) Nothing in paragraph (1) precludes the meeting of the requirements of that paragraph within systems or other arrangements established for other medicinal products (including for an authorised product the marketing authorisation of which may, in due course, be varied to take account of the advantage identified in the EAMS scientific opinion in respect of the EAMS medicinal product).

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

Early Access to Medicines Scheme: data collection

167H.—(1) Data may be collected and handled in respect of patients for the purposes of assessing the quality, safety and efficacy of an EAMS medicine as part of the Early Access to Medicines Scheme without the need for an authorisation granted by the licensing authority under the Clinical Trials Regulations, if—

(a) informed consent is obtained from the patient and such consent is evidenced in writing, dated and signed, or otherwise marked by the patient as to indicate their consent; and

(b) the licensing authority has consented to the data collection.

(2) This is without prejudice to—

(a) the need for the EAMS scientific opinion holder to obtain other approvals in respect of the handling of patient data, where appropriate; and

(b) the powers that the EAMS scientific opinion holder and the licensing authority have to handle patient data (in accordance with the requirements of the Data Protection Act 2018) without the patient's consent.

(3) For the avoidance of doubt, patient consent to data collection or handling is not, and must not be made, a condition of the supply of an EAMS medicinal product to a patient as part of the Early Access to Medicines Scheme.**]**

Textual Amendments

F491 Regs. 167C-167H inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **8** (with reg. 19)

Use of non-prescription medicines in the course of a business

168.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to anything done in relation to a medicinal product if the following conditions are met.

(2) Condition A is that the medicinal product is not a prescription only medicine.

(3) Condition B is that the medicinal product is sold or supplied to a person who is a health care professional ("P") exclusively for use by P—

(a) in the course of a business carried on by P, and

(b) for the purposes of administering it or causing it to be administered otherwise than by selling it.

(4) Condition C is that the medicinal product is—

(a) manufactured and assembled in accordance with the specification of P; and

(b) for use by a patient for whose treatment P is directly responsible in order to fulfil the special needs of that patient

(5) Condition D is that if sold or supplied through the holder of a wholesale dealer's licence the medicinal product is sold or supplied to such a person and for such use as mentioned in condition B.

(6) Condition E is that no advertisement relating to the medicinal product is published by any person.

(7) Condition F is that the sale or supply of the medicinal product is in response to an unsolicited order.

[[F492](8) Condition G is that if the medicinal product is—

(a) manufactured or assembled in the United Kingdom or imported into the United Kingdom from—

(i) in the case of a product for sale or supply in Northern Ireland, a country other than an EEA State, or

(ii) in the case of a product for sale or supply in Great Britain, a country other than an approved country for import,

it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products, or

(b) imported into—

(i) Northern Ireland from an EEA State, it is manufactured or assembled in that State by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with the provisions of the 2001 Directive as implemented in that State, or

(ii) Great Britain from an approved country for import—

(aa) it is manufactured or assembled in that country by a person who is the holder of an authorisation in that country in relation to its manufacture or assembly, and

(bb) it is imported by the holder of a wholesale dealer's licence under Part 3 that includes the import of a medicinal product from such a country.**]**

(9) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Textual Amendments

F492 Reg. 168(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 135** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 103**)

Mixing of general sale medicinal products

169.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply to a medicinal product ("the product") in respect of which the following conditions are met.

(2) Condition A is that the product is manufactured by the mixing of authorised medicinal products with other authorised medicinal products, or with substances that are not medicinal products.

(3) Condition B is that any authorised medicinal product that is so mixed is subject to general sale.

(4) Condition C is that the product is manufactured by a person ("H") who is the holder of a manufacturer's licence that—

(a) relates specifically to the manufacture of medicinal products in accordance with this regulation; and

(b) was granted or renewed not more than five years before the date on which the product is sold or supplied in accordance with paragraphs (5) and (6),

and that the product is manufactured in accordance with the terms of that licence.

(5) Condition D is that the product is sold or supplied by H to a person ("P") for administration to P or to a member of P's household.

(6) Condition E is that P is present and asks H to use H's judgment as to the treatment required.

(7) Condition F is that no advertisement relating to the product is published by any person.

(8) Condition G is that written records of the manufacture of the product and of the sale or supply of the product are maintained and are made available to the licensing authority or to the enforcement authority on request.

(9) In this regulation, "authorised medicinal product" means a medicinal product that is the subject of—

(a) a **[**F493UK marketing authorisation or EU marketing authorisation**]**;

(b) a certificate of registration; or

(c) a traditional herbal registration.

Textual Amendments

F493 Words in reg. 169(9)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 136** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 104**): 2020 c. 1, **Sch. 5 para. 1(1)**

Record-keeping requirements

170.—(1) Where the sale or supply of a medicinal product relies on the exemptions under regulations 167, 168 or, subject to paragraph (4), 169, the person who sells or supplies the product must maintain for at least five years a record showing—

(a) the source from which and the date on which the person obtained the product;

(b) the person to whom and the date on which the sale or supply was made;

(c) the quantity of the sale or supply;

(d) the batch number of the batch of that product from which the sale or supply was made; and

(e) details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware.

(2) The person must make the records available for inspection by the licensing authority on request.

(3) The person must notify the licensing authority of any suspected adverse reaction to the medicinal product which is a serious adverse reaction.

(4) In the case of a medicinal product that is sold or supplied in reliance on the exemption in regulation 169—

(a) the reference in paragraph (1)(a) to "the product" means all the medicinal products that were mixed in the course of the manufacture of the product; and

(b) paragraph (1)(d) shall not apply.

Exempt advanced therapy medicinal products

171.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an advanced therapy medicinal product (an "exempt advanced therapy medicinal product") if the following conditions are met.

(2) Condition A is that the product is prepared—

(a) on a non-routine basis;

(b) in the United Kingdom; and

(c) according to specific quality standards equivalent to those provided for advanced therapy medicinal products authorised under **[**F494—

(i) in the case of a product for sale or supply in Northern Ireland, Regulation (EC) No 726/2004, and

(ii) in the case of a product for sale or supply in Great Britain, regulation 49(1).**]**

(3) Condition B is that the product is used—

(a) in a hospital in the United Kingdom;

(b) under the exclusive professional responsibility of a doctor; and

(c) in order to comply with an individual medical prescription for a product made to order for an individual patient.

(4) Condition C is that no advertisement relating to the medicinal product is published by any person.

(5) Condition D is that the sale or supply of the medicinal product is in response to an unsolicited order.

(6) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation Part 14 advertising).

Textual Amendments

F494 Reg. 171(2)(c)(i)(ii) substituted for words in reg. 171(2)(c) (31.12.2020) by S.I. 2019/775, **reg. 137** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 105**); 2020 c. 1, **Sch. 5 para. 1(1)**

Parallel import licences

172.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not prevent—

(a) the holder of a parallel import licence from placing the medicinal product to which the licence relates on the market; or

(b) the sale or supply, or offer for sale or supply, of a medicinal product to which a parallel import licence relates, in accordance with the terms of that licence.

[F495(2) In this regulation "parallel import licence" has the same meaning as in regulation 48(2).**]**

Textual Amendments

F495 Reg. 172(2) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **18** and reg. 172(2) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **18**

Exemption for certain radiopharmaceuticals

173. Regulation 46 (requirement for authorisation) does not apply where a radiopharmaceutical is prepared—

(a) at the time when it is intended to be administered;

(b) in accordance with the manufacturer's instructions and by the person by whom it is to be administered;

(c) from radionuclide generators, radionuclide kits and radionuclide precursors in respect of which a **[**F496UK marketing authorisation or EU marketing authorisation**]** is in force; and

[F497(d) for administration—

(i) in England and Wales and Scotland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(ii) in Northern Ireland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.**]**

Textual Amendments

F496 Words in reg. 173(c) substituted (31.12.2020) by S.I. 2019/775, **reg. 138** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 106**); 2020 c. 1, **Sch. 5 para. 1(1)**

F497 Reg. 173(d) substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322), reg. 1, **Sch. 4 para. 2(2)** (as substituted (6.2.2018) by S.I. 2018/121, regs. 1(2), **2(4)(b)(i)**)

Supply in response to spread of pathogenic agents etc

174. The prohibitions in regulation 46 (requirement for authorisation) do not apply where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis in response to the suspected or confirmed spread of—

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.

[F498Conditions of temporary authorisations under regulation 174

174A.—(1) Where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis under regulation 174, the licensing authority may attach conditions to that authorisation, those being conditions to which the following are subject—

(a) its recommendation or requirement as to the use of that product for the purposes of regulation 345; and

(b) its authorisation of the sale or supply of that product.

(2) The sale or supply of that medicinal product is not authorised by the licensing authority for the purposes of regulation 174 if—

(a) the sale or supply is for the purpose of any use other than the recommended or required use, as mentioned in paragraph (1)(a); or

(b) a condition attached in accordance with paragraph (1) to the authorisation of the sale or supply is breached.

(3) The use of that medicinal product is not in accordance with a recommendation or requirement of the licensing authority for the purposes of regulation 345 if—

(a) a condition attached in accordance with paragraph (1) to the authorisation of its sale or supply is breached; and

(b) any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person with relevant expertise in the subject matter of the breach would regard the breach as sufficiently serious to justify the licensing authority setting aside the recommendation or requirement.

(4) Notwithstanding paragraph (3), the persons mentioned in regulation 345(3) are not subject to any civil liability resulting from a use of that medicinal product that was (but for the operation of that paragraph) in accordance with the recommendation or requirement of the licensing authority, if those persons were not wholly or partly responsible for the breach in question.

(5) As soon as is reasonably practical after the end of one year beginning on the day on which the first conditions are attached in accordance with paragraph (1), the Secretary of State must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F498 Reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **6** and reg. 174A inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **6**

Offences

Offences relating to exceptions

175.—(1) A person to whom this paragraph applies is guilty of an offence if the person provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product that is false or misleading in a material particular.

(2) Paragraph (1) applies to any person who for the purposes of regulation 167 (special patient needs)—

(a) sells or supplies the product; or

(b) provides a specification for the product.

(3) A person is guilty of an offence if the person fails to—

(a) maintain any record required by regulation **[**F499167G(1)(g)(ii) (EAMS medicinal products: pharmacovigilance) or**]** 170(1) (records in connection with special medicinal products etc);

(b) make any record available as required by regulation **[**F500167G(1)(g)(iii) or**]** 170(2); or

(c) notify the licensing authority of any suspected serious adverse reaction as required by regulation 170(3) **[**F501or of any relevant changes as required by regulation 167G(1)(f)**]**.

Textual Amendments

F499 Words in reg. 175(3)(a) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(2)** (with reg. 19)

F500 Words in reg. 175(3)(b) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(3)** (with reg. 19)

F501 Words in reg. 175(3)(c) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **9(4)** (with reg. 19)

Penalties and supplementary provision about offences

176.—(1) A person guilty of an offence under regulation 175 is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

(2) It is a defence for a person charged with an offence under regulation 175(1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(3) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (2), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

PART 11

Pharmacovigilance

Application of this Part and interpretation

177.—(1) This Part and Schedule 33 apply, except to the extent set out in paragraph (4)(b), in relation to medicinal products that are the subject of—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation.

[F502(1A) Schedule 12A applies in relation to medicinal products that are the subject of a UKMA(GB) ora THR(GB).**]**

[F503(1B) Regulations 178 and 179 apply in relation to EAMS medicinal products.**]**

(2) **[**F504Except in regulation 191A, references in**]** this Part **[**F505and Schedule 12A**]** to a "holder" are to the holder of—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation,

and, in relation to such references, "product" means the product to which the authorisation or registration relates.

(3) References to an "authorisation or registration" in this Part and in **[**F506Schedules 12A and 33**]** are references to—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation

and "authorised or registered" is to be read accordingly.

[F507(4) The following provisions of this Part and Schedule 33 apply in relation to medicinal products that are the subject of an EU marketing authorisation—

(a) regulation 206 (infringement notices);

(b) regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004), and paragraphs 2 and 4 of Schedule 33 (transitional arrangements: pharmacovigilance), but that regulation and those paragraphs do not apply in relation to the medicinal products specified in paragraph (1); and

(c) regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation).**]**

(5) In this Part and in **[**F508Schedules 33 and 33A**]**—

"co-ordination group" means the group of that name established under Article 27 of the 2001 Directive;

"Eudravigilance database" means the database and data-processing network set up and maintained by the EMA under Article 24 of Regulation (EC) No 726/2004;

[F509"Implementing Regulation" means Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in

Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.**]**

"infringement notice" has the meaning given to it in regulation 206 (infringement notices);

"relevant competent authorities" means the competent authority of each EEA state other than the United Kingdom which has granted in relation to a medicinal product—

(a) an authorisation in accordance with Chapter 1 of Title III to the 2001 Directive (marketing authorization);

(b) an authorisation in accordance with Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure);

(c) a registration in accordance with Chapter 2a of Title III to the 2001 Directive (traditional use registration for herbal medicinal products); or

(d) an authorisation in accordance with Article 126a of the 2001 Directive;

"relevant post-authorisation safety study" means a post-authorisation safety study which—

(a) is non-interventional;

(b) is initiated, managed or financed by the holder voluntarily or pursuant to conditions imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation); and

(c) involves the collection of safety data from patients or health care professionals; [F510]...

[[F511]"signal" means, in relation to a UKMA(GB) or THR(GB), information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, which is judged to be of sufficient likelihood to justify verificatory action; and**]**

"UK web-portal" has the meaning given in regulation 203 (obligations on licensing authority in relation to national medicines web-portal).

Textual Amendments

F502 Reg. 177(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 139(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(a)**)

F503 Reg. 177(1B) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **10** (with reg. 19)

F504 Words in reg. 177(2) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **19** and words in reg. 177(2) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **19**

F505 Words in reg. 177(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **139(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F506 Words in reg. 177(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **139(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F507 Reg. 177(4) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **21(2)**

F508 Words in reg. 177(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 139(6)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(e)**)

F509 Words in reg. 177(5) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **21(3)**

F510 Word in reg. 177(5) omitted virtue of (31.12.2020) by S.I. 2019/775, **reg. 139(6)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(e)**)

F511 Words in reg. 177(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 139(6)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(e)**)

Obligations on licensing authority in relation to pharmacovigilance

General obligations of the licensing authority

178. The licensing authority must—

(a) take all appropriate measures to encourage the reporting to it of suspected adverse reactions;

(b) facilitate reporting through the provision of alternative reporting formats in addition to web-based formats;

(c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;

(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner, through publication on the UK web-portal, and through other means of publicly available information as necessary; and

(e) ensure that all appropriate measures are taken to identify any biological medicinal product (including name and batch number) prescribed, dispensed or sold in the United Kingdom which is the subject of a suspected adverse reaction report through—

(i) the methods for collecting data, and

(ii) where necessary, the follow up of suspected adverse reaction reports.

Obligation on licensing authority to operate pharmacovigilance system

179.—(1) The licensing authority must operate a pharmacovigilance system **[**F512in relation to medicinal products for sale or supply in Great Britain**]**.

[F513(1A) The licensing authority must operate a pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland.**]**

(2) **[**F514Each pharmacovigilance system**]** must in particular enable the collection of information on the risks that medicinal products present to patients' health or public health, including information on—

(a) adverse reactions in humans arising from use of a medicinal product (irrespective of whether the use was within the terms of an authorisation or registration); and

(b) adverse reactions associated with occupational exposure.

(3) The licensing authority must on an ongoing basis—

(a) evaluate scientifically the information collected under **[**F515each pharmacovigilance system**]**;

(b) consider options for minimising and preventing risks presented by medicinal products; and

(c) take appropriate regulatory action, if any.

Textual Amendments

F512 Words in reg. 179(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 139A(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**)

F513 Reg. 179(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 139A(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**)

F514 Words in reg. 179(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 139A(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**)

F515 Words in reg. 179(3)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 139A(d)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**)

Obligation on licensing authority to audit pharmacovigilance system

180.—(1) The licensing authority must perform a regular audit of its pharmacovigilance system **[**F516relating to medicinal products for sale or supply in Great Britain**]**F517....

[F518(1A) The licensing authority must perform a regular audit of its pharmacovigilance system relating to medicinal products for sale or supply in Northern Ireland and report the results of that audit to the European Commission.**]**

(2) The F519... audit referred to in paragraph (1) must be **[**F520performed**]**—

(a) on the first occasion no later than 21st September 2013; and

(b) every two years after the first occasion.

[F521(3) The results of the audit referred to in paragraph (1A) must be reported to the European Commission—

(a) on the first occasion no later than 21st September 2021;

(b) every two years after the first occasion.**]**

Textual Amendments

F516 Words in reg. 180(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(2)(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(a)(i)**)

F517 Words in reg. 180(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **140(2)(b)** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 109(a)(ii)); 2020 c. 1, Sch. 5 para. 1(1)

F518 Reg. 180(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(b)**)

F519 Words in reg. 180(2) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **140(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F520 Word in reg. 180(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **140(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F521 Reg. 180(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 140(4)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(c)**)

Delegation of obligations under this Part

181.—(1) The licensing authority may delegate any of its obligations under this Part **[**[F522]in connection with its pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland to an EEA State**]** where the conditions in paragraph (2) are met.

(2) The conditions in this paragraph are that the EEA State to whom the obligations are to be delegated—

(a) has given its written agreement to the delegation; and

(b) is not performing delegated obligations under this Part on behalf of another EEA State.

(3) Where the licensing authority has delegated any of its obligations under paragraph (1), it must—

(a) inform the European Commission, the EMA and all other EEA States in writing of the delegation as soon as is reasonably practicable; and

(b) make the delegation public as soon as is reasonably practicable.

(4) The licensing authority may agree to carry out any of the obligations of another EEA State under Title IX of the 2001 Directive on a delegated basis, but may carry out obligations under that Title only for one EEA State at any time.

Textual Amendments

F522 Words in reg. 181(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 141** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 110**)

Obligations on holders in relation to pharmacovigilance system

Obligation on holder to operate pharmacovigilance system

182.—(1) The holder must operate a pharmacovigilance system.

(2) The holder must (as part of its pharmacovigilance system)—

(a) have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance who resides and operates in the EU **[**[F523]or United Kingdom**]** and is responsible for the establishment and maintenance of the pharmacovigilance system;

(b) maintain and make available on the request of the licensing authority a pharmacovigilance system master file **[**[F524]and ensure it is permanently and immediately available for inspection electronically in the United Kingdom at the single point from which the reports referred to in regulation 187(4) are accessible**]**;

(c) operate a risk management system for the product in accordance with the risk management plan (if any) for the product (subject to regulation 183);

(d) monitor the outcome of the risk minimisation measures which are contained in the risk management plan (if any) for the product or which are laid down as conditions of the authorisation of the product under regulations 59 to 61 (conditions of UK marketing authorisation); and

(e) update the risk management system for the product and monitor pharmacovigilance data to determine whether in relation to the product—

(i) there are new risks,

(ii) risks have changed, or

(iii) there are changes to the risk-benefit balance.

[F525(2A) Where the person the holder has permanently and continuously at its disposal under paragraph (2)(a) ("the qualified person") does not reside and operate in the United Kingdom, the holder must nominate a contact person for pharmacovigilance at a national level who reports to the qualified person, resides and operates in the United Kingdom and has permanent access to the pharmacovigilance system master file.

(2B) Paragraph (2A) has effect from the day twelve months after IP completion day.**]**

[F526(3) Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation) the holder must keep the licensing authority informed at all times of the name and contact details of—

(a) the appropriately qualified person mentioned in paragraph (2)(a); and

(b) the nominated person mentioned in paragraph (2A).

(3A) The holder must—

(a) ensure that the pharmacovigilance system master file is accessible electronically from the single point within the United Kingdom from which the reports referred to in regulation 187(4) are accessible; and

(b) immediately notify the licensing authority of any change to the single point where the pharmacovigilance system master file may be accessed electronically.**]**

(4) The holder must use its pharmacovigilance system to—

(a) evaluate scientifically all information relevant to the product;

(b) consider options for minimising and preventing the risk presented by the use of the product; and

(c) take appropriate measures as soon as is reasonably practicable to—

(i) investigate the potential risks of the product,

(ii) communicate the risks, and

(iii) implement actions for minimising and preventing the risks, including updating the risk management system for the product.

(5) Where the licensing authority requests that the pharmacovigilance system master file is made available under paragraph (2)(b), the holder must submit a copy of the pharmacovigilance system master file to the licensing authority before the end of the period of 7 days beginning on the day after the day when the request was made.

F527(6) . . . . . .

Textual Amendments

F523 Words in reg. 182(2)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(a)**)

F524 Words in reg. 182(2)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**)

F525 Reg. 182(2A)(2B) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2B)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**)

F526 Reg. 182(3)(3A) substituted for reg. 182(3) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(c)**)

F527 Reg. 182(6) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **142(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Exception to obligation to operate risk management system

183.—(1) The holder is not required to operate a risk management system under regulation 182(2)(c) in relation to a medicinal product which has an authorisation or registration that was granted before 21st July 2012.

(2) The licensing authority may impose an obligation on the holder to operate a risk management system in relation to a medicinal product referred to in paragraph (1) if there are concerns about new or changed risks affecting the risk-benefit balance of that product.

(3) Paragraphs (4) to (6) apply where the licensing authority imposes an obligation to operate a risk management system on the holder under paragraph (2).

(4) The licensing authority must without delay notify the holder in writing of—

(a) the imposition of the obligation;

(b) the justification for the obligation;

(c) the timeframe for submission of the detailed description of the risk management system required under paragraph (8)(a); and

(d) the opportunity to present written observations in accordance with paragraph (5).

(5) Where the holder so requests before the end of the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (4), the licensing authority must provide the holder with an opportunity to present written observations in response to the imposition of the obligation within such a time limit as the licensing authority may specify.

(6) Where a holder presents written observations under paragraph (5), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (2), having regard to the written observations, as soon as is reasonably practicable.

(7) Paragraphs (8) and (9) apply where the licensing authority—

(a) imposes an obligation under paragraph (2) and the holder does not present written obligations under paragraph (5); or

(b) confirms the imposition of the obligation under paragraph (2) pursuant to paragraph (6).

(8) The holder must—

(a) submit to the licensing authority in writing a detailed description of the risk management system which it intends to introduce for the product in accordance with the timeframe set out in the notification under paragraph (4); and

(b) comply with the obligation to operate a risk management system.

(9) Where the imposition relates to a product with a UK marketing authorisation, the licensing authority must vary the authorisation to include the measures to be taken as part of the risk management system as conditions of the authorisation as if they were conditions imposed under regulation 59 (conditions of UK marketing authorisations: general).

Obligation on holder to audit pharmacovigilance system

184.—(1) The holder must—

(a) perform a regular audit of its pharmacovigilance system;

(b) place a note concerning the main findings of each audit on the pharmacovigilance system master file on completion of each audit; and

(c) ensure that an appropriate corrective action plan is prepared and implemented as soon as is reasonably practicable after completion of each audit.

(2) The holder may remove the note placed on the pharmacovigilance system master file under paragraph (1)(b) when all the measures in the corrective action plan under paragraph (1)(c) have been fully implemented.

[F528(3) The holder of a UKMA(GB) or THR(GB) must also comply with the requirements of paragraph 13 of Schedule 12A in relation to auditing the pharmacovigilance system.**]**

Textual Amendments

F528 Reg. 184(3) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **143** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 112**); 2020 c. 1, **Sch. 5 para. 1(1)**

Recording, reporting and assessment of pharmacovigilance data

Recording obligations on the licensing authority

185. The licensing authority must record all suspected adverse reactions to medicinal products that—

(a) occur in the United Kingdom; and

(b) are reported to it by **[**F529a holder,**]** a patient or a patient's carer, a health care professional, a coroner or a procurator fiscal.

Textual Amendments

F529 Words in reg. 185(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **144**; 2020 c. 1, Sch. 5 para. 1(1)

Reporting obligations on the licensing authority

186.—(1) The licensing authority must—

(a) when it receives a suspected adverse reaction report from a person mentioned in regulation 185(b), follow up the report with that person as appropriate;

(b) ensure that reports of suspected adverse reactions in the United Kingdom may be submitted to it, whether by the UK web-portal or by other means;

(c) collaborate with the EMA and the holders of authorisations or registrations in the detection of duplicates of suspected adverse reaction reports;

[F530(d) submit reports of serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

(i) a UKMA(NI),

(ii) a UKMA(UK),

(iii) a THR(NI),

(iv) a THR(UK), or

(v) an Article 126a authorisation,

to the EMA before the end of the period of 15 days beginning on the day following the day on which the report was received; and

(e) submit reports of non-serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

(i) a UKMA(NI),

(ii) a UKMA(UK),

(iii) a THR(NI),

(iv) a THR(UK), or

(v) an Article 126a authorisation,

to the EMA before the end of the period of 90 days beginning on the day following the day on which the report was received.**]**

(2) Paragraph (3) applies where the licensing authority has received a report of a suspected adverse reaction arising from an error associated with the use of a medicinal product.

(3) The licensing authority must (in addition to meeting the requirements in paragraph (1) in respect of the report) ensure that the report is made available to any statutory body with functions in relation to patient safety within the United Kingdom.

F531(4) . . . . . .

Textual Amendments

F530 Reg. 186(1)(d)(e) substituted (31.12.2020) by S.I. 2019/775, **reg. 145(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 113**)

F531 Reg. 186(4) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 145(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 113**)

[F532186A. The licensing authority must collaborate with the World Health Organisation in matters of pharmacovigilance, and must in particular—

(a) take the necessary steps to promptly submit to the World Health Organisation appropriate and adequate information regarding the measures taken in the United Kingdom which may have a bearing on public health protection in other countries; and

(b) make available promptly all suspected adverse reaction reports occurring in the United Kingdom to the World Health Organisation.**]**

Textual Amendments

F532 Reg. 186A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **146**; 2020 c. 1, Sch. 5 para. 1(1)

Recording obligations on holders

187.—(1) Subject to paragraph (2), the holder must record all suspected adverse reactions to the product **[**F533(including listed NIMAR products in Northern Ireland)**]** occurring **[**F534in the United Kingdom or another country**]** which are brought to its attention irrespective of whether the reaction—

(a) is reported spontaneously by patients or health care professionals; or

(b) occurred in the context of a post-authorisation study.

(2) Paragraph (1) does not apply where the suspected adverse reaction occurred in the context of a clinical trial within the meaning of the Clinical Trials Regulations.

(3) The holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(4) The holder must ensure that reports recorded under paragraph (1) are accessible (electronically or physically) at a single point within the **[**F535United Kingdom**]**.

Textual Amendments

F533 Words in reg. 187(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **15**

F534 Words in reg. 187(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 147(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 114**)

F535 Words in reg. 187(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **147(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Reporting obligations on holders

188.—(1) **[**F536The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation**]** must in relation to the product **[**F537(including listed NIMAR products in Northern Ireland)**]**—

(a) submit electronically to the **[**F538licensing authority**]** a report on all serious suspected adverse reactions that occur in the **[**F539United Kingdom**]** and **[**F540countries other than the United Kingdom**]** before the end of the period of 15 days beginning on the day following the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the **[**F538licensing authority**]** a report on all non-serious suspected adverse reactions that occur in the **[**F541United Kingdom**]** before the end of the period of 90 days beginning on the day following the day on which the holder gained knowledge of the reaction;

(c) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;

(d) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the **[**F538licensing authority**]** by way of an update to the original report within the specified time period; and

(e) collaborate with the **[**F542licensing authority**]** in the detection of duplicates of suspected adverse reaction reports.

[F543(1A) The holder of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation must, in relation to the product—

(a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the UK and other countries before the end of the period of 15 days beginning on the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the Eudraviligance database a report on all non-serious suspected adverse reactions that occur in an EEA State or Northern Ireland before the end of the

period of 90 days beginning on the day on which the holder gained knowledge of the reaction;

(c) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and

(d) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.**]**

(2) The holder **[**F544of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation**]** is not required to submit a report of a suspected adverse reaction to the product under **[**F545paragraph (1A)(a) or (b)**]**, or to provide follow-up information under **[**F546paragraph (1A)(c)**]**, where—

(a) the suspected adverse reaction relates to a medicinal product which contains a monitored active substance; and

(b) the suspected adverse reaction is recorded in a monitored publication.

(3) **[**F547Paragraph (4A)**]** applies to medicinal products containing a monitored active substance.

(4) The holder must—

(a) monitor medical literature F548... for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1).

[F549(4A) The holder of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation must—

(a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1A).**]**

(5) In this regulation—

F550...

F550...

"the specified time period" means—

(a) in the case of serious adverse reactions, the period of 15 days beginning on the day following the day on which the follow up information became known to the holder; and

(b) in the case of non-serious adverse reactions, the period of 90 days beginning on the day following the day on which the follow up information became known to the holder.

F551(6) . . . . . .

Textual Amendments

F536 Words in reg. 188(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 148(3)(za)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(a)**)

F537 Words in reg. 188(1) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **16**

F538 Words in reg. 188 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F539 Words in reg. 188(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F540 Words in reg. 188(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F541 Words in reg. 188(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F542 Words in reg. 188(1)(e) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F543 Reg. 188(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 148(3A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(b)**)

F544 Words in reg. 188(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 148(4)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**)

F545 Words in reg. 188(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 148(4)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**)

F546 Words in reg. 188(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 148(4)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**)

F547 Words in reg. 188(3) substituted (31.12.2020) by S.I. 2019/775, **reg. 148(4A)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**)

F548 Words in reg. 188(4)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F549 Reg. 188(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 148(5A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(d)**)

F550 Words in reg. 188(5) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(6)**; 2020 c. 1, Sch. 5 para. 1(1)

F551 Reg. 188(6) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **148(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Signal detection

Signal detection: licensing authority obligations

189.—(1) The licensing authority must in relation to each medicinal product—

(a) monitor the data **[**[F552]that it collects by virtue of operating its pharmacovigilance system under this Part**]** to determine whether there are any relevant changes;

(b) assess updates to the risk management system for the product;

(c) monitor the outcome of risk minimisation measures contained in the risk management plan (if any); and

(d) monitor the outcome of conditions imposed under **[**[F553]regulations 59, 60 and 61**]** (conditions of UK marketing authorisations) (if any).

(2) **[**[F554]In relation to medicinal products subject to a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the licensing**]** authority must collaborate with the EMA in carrying out its functions under paragraph (1).

(3) **[**[F555]In relation to medicinal products subject to a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the licensing**]** authority must inform the bodies specified in paragraph (4) without delay if it detects any relevant changes in relation to a medicinal product.

(4) The bodies specified in this paragraph are—

(a) the EMA; and

(b) the relevant competent authorities.

(5) In this regulation "relevant changes" in relation to a medicinal product means—

(a) new risks;

(b) risks that have changed; or

(c) changes to the risk-benefit balance.

Textual Amendments

F552 Words in reg. 189(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **149(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F553 Words in reg. 189(1)(d) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **149(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F554 Words in reg. 189(2) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 149(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 116**)

F555 Words in reg. 189(3) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 149(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 116**)

Signal detection: holder obligation

190.—**[**[F556](1) The holder must inform—

(a) the licensing authority, and

(b) in respect of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the EMA,

without delay if it detects any relevant changes in relation to the product.**]**

(2) In this regulation, "relevant changes" has the meaning given in regulation 189(5).

Textual Amendments

F556 Reg. 190(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 150** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 117**)

Periodic Safety Update Reports

Obligation on holder to submit periodic safety update reports: general requirements

191.—(1) The holder must submit reports known as periodic safety update reports ("PSURs") in relation to the product to the EMA **[**[F557]and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]** in accordance with this regulation, or in a case where paragraph (2) applies, in accordance with regulation 192.

(2) This paragraph applies to—

(a) a **[**F558UK**]** marketing authorisation granted pursuant to regulations 51 (applications for UK marketing authorisations relating to generic medicinal products) or 54 (application relating to products in well-established medicinal use); or

(b) a traditional herbal registration.

(3) In the following paragraphs of this regulation—

"authorisation" means a UK marketing authorisation or an Article 126a authorisation;

"the holder" means the holder of a UK marketing authorisation or an Article 126a authorisation; and

"product" means a product to which a UK marketing authorisation or Article 126a authorisation relates.

(4) Each PSUR must contain—

(a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the authorisation for the product;

(b) a scientific evaluation of the risk-benefit balance of the product; and

(c) all data relating to the volume of sales of the product and any data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the product.

[F559(4A) A PSUR in relation to a product authorised under a UKMA(GB) must also include the content, and be submitted in the format, specified in Part 8 of Schedule 12A.**]**

(5) For the purposes of paragraph (4)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation for the product.

(6) Each PSUR must be submitted electronically.

(7) PSURs must be submitted to the EMA **[**F560and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]** with the frequency and on the dates as set out in paragraphs (8) to (10).

(8) In the case of an authorisation granted on or after 21st July 2012, the holder must submit PSURs with the frequency as specified in the authorisation for the product, with the dates of submission being calculated from the date of authorisation.

[F561(8A) In the case of a conditional marketing authorisation in relation to a product authorised under a UKMA(GB), the holder must submit PSURs immediately upon the request of the licensing authority and at least every six months beginning with the date on which the authorisation for the medicinal product is granted or renewed by the licensing authority.**]**

(9) In the case of an authorisation granted before 21st July 2012 which specifies the frequency and dates of submission of PSURs, the holder must submit PSURs with the frequency and on the dates as specified in the authorisation for the product.

(10) In the case of an authorisation granted before 21st July 2012 which does not specify the frequency and dates of submission of PSURs, the holder must submit a PSUR—

(a) immediately upon the request of the licensing authority;

[F562(b) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has not yet been placed on the market within the EEA or Northern Ireland, at least every six months following authorisation until the placing on the market within the EEA or Northern Ireland, or

(ii) in relation to a product authorised under a UKMA(GB), the product has not yet been placed on the market in Great Britain, at least every six months following authorisation until the placing on the market within Great Britain; and**]**

[F563(c) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has been placed on the market within the EEA or Northern Ireland—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that;

(ii) in relation to a product authorised under a UKMA(GB), the product has been placed on the market in Great Britain—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that.**]**

F564(11) . . . . . .

Textual Amendments

F557 Words in reg. 191(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 151(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 118(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F558 Word in reg. 191(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **151(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F559 Reg. 191(4A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **151(5)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 118(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F560 Words in reg. 191(7) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 15** (1(2) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 118(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F561 Reg. 191(8A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **151(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 118(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F562 Reg. 191(10)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 151(7)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(e)**)

F563 Reg. 191(10)(c) substituted (31.12.2020) by S.I. 2019/775, **reg. 151(7)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(e)**)

F564 Reg. 191(11) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **151(8)**; 2020 c. 1, Sch. 5 para. 1(1)

[F565**Obligation on holder of a parallel import licence to submit periodic safety update reports**

191A.—(1) The holder of a parallel import licence must submit reports known as periodic safety update reports ("PSURs") to the licensing authority if notified to do so by the licensing authority.

(2) Each PSUR must contain—

(a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the licence for the product;

(b) a scientific evaluation of the risk-benefit balance of the product; and

(c) all data relating to the volume of sales of the product and any data the holder of the licence has relating to the volume of prescriptions, including an estimate of the population exposed to the product.

(3) For the purposes of paragraph (2)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation for the product.

(4) Each PSUR must be submitted electronically.

(5) The PSUR must be submitted to the licensing authority within the period specified by that authority.**]**

Textual Amendments

F565 Reg. 191A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **20** and reg. 191A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **20**

Obligation on holder to submit periodic safety update reports: derogation from general requirements

192.—(1) This regulation applies in relation to medicinal products granted—

(a) a **[**F566UK**]** marketing authorisation pursuant to regulations 51 (applications for UK marketing authorisations relating to generic medicinal products) or 54 (application relating to products in well-established medicinal use); or

(b) a traditional herbal registration.

(2) In the following paragraphs of this regulation—

"authorisation or registration" means a marketing authorisation to which paragraph (1)(a) applies or a traditional herbal registration;

"the holder" means the holder of a marketing authorisation to which paragraph (1)(a) applies or of a traditional herbal registration; and

"product" means a product to which a marketing authorisation referred to in paragraph (1)(a) or a traditional herbal registration relates.

(3) The holder must submit PSURs in relation to the product to the EMA **[**F567and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]** in accordance with paragraph (5)—

(a) where requested to do so by the licensing authority in accordance with paragraph (4); or

(b) in the case of a product to which paragraph (1)(a) applies, where it is a condition to which the marketing authorisation for the product is subject by virtue of regulations 59 (conditions of UK marketing authorisation: general) or 60 (conditions of UK marketing authorisation: exceptional circumstances) to do so.

(4) The licensing authority may request the holder to submit PSURs where—

(a) it has concerns relating to the product's pharmacovigilance data; or

(b) it considers there is a lack of PSUR data relating to an active substance of the product after the authorisation or registration is granted.

(5) The submission of PSURs under paragraph (3) must be in accordance with—

(a) where the PSUR is submitted pursuant to a request under paragraph (3)(a), the terms of the request; and

(b) where the PSUR is submitted pursuant to a condition under paragraph (3)(b), the terms of the condition.

(6) Each PSUR must contain—

(a) summaries of data relevant to the benefits and risks of the product, including results of all studies, with a consideration of their potential impact on the authorisation or registration for the product;

(b) a scientific evaluation of the risk-benefit balance of the product; and

(c) all data relating to the volume of sales of the product and any data the holder has relating to the volume of prescriptions, including an estimate of the population exposed to the product.

(7) For the purposes of paragraph (6)(b), the scientific evaluation must be based on all available data, including data from clinical trials conducted outside the terms of the authorisation or registration for the product.

(8) Each PSUR must be submitted electronically.

(9) Where the licensing authority requests submission of PSURs under paragraph (3)(a) **[**F568from the holder of a UKMA(UK), UKMA(NI), THR(UK), THR(NI) or Article 126a authorisation**]**, it must communicate a PSUR assessment report to the EMA as soon as is reasonably practicable after each report is received.

(10) In this regulation "PSUR assessment report" means a report which evaluates the information provided in a PSUR.

(11) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F566 Word in reg. 192(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **152(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F567 Words in reg. 192(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 152(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(a)**)

F568 Words in reg. 192(9) inserted (31.12.2020) by S.I. 2019/775, **reg. 152(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(b)**)

Harmonisation of PSUR frequency or date of submission

193.—**[**F569(1) Where products that are subject to different authorisations or registrations contain the same active substance or the same combination of active substances, the frequency and dates of submission may be amended and harmonised in accordance with—

(a) Article 107c(4) of the 2001 Directive, where—

(i) any of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation; and

(ii) none of the authorisations or registrations is a UKMA(GB) or THR(GB); or

(b) paragraphs (2A), (3) and (4A), where—

(i) any of the authorisations or registrations is a UKMA(GB) or THR(GB); and

(ii) none of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation.**]**

(2) The holder **[**F570of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]** may, where one or more of the grounds in paragraph (3) is met, submit a request in relation to the product to the EMA—

(a) to determine an EU reference date; or

(b) to change the frequency of submission of the PSUR.

[F571(2A) Where one or more of the grounds in paragraph (3) is met, the holder of a UKMA(GB) or THR(GB) may submit a request in writing to the licensing authority, or the licensing authority may in any event decide, to—

(a) determine a UK reference date from which submission dates are calculated in respect of products that fall under paragraph (1); or

(b) change the frequency and date of submission of the PSUR.**]**

(3) The grounds in this paragraph are—

(a) reasons relating to public health;

(b) in order to avoid duplication of the assessment; or

(c) in order to achieve international harmonisation.

(4) The second paragraph of Article 107c(6) of the 2001 Directive has effect in relation to the submission and determination of a request under paragraph (2).

[F572(4A) Where the licensing authority makes a decision under paragraph (2) following a written request from a holder of a UKMA(GB) or THR(GB), it must notify that holder in writing of its decision to approve or refuse the request.**]**

(5) Where the frequency or dates of submission of a PSUR are changed in accordance with Article 107c(4) or Article 107c(6) of the 2001 Directive **[**F573or paragraph (2A) (as the case may be)**]**, the holder must apply to vary the product's authorisation or registration to reflect the new frequency or date of submission before the end of the period of six months beginning on the day after the change is made public by the EMA **[**F574or licensing authority (as the case may be)**]**.

(6) In this regulation, "EU reference date" in relation to a product means—

(a) the date of the first marketing authorisation in the EEA of a medicinal product containing the same active substance or the same combination of active substances as that product; or

(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations in the EEA for a medicinal product containing the same active substance or the same combination of active substances as that product.

[F575(6A) Subject to paragraph (6B), in this regulation, "UK reference date" means a date determined by the licensing authority under paragraph (2)(a) in respect of medicinal products containing the same active substance or the same combination of active substances.

(6B) Until the licensing authority makes a decision under paragraph (2), any—

(a) Union reference date in respect of medicinal products containing the same active substance or the same combination of active substances; or

(b) date of submission and frequency of periodic safety reports in respect of such products,

published by the EMA under Article 107c(7) of the 2001 Directive, is deemed to be the UK reference date or, as the case may be, the required date or frequency of PSUR submission, in respect of those medicinal products.**]**

[F576(7) The licensing authority must publish a list of—

(a) UK reference dates it determines under paragraph (2); and

(b) the required date of submission and frequency for PSURs in respect of medicinal products containing the same active substance or the same combination of active substances.

(8) Any change to the date of submission and frequency of PSURs as a result of the application of this regulation is to take effect after a 6 month period, such period beginning with the day after the licensing authority publishes that change under paragraph (7).**]**

Textual Amendments

F569 Reg. 193(1) substituted (31.12.2020) by virtue of S.I. 2019/775, **reg. 153(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(a)**)

F570 Words in reg. 193(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(b)**)

F571 Reg. 193(2A) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F572 Reg. 193(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F573 Words in reg. 193(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(5)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(i)**)

F574 Words in reg. 193(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(5)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(ii)**)

F575 Reg. 193(6A)(6B) inserted (31.12.2020) by S.I. 2019/775, **reg. 153(6)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F576 Reg. 193(7)(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **153(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Responding to a single assessment of PSUR under Article 107e of the 2001 Directive

194.—(1) This regulation applies where PSURs relating to a medicinal product **[**[F577]authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]** have been assessed under the EU single assessment procedure.

(2) The licensing authority must implement—

(a) the necessary measures that are consequent upon any agreement reached under Article 107g(2) of the 2001 Directive as part of the EU single assessment process, in accordance with the implementation timetable determined in the agreement; or

(b) any decision adopted under Article 107g(4)(a) of the 2001 Directive before the end of the period of 30 days beginning on the day after the day on which the licensing authority received notification of the decision.

(3) Paragraph (4) applies where—

(a) an agreement reached under Article 107g(2) of the 2001 Directive requires a variation to be made to an authorisation or registration; and

(b) the terms of the agreement are known to the holder of that authorisation or registration.

(4) A holder of an authorisation or registration referred to in paragraph (3)(a) must submit to the licensing authority in accordance with the implementation timetable determined in the agreement an appropriate application for a variation, including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.

(5) In this regulation, "EU single assessment procedure" means the single assessment procedure laid down in Article 107e of the 2001 Directive, which covers—

(a) medicinal products that are authorised in more than one member State; and

(b) medicinal products that contain the same active substance or the same combination of active substances and for which a harmonised EU reference date and frequency of submission of PSURs have been established under Article 107c of the 2001 Directive.

Textual Amendments

F577 Words in reg. 194(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 154** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 121**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligation on licensing authority to assess PSURs [F578]...

195.—**[**[F579](A1) This regulation applies in the circumstances specified in paragraphs (1) and (1A).**]**

(1) This regulation applies where PSURs relating to a medicinal product **[**[F580]authorised for sale or supply authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]** have not been assessed under the EU single assessment procedure because—

[[F581](a) the medicinal product to which the PSUR relates—

(i) has not been authorised to be placed on the market in accordance with the 2001 Directive in an EEA State [F582]...; and

(ii) a harmonised EU reference date and frequency of submission of PSURs have not been established for that product under Article 107c of the 2001 Directive; or

(b) the medicinal product is one that is imported into the UK under a parallel import licence.**]**

[[F583](1A) This regulation applies where PSURs relating to a medicinal product authorised for sale or supply under a UKMA(GB) or THR(GB) have been submitted to the licensing authority under regulations 191 to 192.**]**

(2) The licensing authority must assess the PSURs to determine whether there are any relevant changes.

(3) Where the licensing authority has assessed a PSUR under paragraph (2) it must—

(a) consider whether any action concerning the authorisation or registration of the product to which the PSUR relates is necessary; and

(b) vary, suspend, or revoke the authorisation or registration as appropriate.

[[F584](3A) If the licensing authority considers under paragraph (3)(b) that an authorisation or registration needs to be varied, it may require the holder to submit to the licensing authority, within a time period that the licensing authority specifies, an application for a variation, including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.**]**

(4) In this regulation—

"EU reference date" has the meaning given in regulation 193(6);

"EU single assessment procedure" has the meaning given in regulation 194(5); and

"relevant changes" in relation to a medicinal product means—

(a) new risks,

(b) risks that have changed, or

(c) changes to the risk-benefit balance.

Textual Amendments

F578 Words in reg. 195 heading omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **155(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F579 Reg. 195(A1) inserted (31.12.2020) by S.I. 2019/775, **reg. 155(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(a)**)

F580 Words in reg. 195(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 155(2B)(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(a)**)

F581 Reg. 195(1)(a)(b) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **21** and reg. 195(1)(a)(b) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **21**

F582 Words in reg. 195(1)(a)(i) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 155(2B)(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(a)**)

F583 Reg. 195(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 155(3)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F584 Reg. 195(3A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **155(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Urgent action ***[****F585****and major safety review]***

Textual Amendments

F585 Words in reg. 196 cross-heading inserted (31.12.2020) by S.I. 2019/775, **reg. 156(ZA)(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**)

Urgent action

196.—[F586(1) **[**F587In the case of a medicinal product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, the licensing authority must inform**]** the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities,—

(a) it considers suspending or revoking an authorisation or registration of a medicinal product or class of medicinal products;

(b) it considers prohibiting the supply of a medicinal product or class of medicinal products;

(c) it considers refusing the renewal of an authorisation or registration of a medicinal product; or

(d) it is informed by a holder that, on the basis of safety concerns, the holder has—

(i) interrupted the sale or supply, or offer of sale or supply, of the product,

(ii) taken action to have the product's authorisation or registration cancelled or intends to do so, or

(iii) not applied for the renewal of the product's authorisation or registration.

(2) The licensing authority must inform the specified bodies where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, it considers it necessary to vary an authorisation or registration or a class of authorisations or registrations to include—

(a) a new contra-indication,

(b) a reduction to the recommended dose, or

(c) a restriction to the therapeutic indications.

(2A) The information provided under paragraph (2) must outline the action considered and the reasons for the action.

F588(2B) . . . . . .

(2C) The information required to be provided under paragraph (1) or (2) must be provided by the end of the day on which the consideration arose under paragraph (1)(a) to (c) or (2) or the information was received under paragraph (1)(d) (as the case may be).**]**

(3) When informing the EMA under paragraph **[**F589(1) or**]** (2), the licensing authority must make available to the EMA in relation to the medicinal product or class of medicinal products—

(a) all relevant scientific information at its disposal; and

(b) any assessment it has carried out.

F590(4) . . . . . .

F590(5) . . . . . .

F590(6) . . . . . .

F590(7) . . . . . .

[F591(8) In this regulation—

F592...

F592...

"specified bodies" means—

(a) the competent authority of each EEA State other than the United Kingdom,

(b) the EMA, and

(c) the European Commission.**]**

Textual Amendments

F586 Reg. 196(1)-(2C) substituted for reg. 196(1) (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **7(2)**

F587 Words in reg. 196(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 156(ZA)(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**)

F588 Reg. 196(2B) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 156(ZA)(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**)

F589 Words in reg. 196(3) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **7(3)**

F590 Reg. 196(4)-(7) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 156(ZA)(d)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**)

F591 Reg. 196(8) substituted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **7(7)**

F592 Words in reg. 196(8) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 156(ZA)(e)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**)

[F593Major safety review by the licensing authority

196A.—(1) The licensing authority may conduct a major safety review where—

(a) on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities it considers—

(i) suspending or revoking a UK marketing authorisation or traditional herbal registration of a medicinal product or in respect of a class of medicinal products,

(ii) prohibiting the supply of a medicinal product or a class of medicinal products,

(iii) refusing the renewal of a UK marketing authorisation or traditional herbal registration, or

(iv) action is necessary to vary a UK marketing authorisation or traditional herbal registration or a class of such authorisations or registrations, including to impose new conditions; or

(b) it is informed by a holder that, on the basis of safety concerns, the holder has—

(i) interrupted the sale or supply, or offer of sale or supply, of the product to which a UK marketing authorisation or traditional herbal registration relates,

(ii) taken action to have that product's authorisation or registration cancelled or intends to do so, or

(iii) not applied for the renewal of that product's authorisation or registration.

(2) If the licensing authority conducts a review under paragraph (1), it must—

(a) announce the initiation of that review on the UK web-portal as soon as reasonably practicable;

(b) include in that announcement—

(i) an outline of its reasons for conducting a major safety review, the medicinal products concerned and, where applicable, the active substances concerned, and

(ii) the proposed structure and time-scale of the review;

(c) notify a holder if the product to which that holder's authorisation or registration relates is within the scope of the review; and

(d) publish the outcome of that review, including any recommendations it is making, or action it is proposing to take, as soon as reasonably practicable after the conclusion of that review.

(3) A holder who is notified under paragraph (2)(c)—

(a) must provide to the licensing authority such information as the licensing authority notifies that holder it requires, within such time period as the licensing authority specifies; and

(b) may, where such information contains confidential data relevant to the subject matter of the review, because the data relates to a manufacturing process or trade secret, notify the licensing authority that that data is provided in confidence.

(4) Where the licensing authority proposes that action should be taken in respect of any UK marketing authorisation or traditional herbal registration—

(a) during the conduct of the major safety review, because urgent action is necessary to protect public health; or

(b) upon the conclusion of such a review,

it may exercise its powers under Part 5 or 7 (as the case may be) in relation to that authorisation or registration.**]**

Textual Amendments

F593 Reg. 196A inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **156** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 124**); 2020 c. 1, **Sch. 5 para. 1(1)**

EU urgent action procedure

197.—(1) Where the EU urgent action procedure is initiated in relation to a medicinal product or class of medicinal products **[**[F594]authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]**, the licensing authority—

(a) may publicly announce the initiation of the EU urgent action procedure on the UK web-portal; and

(b) must implement the measures set out in any agreement reached under Article 107k of the 2001 Directive in relation to the medicinal product or class of medicinal products in accordance with the implementation timetable determined in the agreement.

(2) Paragraph (3) applies where an agreement under Article 107k of the 2001 Directive in relation to a medicinal product or class of medicinal products requires a variation to be made to one or more authorisation or registration.

(3) Each holder of an authorisation or registration covered by the agreement referred to in paragraph (2) must submit to the licensing authority in accordance with the terms of the agreement (including its implementation timetable) an application for a variation in respect of the authorisation or registration including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.

(4) In this regulation, "EU urgent action procedure" has the same meaning as it is given in regulation 196(8).

Textual Amendments

F594 Words in reg. 197(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 157** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125**); 2020 c. 1, **Sch. 5 para. 1(1)**

Post-authorisation safety studies

Post-authorisation safety studies: general provisions

198.—(1) A relevant post-authorisation safety study—

(a) may not be conducted where the act of conducting the study promotes the use of a medicinal product; and

(b) may not provide for payments to health care professionals for participating in the study except in compensation for time and expenses incurred.

(2) The licensing authority may require the holder for the product which is the subject of a relevant post-authorisation safety study to submit the protocol and progress reports for the study to

[F595(a)**]** the competent authorities of the EEA States in which the study is conducted **[**F596and the licensing authority, where the product is subject to a marketing authorisation, traditional herbal registration or Article 126a authorisation for sale or supply in Northern Ireland;**]**

[F597(b) the licensing authority, where the product is subject to a marketing authorisation or traditional herbal registration for sale or supply in Great Britain only.**]**

(3) The holder for the product which is the subject of a relevant post-authorisation safety study must—

(a) comply with a requirement imposed by the licensing authority under paragraph (2) (if any);

(b) while the study is being conducted—

(i) monitor the data generated, and

(ii) consider its implications for the risk-benefit balance of the product which is the subject of the study;

(c) communicate to

[F598(i) the relevant competent authorities and the licensing authority, where paragraph (2)(a) applies;

(ii) the licensing authority where paragraph (2)(b) applies,**]**

[F599any new information that arises at any point during the study which might influence the evaluation of the risk-benefit balance for that product as soon as is reasonably practicable after it becomes known to the holder; and**]**

(d) send the final report on the study to

[F600(i) the competent authorities of the EEA States in which the study was conducted **[**F601and the licensing authority, where paragraph (2)(a) applies;**]]**

[F602(ii) the licensing authority, where paragraph (2)(b) applies,**]**

[F603before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended.**]**

(4) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F595 Words in reg. 198(2) renumbered as reg. 198(2)(a) (31.12.2020) by S.I. 2019/775, **reg. 158(2)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(a)**)

F596 Words in reg. 198(2)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 158(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(a)**)

F597 Reg. 198(2)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 158(2)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(a)**)

F598 Reg. 198(3)(c)(i)(ii) substituted for words in reg. 198(3)(c) (31.12.2020) by S.I. 2019/775, **reg. 158(3)(a)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(i)**)

F599 Words in reg. 198(3)(c) become full-out words (31.12.2020) by S.I. 2019/775, **reg. 158(3)(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(i)**)

F600 Words in reg. 198(3)(d) renumbered as reg. 198(3)(d)(i) (31.12.2020) by S.I. 2019/775, **reg. 158(3)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**)

F601 Words in reg. 198(3)(d)(i) inserted (31.12.2020) by S.I. 2019/775, **reg. 158(3)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**)

F602 Reg. 198(3)(d)(ii) inserted (31.12.2020) by S.I. 2019/775, **reg. 158(3)(b)(iii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**)

F603 Words in reg. 198(3)(d) become full-out words (31.12.2020) by S.I. 2019/775, **reg. 158(3)(b)(iv)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**)

Submission of draft study protocols for required studies

199.—(1) This regulation applies to a relevant post-authorisation safety study that is to be conducted pursuant to a condition of a UK marketing authorisation imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).

(2) The holder for the product which is the intended subject of the study must submit a draft protocol for the study **[**[F604]to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation is a UKMA(GB),

before the study is commenced.**]**

(3) The body specified in this paragraph is—

(a) where the study is to be conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a draft protocol is submitted **[**[F605]only**]** to the licensing authority under paragraphs (2) and (3)(a) **[**[F606](and is not submitted to the Pharmacovigilance Risk Assessment Committee)**]**.

(5) Where this paragraph applies, the licensing authority, before the end of the period of 60 days beginning on the day after the day on which the draft protocol is submitted, must issue—

(a) a letter endorsing the draft protocol;

(b) a letter objecting to the draft protocol on the grounds that—

(i) it considers that the conduct of the study promotes the use of a medicinal product, or

(ii) it considers that the design of the study does not fulfil the study objectives; or

(c) a letter notifying the holder for the product which is the intended subject of the study that the study is a clinical trial within the meaning of the Clinical Trials Regulations.

(6) A study may not commence unless a letter endorsing the draft protocol has been issued by—

(a) the licensing authority under paragraph (5)(a); or

(b) the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(7) Paragraph (8) applies where a letter endorsing the draft protocol has been issued by the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(8) Where this paragraph applies, the holder for the product which is the intended subject of the study must forward the protocol to the competent authorities of the EEA States in which the study is to be conducted before commencing the study.

(9) In this regulation, "a letter" includes email correspondence.

(10) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F604 Reg. 199(2)(a)(b) substituted for words in reg. 199(2) (31.12.2020) by S.I. 2019/775, **reg. 159(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(a)**)

F605 Word in reg. 199(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 159(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(b)**)

F606 Words in reg. 199(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 159(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(b)**)

Amendment to study protocols for required studies

200.—(1) This regulation applies where a study to which regulation 199 applies has been commenced.

(2) The holder for the product which is the subject of the study must submit any substantial amendments to the study protocol **[**[F607]to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB),

before their implementation.**]**

(3) The body specified in this paragraph is—

(a) where the study is being conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a proposed amendment to a study protocol is submitted **[**[F608]only**]** to the licensing authority under paragraphs (2) and (3)(a) **[**[F609](and is not submitted to the Pharmacovigilance Risk Assessment Committee)**]**.

(5) Where this paragraph applies, the licensing authority must as soon as is reasonably practicable—

(a) assess the amendment; and

(b) inform the holder of its endorsement of, or objection to, the proposed amendment.

(6) Paragraph (7) applies where the proposed amendment to a study protocol is submitted to the Pharmacovigilance Risk Assessment Committee under paragraphs (2) and (3)(b).

(7) Where this paragraph applies, the holder who submitted the amendment must inform the competent authorities of the EEA States in which the study is being conducted of any amendment to the study protocol approved by the Pharmacovigilance Risk Assessment Committee as soon as is reasonably practicable.

(8) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F607 Reg. 200(2)(a)(b) substituted for words in reg. 200(2) (31.12.2020) by S.I. 2019/775, **reg. 160(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(a)**)

F608 Word in reg. 200(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 160(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(b)**)

F609 Words in reg. 200(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 160(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(b)**)

Submission and evaluation of final study reports for required studies

201.—(1) This regulation applies where a study to which regulation 199 applies has been completed.

(2) Subject to paragraph (4), the holder for the product which is the subject of the study must submit electronically, before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended, **[**F610to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB),

a final study report and an abstract of the study results.**]**

(3) The body specified in this paragraph is—

(a) where the study was conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (2) does not apply where a written waiver has been granted by the licensing authority F611..., or by the Pharmacovigilance Risk Assessment Committee F611....

(5) The holder must without delay—

(a) evaluate whether the results of a final study report submitted under paragraph (2) have an impact on the authorisation or registration of the medicinal product to which the report relates; and

(b) if necessary, submit an application to vary the authorisation or registration for the product.

(6) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F610 Reg. 201(2)(a)(b) substituted for words in reg. 201(2) (31.12.2020) by S.I. 2019/775, **reg. 161(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(a)**)

F611 Words in reg. 201(4) omitted (31.12.2020) by S.I. 2019/775, **reg. 161(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Follow-up of final study reports

202.—(1) This regulation applies **[**F612in respect of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation**]** where—

(a) the Pharmacovigilance Risk Assessment Committee has made recommendations concerning an authorisation or registration or a class of authorisations or registrations based on a final study report under Article 107q(1) of the 2001 Directive; and

(b) an agreement on the action to be taken in respect of the authorisation or registration or the class of authorisations or registrations has been reached by the co-ordination group under the procedure laid out in Article 107q(2) of the 2001 Directive ("the agreement").

(2) The licensing authority must implement the measures set out in the agreement in accordance with the implementation timetable determined in the agreement.

(3) Paragraph (4) applies where—

(a) the agreement requires a variation to be made to one or more authorisation or registration; and

(b) the terms of the agreement are known to the holder or holders for the product or products which is, or which are, the subject of the agreement.

(4) Where this paragraph applies, each holder must submit to the licensing authority in accordance with the terms of the agreement (including its implementation timetable) an application for a variation including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.

(5) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F612 Words in reg. 202(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 162** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 130**)

[F613Medicinal products subject to additional monitoring

Textual Amendments

F613 Reg. 202A and cross-heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **163**; 2020 c. 1, Sch. 5 para. 1(1)

Licensing authority power in relation to medicinal products subject to additional monitoring

202A.—(1) The licensing authority may establish a list of medicinal products that are subject to additional monitoring.

(2) The list referred to in paragraph (1) is to include the names and active substances of—

(a) medicinal products authorised in the United Kingdom that contain a new active substance which, on 1st January 2011, was not contained in any medicinal product authorised in the United Kingdom;

(b) any biological medicinal product not covered by sub-paragraph (a) that was authorised in the United Kingdom after 1st January 2011;

(c) medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 50I, 59(2)(b) or (c), 60 or 61(4).

(3) If the licensing authority considers it appropriate, medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 59(2)(a), (d), (e) or (f), 61(5) or 183(2), may also be included in the list referred to in paragraph (1).

(4) For medicinal products included in the list referred to in paragraph (1)—

(a) the summary of product characteristics and the package leaflet must include a symbol and statement as follows: "▼ This medicinal product is subject to additional monitoring"; and

(b) that symbol must be proportional to the font of the subsequent standardised text, and each side of the triangle must have a minimum length of 5 millimetres.

(5) In the cases referred to in paragraph (2)(a) and (b), the licensing authority must, unless paragraph (6) applies, remove a medicinal product from the list after five years, beginning with the day after the UK reference date referred to in regulation 193.

(6) In the cases referred to in paragraph (2)(c) and (3), the licensing authority must remove a medicinal product from the list once the condition or obligation under a provision specified in those paragraphs has been fulfilled.

(7) Until the licensing authority publishes a list of medicinal products under paragraph (1), the reference to that list is instead to be read as a reference to the list referred to in Article 23 of Regulation (EC) No 726/2004, as that list may be amended from time to time.**]**

Transparency and communications

Obligations on licensing authority in relation to national medicines web-portal

203.—(1) The licensing authority must set up and maintain a national medicines web-portal ("the UK web-portal") [F614]...

(2) The licensing authority must make available publicly by means of the UK web-portal the following (at a minimum)—

(a) the assessment reports prepared or revised by the licensing authority under regulation 64(5) and (6) (duties of licensing authority in connection with determination), each with a summary;

(b) the summary of the product characteristics for the medicinal products concerned;

(c) the package leaflet for the medicinal products concerned;

(d) a summary of the risk management plan (if any) for the medicinal products concerned;

[[F615](da) the list published by the licensing authority under, or which applies by virtue of, regulation 202A;**]**

(e) the list of medicinal products that are subject to additional monitoring referred to in Article 23 of Regulation (EC) No 726/2004; and

(f) information on the different ways of reporting suspected adverse reactions to medicinal products to the licensing authority by patients or their carers, health care professionals, coroners or procurators fiscal (including by way of the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004).

Textual Amendments

F614 Words in reg. 203(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **164(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F615 Reg. 203(2)(da) inserted (31.12.2020) by S.I. 2019/775, **reg. 164(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 131**)

Obligation on licensing authority in relation to public announcements

204.—(1) This regulation applies where the licensing authority intends to make a public announcement relating to information on pharmacovigilance concerns **[**[F616]which relate to products authorised under a UKMA(NI) or UKMA(UK)**]**.

(2) Subject to paragraph (4), the licensing authority must inform the bodies specified in paragraph (3) not less than 24 hours prior to making the public announcement.

(3) The bodies specified in this paragraph are—

(a) the EMA;

(b) the European Commission; and

(c) the competent authority of each EEA State other than the United Kingdom.

(4) Paragraph (2) does not apply if the information in the announcement needs to be made public urgently for the protection of public health.

Textual Amendments

F616 Words in reg. 204(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 165** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132**); 2020 c. 1, **Sch. 5 para. 1(1)**

Obligations on holders in relation to public announcements

205.—(1) This regulation applies where the holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product.

(2) The holder must inform the bodies listed in paragraph (3) **[**[F617]where the product is subject to a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, or the licensing authority where the product is subject to a UKMA(GB) or THR(GB),**]** of its intention to make the public announcement—

(a) as soon as is practicable once it forms that intention; and

(b) in any event no later than at the same time as, or before, the public announcement is made.

(3) The bodies listed in this paragraph are—

(a) the licensing authority;

(b) the EMA; and

(c) the European Commission.

(4) The holder must ensure that the information in the public announcement—

(a) is presented objectively; and

(b) is not misleading.

Textual Amendments

F617 Words in reg. 205(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 166(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 133(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F618 Further obligations in respect of pharmacovigilance activities

Textual Amendments

F618 Reg. 205A and cross-heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **167** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 134**); 2020 c. 1, **Sch. 5 para. 1(1)**

Further obligations in respect of pharmacovigilance activities

205A.—(1) Schedule 12A applies in relation to medicinal products for sale or supply under a UKMA(GB) or THR(GB) and makes further provision as to the obligations of a holder and the licensing authority in respect of the performance of pharmacovigilance activities under this Part.

(2) The Secretary of State may by regulations in respect of Great Britain amend Schedule 12A.

(3) Regulations under paragraph (2) may make provision regarding the performance of pharmacovigilance activities under this Part as to—

(a) the content and maintenance of the pharmacovigilance system master file kept by the holder;

(b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the holder and the licensing authority;

(c) the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

(d) the minimum requirements for the monitoring of data recorded by the licensing authority pursuant to regulation 185 (recording obligations on the licensing authority) to determine whether there are new risks or whether risks have changed;

(e) the format and content of electronic transmission of suspected adverse reactions by a holder;

(f) the format and content of electronic periodic safety reports and risk management plans; and

(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.

[F619 Guidance in respect of pharmacovigilance

Textual Amendments

F619 Reg. 205B and cross-heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **169**; 2020 c. 1, Sch. 5 para. 1(1)

Guidance in respect of good pharmacovigilance practice and post authorisation efficacy studies

205B.—(1) The licensing authority may publish—

(a) guidance on good pharmacovigilance practices for both the licensing authority and UK marketing authorisation holders;

(b) scientific guidance on post authorisation efficacy studies.

(2) Subject to paragraph (3), the guidance issued by the Commission under Article 108a of the 2001 Directive on the matters specified in paragraph (1)(a) and (b) continues to apply until the date on which the licensing authority publishes guidance under paragraph (1).

(3) The licensing authority—

(a) may determine that provisions of the guidance specified in paragraph (2) no longer apply, or apply subject to specified modifications, from a date that it specifies; and

(b) must, if it so determines, publish its determination.

(4) Guidance published under paragraph (1), or which applies by virtue of paragraph (2) (as modified by any determination under paragraph (3), as the case may be), is to be taken into account in consideration of whether there has been any failure to comply with a provision in this Part, or Schedule 12A, to which the guidance is relevant.**]**

Enforcement

Infringement notices

206.—**[**F620(1) If an enforcement authority has objective grounds for considering that any person ("P") has contravened any relevant provision, it may serve upon P a notice in writing (referred to in this Part as an "infringement notice")—

(a) informing P of the authority's grounds for considering that P has contravened one or more relevant provision;

(b) specifying the relevant provision;

(c) specifying the measures which P must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;

(d) requiring P to take those measures, within such period as may be specified in the notice;

(e) specifying the further action (if any) that the enforcement authority may take.**]**

(2) An infringement notice may include directions as to the measures to be taken by P to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(3) If an enforcement authority serves an infringement notice in accordance with paragraph (1) **[**F621in relation to a product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI) or THR(UK)**]**, it shall as soon as is reasonably practicable inform—

(a) the EMA; and

(b) the European Commission.

[F622(4) In this regulation "relevant provision" means a provision of—

(a) this Part;

[Schedule 12A;**]**

F623(aa)

(b) Chapter 3 of Title II of Regulation (EC) No 726/2004; or

(c) the Implementing Regulation.**]**

Textual Amendments

F620 Reg. 206(1) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **23(2)**

F621 Words in reg. 206(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 170(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 135**)

F622 Reg. 206(4) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **23(3)**

F623 Reg. 206(4)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 170(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 135**)

Offences

207.—(1) A person is guilty of an offence if the person commits a breach of a provision in this Part, other than **[**F624Schedule 12A (further requirements in respect of pharmacovigilance activities) and**]** regulation 199(2) or (6) (submission of draft study protocols for required studies).

(2) A breach of a provision in this Part includes any—

(a) failure by a holder to comply with any requirement or obligation in this Part; or

(b) contravention by any person of any prohibition in this Part.

Textual Amendments

F624 Words in reg. 207(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **171**; 2020 c. 1, Sch. 5 para. 1(1)

False and misleading information

208. A person is guilty of an offence if the person provides information to the licensing authority or the EMA, pursuant to an obligation in this Part, but that information is false or misleading in a material particular.

Penalties

209.—(1) Subject to paragraph (2), a person guilty of an offence under regulation 207 or 208 is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(2) A person guilty of an offence under regulation 207 which relates to a breach of a provision listed in paragraph (3) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine.

(3) Those provisions are regulations—

(a) 182(2)(a) and (b), (3) and (5);

(b) 183(8)(a);

(c) 184(1)(a) and (b);

(d) 187(4);

(e) 188(1)(c) and (e);

(f) 193(5);

(g) 198(1) and (3)(a) and (d);

(h) 199(8); and

(i) 200(7).

Offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004

210.—(1) A person is guilty of an offence if the person—

(a) commits a breach of a provision of Regulation (EC) No 726/2004 listed in paragraph (3); or

(b) provides information which is false or misleading in a material particular to the licensing authority or the EMA pursuant to an obligation in Chapter 3 of Title II of Regulation (EC) No 726/2004.

(2) A breach of a provision listed in paragraph (3) includes any—

(a) failure to comply with any requirement or obligation contained in any of those provisions;

(b) contravention of any prohibition contained in any of those provisions; or

(c) failure to comply with any requirement imposed by the licensing authority or the EMA pursuant to any of those provisions.

(3) Those provisions are—

(a) Article **[**F625 16(3a)**]**, second paragraph[M36];

(b) Article 20(8)[M37];

(c) Article 21(1) and (2)[M38];

(d) Article 22[M39];

(e) Article 28(1), (2) and (5)[M40];

(f) Article 28a(3)[M41]; and

(g) Article 28b(1)[M42], except insofar as it imposes an obligation under Article 107n(1), or the first paragraph of Article 107n(3), of the 2001 Directive.

(4) Subject to paragraph (5), a person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(5) A person guilty of an offence under this regulation in relation to a provision of Regulation (EC) No 726/2004 listed in paragraph (6) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine.

(6) Those provisions are—

(a) Article **[**[F626]16(3a)**]**, second paragraph;

(b) Article 21(1) insofar as it relates to obligations set out in—

(i) the second paragraph of Article 104(2) of the 2001 Directive save the obligation regarding preparing and implementing a corrective action plan,

(ii) Article 104(3)(a) of the 2001 Directive,

(iii) Article 104(3)(b) of the 2001 Directive, or

(iv) the second paragraph of Article 104(3) of the 2001 Directive;

(c) Article 21(2) insofar as it relates to the obligation to submit a detailed description of a risk management system;

(d) Article 28(1) insofar as it relates to obligations set out in—

(i) the second paragraph of Article 107(1) of the 2001 Directive,

(ii) the first sentence of Article 107(4) of the 2001 Directive, or

(iii) Article 107(5) of the 2001 Directive;

(e) Article 28(2) insofar as it relates to the obligation set out in the third paragraph of Article 107c(4) of the 2001 Directive; and

(f) Article 28b(1) insofar as it relates to prohibitions or obligations set out in—

(i) Article 107m(3) to (6) of the 2001 Directive,

(ii) the second paragraph of Article 107n(3) of the 2001 Directive, or

(iii) the last sentence of Article 107o of the 2001 Directive.

(7) This regulation is subject to regulation 212 (transitional arrangements).

Textual Amendments

F625 Word in reg. 210(3)(a) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **24**

F626 Word in reg. 210(6)(a) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **24**

Marginal Citations

M36 Article 16(4), second paragraph, of Regulation (EC) No 726/2004 ("the Regulation") imposes an obligation identical to that set out in Article 23(4), second paragraph, of the 2001 Directive; Article 23(4), second paragraph, of the 2001 Directive is transposed at regulation 182(5).

M37 Article 20(8) of the Regulation applies Article 107i of the 2001 Directive, which in turn applies Articles 107j and 107k of the 2001 Directive; Article 107k(2) second paragraph is implemented in regulation 197(3).

M38 Article 21(1) of the Regulation, first paragraph, cross-refers to obligations set out in Article 104 of the 2001 Directive, implemented in regulation 182 and 185; Article 21(1), second paragraph, and 21(2) of the Regulation are similar in effect to Article 104a of the 2001 Directive, implemented in regulation 183.

M39 Article 22 of the Regulation cross-refers to obligations set out in Article 106a(1) of the 2001 Directive; Article 106a(1) is implemented in regulation 205.

M40 Article 28(1) and (2) of the Regulation cross-refers to obligations set out in Articles 107, 107a, 107b and 107c of the 2001 Directive; those Articles are implemented in regulations 185, 186, 187, 188,

191, 192 and 193; Article 28(5) of the Regulation applies Articles 107e to 107g of the 2001 Directive; Article 107g of the 2001 Directive is implemented in regulation 194.

M41 Article 28a(3) of the Regulation imposes an obligation identical to that set out in the first sentence of Article 107h(3) of the 2001 Directive; Article 107h(3) first sentence is implemented in regulation 190.

M42 Article 28b(1) of the Regulation cross-refers to prohibitions and obligations set out in Articles 107m, 107n, 107o, 107p and 107q of the 2001 Directive; those Articles are implemented in regulations 198, 199, 200, 201 and 202; Article 107n(1) and the first paragraph of Article 107n(3), implemented in regulation 199(2) and (6), are excluded as they are enforced otherwise than by way of criminal offence.

[F627Offences in relation to pharmacovigilance obligations under the Implementing Regulation [F628and Schedule 12A]

210A.—(1) A holder is guilty of an offence if the holder—

(a) **[**F629in relation to a UKMA(NI), UKMA(UK), THR(NI) THR(UK) or Article 126a authorisation,**]** fails to comply with any requirement or obligation contained in a provision of the Implementing Regulation listed in paragraph (2); or

[F630(aa) in relation to a UKMA(GB) or THR(GB), fails to comply with any requirement or obligation contained in a provision of Schedule 12A listed in paragraph (2A); or**]**

(b) provides information which is false or misleading in a material particular to the licensing authority or the EMA pursuant to an obligation in the Implementing Regulation.

(2) The provisions mentioned in paragraph (1)(a) are—

(a) Chapter I (pharmacovigilance system master file);

(b) Sections 1 and 2 of Chapter II (minimum requirements for the quality systems for the performance of pharmacovigilance activities);

(c) Chapter III (minimum requirements for the monitoring of data in the Eudravigilance database);

(d) Chapter V (transmission of reports of suspected adverse reactions);

(e) Article 32 of Chapter VI (updates of risk management plans);

(f) Chapter VII (periodic safety update reports); and

(g) Chapter VIII (post-authorisation safety studies).

[F631(2A) The provisions of Schedule 12A mentioned in paragraph (1)(a) are—

(a) Part 1 (pharmacovigilance system master file);

(b) Parts 2 and 3 (minimum requirements for the quality systems in the performance of pharmacovigilance activities);

(c) Part 6 (transmission of reports of suspected adverse reactions);

(d) paragraph 24 (update of risk management plans);

(e) Part 8 (periodic safety update reports); and

(f) Part 9 (post-authorisation safety studies).**]**

(3) Subject to paragraph (4), a person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine.

(4) A person guilty of an offence under this regulation which relates to a breach of Article 34(5) or 36(3) of the Implementing Regulation **[**F632, or of paragraph 26(8) or 29(1) of Schedule 12A,**]** is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.**]**

Textual Amendments

F627 Reg. 210A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **25**

F628 Words in reg. 210A heading inserted (31.12.2020) by S.I. 2019/775, **reg. 175(2)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(a)**)

F629 Words in reg. 210A(1)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 175(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(b)**)

F630 Reg. 210A(1)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 175(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(b)**)

F631 Reg. 210A(2A) inserted (31.12.2020) by S.I. 2019/775, **reg. 175(4)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)**)

F632 Words in reg. 210A(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 175(5)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(d)**)

Persons liable

211. If an offence under regulation 207(1) (offences) or regulation 210(1)(a) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Transitional arrangements

Transitional arrangements

212. Regulations F633... 198, 199, 200, 201, 202 and 210 are subject to the transitional provisions set out in Schedule 33 (transitional arrangements: pharmacovigilance).

Textual Amendments

F633 Words in reg. 212 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 177** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 139**)

PART 12

Dealings with medicinal products

Modifications etc. (not altering text)

C4 Pt. 12 modified (E.W.) (1.10.2015) by The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 (S.I. 2015/895), regs. 1(3), **4(2)**

CHAPTER 1

Interpretation

Interpretation

213.—(1) In this Part—

[F634"approved country health professional" means a person who is practising in a profession included in the list published under regulation 214(6A) in a country that is included in that list in relation to that profession;**]**

F635...

"the Common Services Agency" means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978 M43;

F636. . . . . .

"the dental care professionals register" means the register established and maintained under section 36B of the Dentists Act 1984 M44;

[F637"Council Directive 2005/36/EC" means Council Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications;**]**

F638...

F639. . . . . .

F640. . . . . .

"food" includes—

(a) beverages;

(b) confectionery;

(c) articles and substances used as ingredients in the preparation of food; and

(d) any manufactured substance—

(i) to which there has been added any vitamin, and

(ii) which is advertised as available and for sale to the general public as a dietary supplement;

"health authority" means—

(a) F641. . . . . .

(b) in relation to Wales, a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006 M45;

(c) in relation to Scotland, a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978 M46; and

(d) in relation to Northern Ireland, the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M47];

"health care" means services for or in connection with the prevention, diagnosis or treatment of disease;

"health prescription" means a prescription issued by a doctor, dentist, supplementary prescriber, nurse independent prescriber, optometrist independent prescriber, **[**[F642]pharmacist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**[F643], paramedic independent prescriber**]** or community practitioner nurse prescriber under—

(a) in England, the National Health Service Act 2006;

(b) in Wales, the National Health Service (Wales) Act 2006;

(c) in Scotland, the National Health Service (Scotland) Act 1978; and

(d) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972 [M48];

[F644] . . . . . .

"independent clinic"—

(a) in relation to England, means an establishment of either of the following kinds—

(i) a walk-in centre, in which one or more medical practitioners provides services of a kind which, if provided in pursuance of the National Health Services Act 2006, would be provided as primary medical services under Part 4 of that Act, or

(ii) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the National Health Services Act 2006 provides medical services of any kind (including psychiatric treatment), except where such medical services are provided only under arrangements made on behalf of the patients by—

(aa) their employer,

(bb) a government department or any executive agency of any government department,

(cc) a prison or other establishment in which patients are held under custody, other than pursuant to any provision under the Mental Health Act 1983 [M49], or

(dd) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

and where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they practise together;

(b) in relation to Wales, has the meaning given by section 2(4) of the Care Standards Act 2000 [M50];

(c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Service (Scotland) Act 1978 [M51]; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 [M52];

"independent hospital"—

(a) in relation to England, means a hospital as defined by section 275 of the National Health Service Act 2006 that is not a health service hospital as defined by that section;

(b) in relation to Wales, has the meaning given by section 2(2) of the Care Standards Act 2000;

(c) in relation to Scotland, has the meaning given by section 10F(2) of the National Health Act 1978; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

"independent medical agency"—

(a) in relation to England, means an undertaking (not being an independent hospital) which consists of or includes the provision of services by medical practitioners, and the term "undertaking" in this definition includes any business or profession and—

(i) in relation to a public or local authority includes the exercise of any functions of that authority, and

(ii) in relation to any other body of persons, whether corporate or unincorporated, includes any of the activities of that body;

(b) in relation to Wales, has the meaning given by section 2(5) of the Care Standards Act 2000;

(c) in relation to Scotland means an undertaking which is neither an independent clinic nor an undertaking comprised in a hospital and which consists of or includes the provision of services, other than in pursuance of the National Health Service (Scotland) Act 1978, by a medical practitioner; and

(d) in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

[[F645]"integrated care board" means an integrated care board established under Chapter A3 of Part 2 of the National Health Service Act 2006;**]**

[[F646]"local authority" has the same meaning as in section 2B of the National Health Service Act 2006;**]**

[[F647]"Maritime and Coastguard Agency" means the executive agency of that name of the Department for Transport;**]**

"maximum daily dose" or "MDD", in relation to a product for internal use, means the maximum quantity of the substance contained in the amount of the product that it is recommended should be taken or administered in any period of 24 hours;

"maximum dose" or "MD", in relation to a product for internal use, means the maximum quantity of the substance contained in the amount of the product that it is recommended should be taken or administered at any one time;

"NHS body" means—

(a) the Common Services Agency;

(b) a health authority;

(c) a special health authority;

(ca) **[**[F648]an integrated care board**]**;

(cb) **[**[F649]NHS England**]**;

(d) F650 . . . . . .

(e) an NHS trust; or

(f) an NHS foundation trust;

"NHS foundation trust" has the meaning given by section 30(1) of the National Health Service Act 2006;

"NHS trust"—

(a) in relation to England, means an NHS trust established under section 25(1) of the National Health Service Act 2006;

(b) in relation to Wales, means an NHS trust established under section 18(1) of the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, means an NHS trust established under section 12A of the National Health Service (Scotland) Act 1978 M53; and

(d) in relation to Northern Ireland, means a Health and Social Care trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991 M54;

"nursing home" has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 M55;

"parenteral administration" means administration by breach of the skin or mucous membrane;

"patient group direction" or "PGD" means a written direction that relates to the sale or supply and to the administration of a description or class of medicinal product and that—

(a) is signed—

(i) by a doctor or dentist and by a pharmacist, and

(ii) by any other person who may be required to sign it in the circumstances specified for its use in any provision of this Part; and

(b) relates to sale or supply and to administration to persons generally (subject to any exclusions that may be specified in the PGD);

F651 . . . . . .

"prison service" means—

(a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952 M56);

(b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989 M57); and

(c) in relation to Northern Ireland, the Department of Justice exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953 M58);

[F652"product subject to special medical prescription" means a prescription only medicine that has been designated as subject to special medical prescription in accordance with paragraph (3);**]**

[F653"Public Health Agency" means the Regional Agency for Public Health and Social Well-being established by section 12 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

"Public Health England" means the executive agency of that name of the Department of Health **[**F654and Social Care**]**;**]**

"registered chiropodist" means a person who is registered in Part 2 of the Health and Care Professions Council register;

"registered dental hygienist" means a person registered under that title in the dental care professionals register;

"registered dental therapist" means a person registered under that title in the dental care professionals register;

F655 . . . . . .

"registered dispensing optician" means a person whose name is entered in the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989 [M59] or the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b) [M60] of that Act;

"registered occupational therapist" means a person who is registered in Part 6 of the Health and Care Professions Council register;

"registered orthoptist" means a person who is registered in Part 7 of the Health and Care Professions Council register;

"registered orthotist and prosthetist" means a person who is registered in Part 10 of the Health and Care Professions Council register;

F656 . . . . . .

F657 . . . . . .

F658 . . . . . .

"registered provider"—

(a) in England, in relation to an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice means the person who is registered as a service provider under Chapter 2 of Part 1 of the Health and Social Care Act 2008 [M61] in respect of regulated activities (within the meaning of that Part) carried on in that hospital, clinic, agency, dental clinic or dental practice;

(b) in Wales, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under Part 2 of the Care Standards Act 2000 as the person who carries on the hospital, clinic or agency;

(c) in Scotland, in relation to an independent hospital, an independent clinic or an independent medical agency, means the person who is registered under section 10P of the National Health Service (Scotland) Act 1978 [M62]; and

(d) in Northern Ireland, in relation to an independent hospital, an independent clinic, a nursing home or an independent medical agency, means the person who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person who carries on the hospital, clinic, nursing home or agency;

F659 . . . . . .

"registered speech and language therapist" means a person who is registered in Part 12 of Health and Care Professions Council register;

"relevant manager"—

(a) in England, means—

(i) a person, other than the registered provider, who is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as the manager of an independent hospital, independent clinic, an independent medical agency, a dental clinic or a dental practice, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, agency, dental clinic or dental practice, that person;

(b) in Wales, means—

(i) a person, other than the registered provider, who is registered under Part 2 of the Care Standards Act 2000 as the manager of an independent hospital, an independent clinic or an independent medical agency, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic or agency, that person;

(c) in Scotland, means a person, other than the registered provider, who was identified as an individual who is to manage an independent hospital, an independent clinic or an independent medical agency on the application for registration of that clinic, hospital or agency under section 10P of the National Health Service (Scotland) Act 1978; and

(d) in Northern Ireland, means—

(i) a person, other than the registered provider, who is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of an independent hospital, an independent clinic, a nursing home or an independent medical agency, or

(ii) if there is no such person, but the registered provider has appointed a person to manage the hospital, clinic, nursing home or agency, that person;

"relevant prescriber" means any of the following—

(a) a doctor;

(b) a dentist;

(c) a supplementary prescriber;

(d) a nurse independent prescriber;

(e) a pharmacist independent prescriber;

(f) a community practitioner nurse prescriber;

(fa) **[**F660a physiotherapist independent prescriber;

(fb) a podiatrist independent prescriber;

(fc) a therapeutic radiographer independent prescriber;**]**

(fd) **[**F661a paramedic independent prescriber;**]**

(g) an optometrist independent prescriber; and

(h) an **[**F662approved country health professional**]**;

"repeatable prescription" means a prescription that contains a direction that it may be dispensed more than once;

[F663"school" means—

(a) a maintained school (as defined in section 20(7) of the School Standards and Framework Act 1998);

(b) a maintained nursery school (as defined in section 22(9) of the School Standards and Framework Act 1998);

(c) an independent school (as defined in section 463 of the Education Act 1996) entered on a register of independent schools kept under section 158 of the Education Act 2002;

(d) an independent educational institution (as defined in section 92(1) of the Education and Skills Act 2008) entered on a register of independent educational institutions kept under section 95 of that Act;

(e) a school approved under section 342 of the Education Act 1996 (non-maintained special schools);

(f) a pupil referral unit (as defined in section 19 of the Education Act 1996);

(g) an alternative provision Academy (as defined in section 1C(3) of the Academies Act 2010);

(h) a school as defined in section 135(1) of the Education (Scotland) Act 1980; and

(i) a school as defined in Article 2(2) of the Education and Libraries (Northern Ireland) Order 1986.**]**

"sell" means sell by retail (and "sale" has a corresponding meaning);

"special health authority" means—

(a) in relation to England, a Special Health Authority established under section 28 of the National Health Service Act 2006;

(b) in relation to Wales, a Special Health Authority established under section 22 of the National Health Service (Wales) Act 2006;

(c) in relation to Scotland, a Special Health Board constituted under section 2(1)(b) of the National Health Service (Scotland) Act 1978 [M63]; and

(d) in relation to Northern Ireland, a special health and social care agency established under Article 3 of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 [M64];

"supply" means supply in circumstances corresponding to retail sale;

"unit preparation" means a preparation, including a mother tincture, that—

(a) is prepared by a process of—

(i) solution,

(ii) extraction, or

(iii) trituration,

with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert dilutent; and

(b) is used—

(i) in that diluted form, or

(ii) where applicable, by impregnating tablets, granules, powders or other inert substances,

for the purpose of being administered to human beings.

(2) In this Part—

(a) a reference to a product being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a person includes a reference to it being supplied in accordance with such directions; and

(b) a reference to a product being sold or supplied for the purpose of being administered in accordance with a patient group direction includes a reference to it being supplied in accordance with a patient group direction.

[[F664](3) In this Part any substance or product for the time being specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002 is designated as a product subject to special medical prescription.**]**

Textual Amendments

F634 Words in reg. 213(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F635 Words in reg. 213(1) omitted (1.7.2022) by virtue of The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **57(2)(a)**

F636 Words in reg. 213(1) omitted (E.W.S.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(i)** and words in reg. 213(1) omitted (N.I.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(i)**

F637 Words in reg. 213(1) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(ii)** and words in reg. 213(1) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(ii)**

F638 Words in reg. 213(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F639 Words in reg. 213(1) omitted (E.W.S.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(iv)** and words in reg. 213(1) omitted (N.I.) (31.3.2014) by virtue of The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(iv)**

F640 Words in reg. 213(1) omitted (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **6** and words in reg. 213(1) omitted (N.I.) (1.10.2017) by virtue of The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **6**

F641 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(b)** (with Sch. 3 para. 28)

F642 Words in reg. 213(1) substituted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(a)** and words in reg. 213(1) substituted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(a)**

F643 Words in reg. 213(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(a)** and words in reg. 213(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(a)**

F644 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(c)** (with Sch. 3 para. 28)

F645 Words in reg. 213(1) inserted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **57(2)(b)**

F646 Words in reg. 213(1) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(d)** (with Sch. 3 para. 28)

F647 Words in reg. 213(1) inserted (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **3(2)(a)** and words in reg. 213(1) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **3(2)(a)**

F648 Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), **Sch. para. 1(1)(3)** (with Sch. para. 1(2))

F649 Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

F650 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(e)(ii)** (with Sch. 3 para. 28)

F651 Words in reg. 213(1) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(2)(f)** (with Sch. 3 para. 28)

F652 Words in reg. 213(1) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(a)(v)** and words in reg. 213(1) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(a)(v)**

F653 Words in reg. 213(1) inserted (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **3(2)(b)** and words in reg. 213(1) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **3(2)(b)**

F654 Words in reg. 213(1) inserted (11.4.2018) by The Secretaries of State for Health and Social Care and for Housing, Communities and Local Government and Transfer of Functions (Commonhold Land) Order 2018 (S.I. 2018/378), art. 1(2), **Sch. para. 20(w)** (with art. 14)

F655 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(b)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(b)**

F656 Words in reg. 213(1) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(b)** and words in reg. 213(1) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(b)**

F657 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(c)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(c)**

F658 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(d)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(d)**

F659 Words in reg. 213(1) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(e)** and words in reg. 213(1) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(e)**

F660 Words in reg. 213(1) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **8(2)(f)** and words in reg. 213(1) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **8(2)(f)**

F661 Words in reg. 213(1) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **5(2)(c)** and words in reg. 213(1) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **5(2)(c)**

F662 Words in reg. 213(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **179(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F663 Words in reg. 213(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **22(b)** and words in reg. 213(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **22(b)**

F664 Reg. 213(3) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **4(b)** and reg. 213(3) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **4(b)**

Marginal Citations

M43 1978 c.29. Section 10(1) was amended by the Health Services Act 1980 (1980 c.53), Schedule 6 paragraph 2. There are other amendments not relevant to these Regulations.

M44 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

M45 2006 c.42.

M46 1978 c.29. Section 2(1)(a) was amended by section 28(a)(i) of the National Health Service and Community Care Act 1990 (1990 c.19) and section 14(2) of, and paragraph 1 of Schedule 7 to, the Health and Social Services and Social Security Adjudications Act 1983 (1983 c.41).
M47 2009 c.1 (N.I.).
M48 S.I. 1972/1265 (N.I. 14).
M49 1983 c.20.
M50 2000 c.14.
M51 1978 c.29. Section 10F was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).
M52 S.I. 2003/431 (N.I. 9).
M53 1978 c.29. Section 12A was inserted by section 31 of the National Health Service and Community Care Act 1990 (1990 c.19), and amended by section 46(1)(a) of the Health Act 1999 (1999 c.8).
M54 S.I. 1991/194 (N.I. 1), Health and Social Services trusts were renamed Health and Social Care trusts by section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)). There are other amendments not relevant to this regulation.
M55 References to a nursing home in these Regulations concern Northern Ireland only.
M56 1952 c.52.
M57 1989 c.45.
M58 1953 c.18 (N.I.). Functions transferred by article 6(1) of, and Schedule 4 to, S.I. 2010/976.
M59 1989 c.44; section 7 was amended by S.I. 2005/848, articles 2 and 7(1).
M60 Section 8B was inserted by S.I. 2007/3101, regulations 178 and 180.
M61 2008 c.14.
M62 1978 c.29. Section 10P was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (2010 asp 8).
M63 Section 2(1)(b) was inserted by section 28(a) of the National Health Service and Community Care Act 1990 (1990 c.19).
M64 S.I. 1990/247 (N.I. 3). Special Health and Social Services Agencies were renamed Special Health and Social Care Agencies by section 1(4) of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I.)).

CHAPTER 2

Sale and supply of medicines

Prescription only medicines

Sale or supply of prescription only medicines

214.—(1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.

(2) A person may not parenterally administer (otherwise than to himself or herself) a prescription only medicine unless the person is—

(a) an appropriate practitioner other than an **[**F665approved country health professional**]**; or

(b) acting in accordance with the directions of such an appropriate practitioner.

(3) The following are appropriate practitioners in relation to any prescription only medicine—

(a) a doctor;

(b) a dentist;

(c) a supplementary prescriber;

(d) a nurse independent prescriber; and

(e) a pharmacist independent prescriber.

(4) A community practitioner nurse prescriber is an appropriate practitioner in relation to a prescription only medicine specified in Schedule 13.

(5) An optometrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine other than—

(a) a medicinal product that is a **[**F666product subject to special medical prescription**]**; or

(b) a medicinal product that is for parenteral administration.

[F667(5A) A podiatrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a **[**F668product subject to special medical prescription**]** other than—

(a) Dihydrocodeine: or

(b) Temazepam.

(5B) A physiotherapist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a **[**F669product subject to special medical prescription**]** other than—

(a) Dihydrocodeine;

(b) Fentanyl;

(c) Morphine;

(d) Oxycodone; or

(e) Temazepam.**]**

[F670(5C) A therapeutic radiographer independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a product subject to special medical prescription other than—

(a) Codeine;

(b) Fentanyl;

(c) Midazolam;

(d) Morphine;

(e) Oxycodone;

(f) Temazepam; or

(g) Tramadol.**]**

[F671(5D) A paramedic independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a product subject to special medical prescription other than—

(a) Codeine;

(b) Fentanyl;

(c) Midazolam; or

(d) Morphine.**]**

(6) An **[**F672approved country health professional**]** is an appropriate practitioner in relation to any prescription only medicine other than a **[**F673product subject to special medical prescription**]**.

[F674(6A) The licensing authority must publish a list of approved countries and professions for the purposes of the definition of "approved country health professional".

(6B) In order to determine whether a country or profession should be included in the list published under paragraph (6A), the licensing authority may, in particular, take into account—

(a) the country's standards of professional qualification;

(b) the country's system for ensuring that qualified professionals have undergone training which meets the requirements that apply in that country;

(c) the effectiveness of enforcement of professional standards;

(d) the mechanisms the country has in place to assist members of the public in obtaining information in respect of a qualified professional who is established there; and

(e) the regularity and rapidity of information provided by that country relating to non-compliant professionals.

(6C) The licensing authority must—

(a) review a country or profession it has included in the list published under paragraph (6A) to determine if it is still satisfied that they should remain on the list, and if it is not so satisfied, remove it from that list; and

(b) undertake such a review at least every 3 years beginning with the date on which that country or profession was included in that list.**]**

(7) This regulation is subject to Chapter 3 (exemptions).

Textual Amendments

F665 Words in reg. 214(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F666 Words in reg. 214(5)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F667 Reg. 214(5A)(5B) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **26**

F668 Words in reg. 214(5A) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5A) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F669 Words in reg. 214(5B) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(5B) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F670 Reg. 214(5C) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **9** and reg. 214(5C) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **9**

F671 Reg. 214(5D) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **6** and reg. 214(5D) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **6**

F672 Words in reg. 214(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F673 Words in reg. 214(6) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(a)** and words in reg. 214(6) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(a)**

F674 Reg. 214(6A)-(6C) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **180(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Prescribing and administration by supplementary prescribers

215.—(1) A supplementary prescriber ("S") may not give a prescription for a prescription only medicine unless S meets conditions A and C.

(2) A supplementary prescriber ("S") may not—

(a) parenterally administer a prescription only medicine; or

(b) give directions for the parenteral administration of a prescription only medicine,

unless S meets conditions B and C.

(3) Condition A is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is prescribed;

(b) has effect when the prescription is given; and

(c) includes the particulars specified in Schedule 14.

(4) Condition B is that S is acting in accordance with the terms of a clinical management plan that—

(a) relates to the patient to whom the product is, or is to be, administered;

(b) has effect when the product is administered or (as the case may be) the direction is given; and

(c) includes the particulars specified in Schedule 14.

(5) Condition C is that S has access to health records that—

(a) are the health records of the patient to whom the plan relates; and

(b) are used by any doctor or dentist who is a party to the plan.

(6) This regulation is subject to regulation 216.

(7) In this regulation—

"clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates;

(b) the doctor or dentist who is a party to the plan; and

(c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

"health record" has the meaning given by section 68(2) of the Data Protection Act 1998 [M65].

Marginal Citations

M65 1998 c.29.

Exceptions to regulation 215

216.—(1) Regulation 215 does not apply if—

(a) S is a community practitioner nurse prescriber; and

(b) the prescription only medicine prescribed or administered, or in respect of which S gives directions for administration, is specified in Schedule 13.

(2) Regulation 215(2) does not apply if S is acting in accordance with the directions of another person who is an appropriate practitioner (other than a supplementary prescriber or an **[**F675approved country health professional**]**) in relation to the prescription only medicine in question.

Textual Amendments

F675 Words in reg. 216(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **181**; 2020 c. 1, Sch. 5 para. 1(1)

Requirements for prescriptions: general

217.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner unless the following conditions are met.

(2) Condition A is that the prescription is signed in ink by the appropriate practitioner giving it.

(3) Condition B is that the prescription—

(a) is written in ink or otherwise so as to be indelible; or

(b) in the case of a health prescription which is not for a **[**F676product subject to special medical prescription**]**, is written as described in sub-paragraph (a) or by means of carbon paper or similar material.

(4) Condition C is that the prescription contains the following particulars—

(a) the address of the appropriate practitioner giving it;

(b) the appropriate date;

(c) an indication of the kind of appropriate practitioner giving it;

(d) the name and address of the person for whose treatment it is given; and

(e) if that person is under 12, that person's age.

(5) Condition D is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the appropriate date; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(6) Condition E is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions, or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the appropriate date.

(7) In this regulation "appropriate date" means, subject to paragraph (8)—

(a) in the case of a health prescription, whichever is the later of—

(i) the date on which it was signed by the appropriate practitioner giving it, or

(ii) a date indicated by the appropriate practitioner as the date before which it should not be dispensed; and

(b) otherwise, the date on which the prescription was signed by the appropriate practitioner giving it.

(8) This regulation—

(a) does not apply to a prescription given by an **[**F677approved country health professional**]** (as to which see regulation 218); and

(b) is subject to regulation 219 (electronic prescriptions).

Textual Amendments

F676 Words in reg. 217(3)(b) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(b)** and words in reg. 217(3)(b) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(b)**

F677 Words in reg. 217(8)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **182**; 2020 c. 1, Sch. 5 para. 1(1)

[F678**Requirements for prescriptions to be dispensed in an EEA state** F679**...**

217A.—(1) In this regulation—

"B" means a person who is an appropriate practitioner for the purposes of regulation 214(3) to (5B);

"P" means a person who is the patient of B.

(2) The information specified in paragraph (3) is to be included in any prescription where—

(a) P requests a prescription that is to be dispensed in an EEA state F680...; and

(b) B determines that such a prescription is appropriate.

(3) The specified information is—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) B's—

(i) surname,

(ii) first names written out in full,

(iii) professional qualification,

(iv) direct contact details including—

(aa) email address,

(bb) telephone or fax number with the appropriate international prefix,

(v) work address,

(vi) confirmation that B works as a health professional in the UK, and

(vii) electronic signature or a signature written in ink;

(d) details about the prescribed product, including where applicable the—

(i) common name of the product as defined by Article 1 of the 2001 Directive,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) B deems it medically necessary for that product to be dispensed and B's reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution, etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen.

(4) A prescription under this regulation may only be issued by B in relation to those products that B is authorised to prescribe under regulation 214(3) to (5B).**]**

Textual Amendments

F678 Reg. 217A inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **6** and reg. 217A inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **6**

F679 Words in reg. 217A heading omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **183(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F680 Words in reg. 217A(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **183(3)**; 2020 c. 1, Sch. 5 para. 1(1)

[F681Original pack dispensing

217B.—(1) Subject to paragraphs (2) to (4) and regulation 217C, for the purposes of this Part, the sale or supply of a prescription only medicine is in accordance with a prescription (and with the directions contained in the prescription) where—

(a) a different quantity is sold or supplied to that ordered on the prescription in order to allow for the sale or supply of the medicine in its manufacturer's original outer packaging; and

(b) the sale or supply is otherwise in accordance with the prescription.

(2) Paragraph (1) does not apply—

(a) to the sale or supply of a different quantity to that ordered on the prescription in circumstances where the different quantity is more than 10% greater or more than 10% less than the quantity ordered on the prescription; or

(b) in circumstances where a pharmacist is carrying out or supervising the sale or supply and the pharmacist considers, in the exercise of their professional skill and judgement, that the sale or supply of a different quantity to that ordered on the prescription may mean that the patient does not, or is not able to, follow the medication regimen as intended by the prescriber.

(3) Paragraph (2) does not apply to—

(a) a medicine in a form that makes it not practicable to dispense in the exact quantity ordered;

(b) a medicine in a container that has an integral means of application or from which it is not practicable to dispense an exact quantity;

(c) a medicine that cannot be dispensed in the quantity ordered without adversely affecting the medicine.

(4) Paragraphs (1) to (3) do not apply in relation to a supply of a prescription only medicine that is subject to—

(a) in England, paragraph 8(1)(b) of Schedule 4, or paragraph 6(1)(b) of Schedule 7, to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013,

(b) in Wales, paragraph 9(1)(b) of Schedule 5 to the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020,

until those Regulations expressly apply paragraphs (1) to (3) to those supplies.

Textual Amendments

F681 Regs. 217B, 217C inserted (E.W.S.) (11.10.2023) by The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 (S.I. 2023/1015), regs. 1(2), **2(2)**

Original pack dispensing: medicinal products containing a relevant substance

217C.—(1) Subject to paragraph (2) and for the purposes of this Part, the sale or supply of a prescription only medicine containing a relevant substance is not in accordance with a prescription unless—

(a) it is sold or supplied in its manufacturer's original outer packaging; and

(b) if the sale or supply is of a quantity that is different to the quantity which has been ordered on the prescription, it is sold or supplied in a quantity which is as close as possible to the quantity in which it has been ordered on the prescription.

(2) Paragraph (1) does not apply where—

(a) the sale or supply is by or under the supervision of a pharmacist; and

(b) the pharmacist is satisfied that—

(i) a risk assessment is in place that refers to the need for the patient to be sold or supplied the medicine containing a relevant substance in different packaging from its manufacturer's original outer packaging (for example in a monitored dosage system); and

(ii) unless the medicine containing a relevant substance is unauthorised (other than by reason of it being an authorised product that has ceased to be so as a result of a process of assembly), processes are in place to ensure the supply to or for the patient of the package leaflet.

(3) In this regulation, "relevant substance" means any of the following—

(a) sodium valproate;

(b) valproic acid;

(c) valproate semisodium.**]**

Textual Amendments

F681 Regs. 217B, 217C inserted (E.W.S.) (11.10.2023) by The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 (S.I. 2023/1015), regs. 1(2), **2(2)**

Requirements for prescriptions: [F682approved country health professional]

218.—(1) For the purposes of this Chapter, a prescription only medicine is not sold or supplied in accordance with a prescription given by an appropriate practitioner who is an **[**F683approved country health professional**]** unless the following conditions are met.

[F684(2) Condition A is that—

(a) the prescription is issued in a **[**F685country included in the list published under regulation 214(6A)**]**; and

(b) the prescribing **[**F683approved country health professional**]** is legally entitled to issue a prescription of that kind in the country in which the prescription is issued.**]**

[F686(3) Condition B is that the prescription is signed in ink by the prescribing **[**F683approved country health professional**].]**

(4) Condition C is that the prescription is written in ink or otherwise so as to be indelible.

[F687(5) Condition D is that the prescription contains—

(a) the patient's—

(i) surname,

(ii) first names written out in full, and

(iii) date of birth;

(b) the issue date of the prescription;

(c) the prescribing **[**F688approved country health professional's**]**—

(i) surname,

(ii) first names written out in full,

(iii) professional qualification,

(iv) direct contact details including—

(aa) email address, and

(bb) telephone or fax number with the appropriate international prefix,

(v) work address, and

(vi) name of the relevant member State in which that **[**F683approved country health professional**]** works; and

(d) details about the prescribed product, including where applicable the—

(i) common name of the product,

(ii) brand name if—

(aa) the prescribed product is a biological medicinal product, or

(bb) the prescribing **[**F683approved country health professional**]** deems it medically necessary for that product to be dispensed and the **[**F689approved country health professional's**]** reasons justifying the use of the branded product,

(iii) pharmaceutical formulation (tablet, solution, etc.),

(iv) quantity,

(v) strength of the medicinal product as defined in Article 1 of the 2001 Directive, and

(vi) dosage regimen.**]**

(6) Condition E is that the prescription—

(a) is not dispensed after the end of the period of six months beginning with the date on which it is signed by the **[**F683approved country health professional**]**; or

(b) in the case of a repeatable prescription—

(i) it is not dispensed for the first time after the end of that period, and

(ii) it is dispensed in accordance with the directions contained in the prescription.

(7) Condition F is that, in the case of a repeatable prescription that does not specify the number of times it may be dispensed—

(a) it is not dispensed on more than two occasions; or

(b) in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months beginning with the date on which it is signed by the **[**F683approved country health professional**]**.

(8) This regulation is subject to regulation **[**F690219A (electronic prescriptions: EEA health professionals)**]**.

Textual Amendments

F682 Words in reg. 218 heading substituted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(2)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F683 Words in reg. 218 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F684 Reg. 218(2) substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **23** and reg. 218(2) substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **23**

F685 Words in reg. 218(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F686 Reg. 218(3) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **7(3)** and reg. 218(3) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **7(3)**

F687 Reg. 218(5) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **7(4)** and reg. 218(5) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **7(4)**

F688 Words in reg. 218(5)(c) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F689 Words in reg. 218(5)(d)(ii)(bb) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **184(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F690 Words in reg. 218(8) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **3** and words in reg. 218(8) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **3**

Electronic prescriptions

219.—(1) This regulation applies to a prescription that is not a health prescription for a **[**F691substance or product for the time being specified in Schedule 1 to the Misuse of Drugs Regulations 2001 or in Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002**]**.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an appropriate practitioner other than an **[**F692approved country health professional**]** if—

(a) conditions A and B in regulation 217 are not met; but

(b) the conditions in paragraph (4) of this regulation and conditions C to E in regulation 217 are met.

F693(3) . . . . . .

(4) The conditions mentioned in **[**F694paragraph (2)(b)**]** are that the prescription is—

(a) created in electronic form;

[F695(b) signed with an advanced electronic signature; and

(c) sent to the person by whom it is dispensed—

(i) as an electronic communication (whether or not through one or more intermediaries), and

(ii) via the electronic prescription service, if it is for a substance or product for the time being specified in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001 or in Schedule 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002.**]**

[F696(5) In this regulation—

[F697"advanced electronic signature" has the meaning given within Article 3(11) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market;**]**

"electronic prescription service" means the service of that name which is managed by **[**F698NHS England, the body corporate established under section 1H of the National Health Service Act 2006.**]]**

Textual Amendments

F691 Words in reg. 219(1) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(2)** and words in reg. 219(1) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(2)**

F692 Words in reg. 219(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **185**; 2020 c. 1, Sch. 5 para. 1(1)

F693 Reg. 219(3) omitted (E.W.S.) (1.7.2015) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(3)** and reg. 219(3) omitted (N.I.) (1.7.2015) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(3)**

F694 Words in reg. 219(4) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(4)(a)** and words in reg. 219(4) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(4)(a)**

F695 Reg. 219(4)(b)(c) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(4)(b)** and reg. 219(4)(b)(c) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(4)(b)**

F696 Reg. 219(5) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **4(5)** and reg. 219(5) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **4(5)**

F697 Words in reg. 219(5) substituted (22.7.2016) by The Electronic Identification and Trust Services for Electronic Transactions Regulations 2016 (S.I. 2016/696), reg. 1, **Sch. 3 para. 8(2)**

F698 Words in reg. 219(5) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 44** (with reg. 3)

[F699Electronic Prescriptions: [F700approved country health professionals]

219A.—(1) This regulation applies to a prescription that is not a health prescription for a product subject to special medical prescription.

(2) A prescription only medicine is also sold or supplied in accordance with a prescription given by an **[**F701approved country health professional**]** if—

(a) conditions B and C in regulation 218 are not met; but

(b) the conditions in paragraph (3) of this regulation and conditions A and D to F in regulation 218 are met.

(3) The conditions mentioned in paragraph (2)(b) are that the prescription is—

(a) created in electronic form;

(b) signed with an electronic signature; and

(c) sent to the person by whom it is dispensed as an electronic communication (whether or not through one or more intermediaries).**]**

Textual Amendments

F699 Reg. 219A inserted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **5** and reg. 219A inserted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **5**

F700 Words in reg. 219A heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **186(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F701 Words in reg. 219A(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **186(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Medicines not subject to general sale

Sale or supply of medicinal products not subject to general sale

220.—(1) Unless paragraph (2) applies, a person ("P") may not sell or supply, or offer for sale or supply, a medicinal product that is not subject to general sale.

(2) This paragraph applies if—

(a) P is a person lawfully conducting a retail pharmacy business;

(b) the product is sold, supplied, or offered for sale or supply, on premises that are a registered pharmacy; and

(c) P or, if the transaction is carried out on P's behalf by another person, that other person is, or acts under the supervision of, a pharmacist.

(3) This regulation is subject to Chapter 3.

General sale medicines

Sale or supply of medicinal products subject to general sale

221.—(1) A person ("P") may not sell or supply, or offer for sale or supply, a medicinal product that is subject to general sale elsewhere than at a registered pharmacy unless the following conditions are met.

(2) Condition A is that the place at which the medicinal product is sold, supplied, or offered for sale or supply, consists of premises of which P is the occupier and which P is able to close so as to exclude the public.

(3) Condition B is that—

(a) the medicinal product was made up for sale in its immediate and outer packaging elsewhere than at the place at which it is sold, supplied, or offered for sale or supply; and

(b) the immediate and outer packaging has not been opened since the product was made up for sale in it.

(4) Condition C is that, if the medicinal product is of a kind specified in Schedule 15, it is presented for sale in accordance with the requirements specified in that Schedule for a product of that kind.

(5) This regulation is subject to Chapter 3.

Sale of medicinal products from automatic machines

222. A person may not sell or offer for sale a medicinal product by means of an automatic machine if the product is not subject to general sale.

CHAPTER 3

Exemptions

Exemptions relating to supply in specific circumstances

Exemptions for doctors and dentists etc

223.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a doctor or dentist to a patient of that doctor or dentist.

(2) Regulations 220 and 221 do not apply to the sale, offer for sale, or supply of a medicinal product by a doctor or dentist—

(a) to a patient of the doctor or dentist, or

(b) to a person under whose care such a patient is.

(3) Regulations 220 and 221 do not apply to the sale, offer for sale or supply of a medicinal product in the course of the business of a hospital or health centre, where—

(a) the product is sold, offered for sale or supplied for the purposes of being administered to a person (whether in the hospital or health centre or elsewhere) in accordance with directions relating to that person; and

(b) those directions have been given by—

(i) a doctor,

(ii) a dentist,

(iii) a supplementary prescriber,

(iv) a pharmacist independent prescriber,

(v) an optometrist independent prescriber,

[F702(vi) a nurse independent prescriber,

(vii) a community practitioner nurse prescriber,

(viii) a podiatrist independent prescriber, F703...

(ix) a physiotherapist independent prescriber**]**[F704]...

[[F705](x) a therapeutic radiographer independent prescriber**][**[F706], or

(xi) a paramedic independent prescriber.**]**

(4) Regulations 220 and 221 do not apply to the sale or supply of a medicinal product to which paragraph (5) applies where—

(a) the product is sold or supplied by a registered midwife in the course of the registered midwife's professional practice; or

(b) the product is delivered or administered by a registered midwife on being supplied the product under arrangements made by the Secretary of State or the Minister for Health, Social Services and Public Safety.

(5) The products to which this paragraph applies are—

(a) medicinal products that are not prescription only medicines;

(b) prescription only medicines which by virtue of an exemption conferred under regulation 235(1) and 235(3) and Part 1 of Schedule 17 may be sold or supplied by a registered midwife otherwise than in accordance with a prescription given by a doctor or a dentist; and

(c) prescription only medicines which by virtue of an exemption conferred under regulation 235(3) and Part 3 of Schedule 17 may be administered by a registered midwife or a student midwife otherwise than in accordance with a prescription given by a doctor or a dentist.

Textual Amendments

F702 Reg. 223(3)(b)(vi)-(ix) substituted for reg. 223(3)(b)(vi)(vii) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **27**

F703 Word in reg. 223(3)(b)(viii) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **10(2)(a)** and word in reg. 223(3)(b)(viii) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **10(2)(a)**

F704 Word in reg. 223(3)(b)(ix) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **7(2)(a)** and word in reg. 223(3)(b)(ix) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **7(2)(a)**

F705 Reg. 223(3)(b)(x) and preceding word inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **10(2)(b)** and reg. 223(3)(b)(x) and preceding word inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **10(2)(b)**

F706 Reg. 223(3)(b)(xi) and preceding word inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **7(2)(b)** and reg. 223(3)(b)(xi) and preceding word inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **7(2)(b)**

Emergency sale etc by pharmacist: prescriber unable to provide prescription

224.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A to E are met.

(2) Condition A is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a relevant prescriber who by reason of an emergency is unable to provide a prescription immediately.

(3) Condition B is that the relevant prescriber has undertaken to provide the person lawfully conducting the retail pharmacy business with a prescription within the period of 72 hours beginning with the sale or supply.

(4) Condition C is that the prescription only medicine is sold or supplied in accordance with the directions of the relevant prescriber.

(5) Condition D is that the prescription only medicine is not a **[**F707product subject to special medical prescription**]**, other than a prescription only medicine that—

(a) consists of or contains phenobarbital or phenobarbital sodium; and

(b) is sold or supplied for use in the treatment of epilepsy.

(6) Condition E is that an entry is made in the record kept under regulation 253 within the time specified in that regulation stating the particulars required under paragraph 2 of Schedule 23.

Textual Amendments

F707 Words in reg. 224(5) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(d)** and words in reg. 224(5) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(d)**

Emergency sale etc by pharmacist: at patient's request

225.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A to E are met.

(2) Condition A is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting it and is satisfied—

(a) that there is an immediate need for the prescription only medicine to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay;

(b) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person requesting it; and

(c) as to the dose which in the circumstances it would be appropriate for that person to take.

(3) Condition B is that for a prescription only medicine shown in column 1 of the following table, the quantity of the product that is sold or supplied does not exceed that shown in column 2 for that prescription only medicine—

Prescription only medicine	*Maximum quantity*
A prescription only medicine that— (a) is a preparation of insulin, an aerosol for the relief of asthma, an ointment or cream, and (b) has been made up for sale in a package elsewhere than at the place of sale or supply.	The smallest pack that the pharmacist has available for sale or supply.
An oral contraceptive.	A quantity sufficient for a full treatment cycle.

An antibiotic for oral administration in liquid form.	The smallest quantity that will provide a full course of treatment.
A controlled drug within the meaning of Schedule 4 or 5 of the Misuse of Drugs Regulations 2001 or Schedule 4 or 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	Five days' treatment.
Any other prescription only medicine.	30 days' treatment.

(4) Condition C is that the prescription only medicine—

(a) does not consist of or contain a substance specified in Schedule 18; and

(b) is not a **[**F708product subject to special medical prescription**]**, other than a prescription only medicine that—

(i) consists of or contains phenobarbital or phenobarbital sodium, and

(ii) is sold or supplied for use in the treatment of epilepsy.

(5) Condition D is that an entry is made in the record kept under regulation 253 within the time specified in that regulation stating the particulars required under paragraph 4 of Schedule 23.

(6) Condition E is that the inner or outer packaging of the prescription only medicine is labelled to show—

(a) the date on which the prescription only medicine is sold or supplied;

(b) the name, quantity and (unless apparent from the name) the pharmaceutical strength of the prescription only medicine;

(c) the name of the person requesting the prescription only medicine;

(d) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied; and

(e) the words "Emergency Supply".

(7) In this regulation "aerosol" means a product that is dispersed from its container by a propellant gas or liquid.

Textual Amendments

F708 Words in reg. 225(4)(b) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(e)** and words in reg. 225(4)(b) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(e)**

Emergency sale etc by pharmacist: pandemic diseases

226.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A and B are met.

(2) Condition A is that the supply is made whilst a disease is, or in anticipation of a disease being imminently,—

(a) pandemic; and

(b) a serious risk, or potentially a serious risk, to human health.

(3) Condition B is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied—

(a) that treatment with the prescription only medicine has on a previous occasion been prescribed by a relevant prescriber for the person to be treated with it; and

(b) as to the dose which in the circumstances it would be appropriate for that person to take.

[F709 Sale etc by a pharmacist in accordance with a serious shortage protocol

226A.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).

(3) Condition B is that the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the prescription only medicine may be sold or supplied for the purpose of being administered.

(4) Condition C is that the sale or supply of the prescription only medicine is by or under the supervision of a pharmacist who is of the opinion, in the exercise of his or her professional skill and judgement, that—

(a) in a case to which paragraph (5)(b)(i) applies, the sale or supply of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or

(b) in a case to which paragraph (5)(b)(ii) applies, the sale or supply of—

(i) a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and

(ii) the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

(a) is issued by the Ministers (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is, in the opinion of the Ministers (either of them forming the opinion alone or both of them forming the opinion jointly), experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—

(i) of a different strength, quantity or pharmaceutical form of the prescription only medicine to the strength, quantity or pharmaceutical form ordered by the prescriber, or

(ii) of a prescription only medicine other than the prescription only medicine ordered by the prescriber;

(c) provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—

(i) a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,

(ii) in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii) a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

(d) specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol issued under this regulation has effect, the Ministers must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F709 Reg. 226A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **9** and reg. 226A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **9**

Exemption for sale or supply in hospitals

227.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine—

(a) in the course of the business of a hospital; and

(b) for the purpose of being administered (in the hospital or elsewhere) to a particular person in accordance with directions that meet the conditions in paragraph (2).

(2) Those conditions are that the directions—

(a) are in writing;

(b) relate to the particular person to whom the prescription only medicine is to be administered; and

(c) are given by a person who is an appropriate practitioner in relation to that prescription only medicine.

(3) But such directions may be given by a supplementary prescriber only where the supplementary prescriber complies with regulations 215 (prescribing and administration by supplementary prescribers) and 216 (exceptions to regulation 215) in relation to the directions as if they were a prescription.

(4) This regulation applies regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

Exemptions relating to prescriptions given by certain health professionals

228.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist where—

(a) the sale or supply is in accordance with a prescription given by a person listed in paragraph (2) who is not an appropriate practitioner in relation to that prescription only medicine; but

(b) the pharmacist, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.

(2) Those persons are—

(a) another pharmacist;

(b) a registered nurse;

(c) a registered midwife;

(d) a person whose name is entered in the part of the Health and Care Professions Council register relating to—

(i) chiropodists and podiatrists,

(ii) physiotherapists, F710...

(iii) radiographers: diagnostic or therapeutic; or

[F711(iv) paramedics; or**]**

(e) a registered optometrist.

(3) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist where—

(a) the sale or supply is in accordance with a prescription given by a supplementary prescriber; and

(b) the pharmacist, having exercised all due diligence, believes on reasonable grounds that the supplementary prescriber has complied with regulation 215.

Textual Amendments

F710 Word in reg. 228(2)(d)(ii) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **8(2)(a)** and word in reg. 228(2)(d)(ii) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **8(2)(a)**

F711 Reg. 228(2)(d)(iv) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **8(2)(b)** and reg. 228(2)(d)(iv) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **8(2)(b)**

Exemption for supply by national health service bodies [F712and local authorities]

229.—(1) Regulations 214(1) **[**F713and (2)**]**, 220 and 221 do not apply to the supply of a medicinal product in accordance with condition A or B by—

(a) the Common Services Agency;

(b) a health authority or special health authority;

(c) an NHS trust;

(d) an NHS foundation trust;

[F714(da) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006); F715...**]**

[F716(db) Public Health England;

(dc) Public Health Agency; or**]**

F717(e) . . . . . .

(f) a person who is not a doctor, dentist or person lawfully conducting a retail pharmacy business, where the person supplies the product pursuant to an arrangement with

[F718**[**F648an integrated care board**]**, **[**F649NHS England**]** or**]** one of the persons specified in paragraphs (a) **[**F719to **[**F720(dc)**]]**.

(2) Condition A is that the product is supplied for the purpose of being administered to a person in accordance with the written directions of a doctor, dentist, nurse independent prescriber, optometrist independent prescriber **[**F721, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F722, paramedic independent prescriber**]** or pharmacist independent prescriber relating to that person, regardless of whether the directions comply with regulation 217 (requirements for prescriptions).

[F723(2A) In relation to a medicinal product that is for parenteral administration, condition A only applies if the person who has given the written directions is an appropriate practitioner in relation to that medicinal product.**]**

(3) Condition B is that—

(a) the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD");

(b) the PGD relates to the supply of a description or class of medicinal product by the person by whom the medicinal product is supplied and has effect at the time at which it is supplied;

(c) the PGD contains the particulars specified in Part 1 of Schedule 16;

(d) the PGD is signed on behalf of the person specified in column 2 of the table in Part 2 of that Schedule ("the authorising person") against the entry in column 1 of that table for the class of person by whom the product is supplied;

(e) the individual who supplies the product—

(i) belongs to one of the classes of individual specified in Part 4 of that Schedule, and

(ii) is designated in writing, on behalf of the authorising person, for the purpose of the supply or administration of products under the PGD; and

[F724(f) when the product is supplied **[**F725, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(i) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F726or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(ii) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

F727(4) . . . . . .

Textual Amendments

F648 Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), **Sch. para. 1(1)(3)** (with Sch. para. 1(2))

F649 Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

F712 Words in reg. 229 heading inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(a)** (with Sch. 3 para. 28)

F713 Words in reg. 229(1) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **5(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **5(a)**

F714 Reg. 229(1)(da) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(b)** (with Sch. 3 para. 28)

F715 Word in reg. 229(1)(da) omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(a)** and word in reg. 229(1)(da) omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(a)**

F716 Reg. 229(1)(db)(dc) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(b)** and reg. 229(1)(db)(dc) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(b)**

F717 Reg. 229(1)(e) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(c)** (with Sch. 3 para. 28)

F718 Words in reg. 229(1)(f) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(d)(i)** (with Sch. 3 para. 28)

F719 Words in reg. 229(1)(f) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(3)(d)(ii)** (with Sch. 3 para. 28)

F720 Word in reg. 229(1)(f) substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **4(2)(c)** and word in reg. 229(1)(f) substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **4(2)(c)**

F721 Words in reg. 229(2) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **11** and words in reg. 229(2) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **11**

F722 Words in reg. 229(2) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **9** and words in reg. 229(2) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **9**

F723 Reg. 229(2A) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **5(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **5(b)**

F724 Reg. 229(3)(f) substituted (31.12.2020) by S.I. 2019/775, **reg. 187** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 141**)

F725 Words in reg. 229(3)(f) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **5(c)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **5(c)**

F726 Words in reg. 229(3)(f)(i) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **17**

F727 Reg. 229(4) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **5**

Exemption for supply etc under a PGD to assist doctors or dentists

230.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product by an individual belonging to one of the classes specified in Part 4 of Schedule 16 where—

(a) the individual supplies or (as the case may be) administers the product to assist a doctor in the provision of NHS primary medical services or a dentist in the provision of NHS primary dental services;

(b) the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD"); and

(c) the following conditions are met.

(2) Condition A is that the PGD relates to the supply or (as the case may be) administration of a description or class of medicinal product in order to assist the doctor or dentist in providing the services (whether or not it relates to such supply in order to assist any other doctor or dentist).

(3) Condition B is that the PGD has effect at the time at which the product is supplied or (as the case may be) administered.

(4) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(5) Condition D is that the PGD is signed—

(a) by the doctor or dentist; or

(b) where it also relates to supply or administration to assist one or more other doctors or dentists, by one of those doctors or dentists.

(6) Condition E is that the PGD is signed—

(a) in the case of—

(i) NHS primary medical services, or

(ii) NHS primary dental services in England or Wales,

on behalf of the health authority**[**F728, local authority or National Health Service Commissioning Board**]** with which a contract or agreement for the provision of those services has been made or which provides those services;

(b) in the case of dental services in Scotland under the National Health Service (Scotland) Act 1978 M66, or general dental services in Northern Ireland, on behalf of the health authority with which an arrangement for the provision of those services has been made; and

(c) in the case of personal dental services provided under a pilot scheme in Scotland or Northern Ireland, on behalf of the health authority which is a party to the pilot scheme.

(7) Condition F is that the individual supplying the product is designated in writing for the purpose of the supply or (as the case may be) administration of medicinal products under the PGD—

(a) by the doctor or dentist; or

(b) where it also relates to supply to assist one or more other doctors or dentists, by one of those doctors or dentists.

[F729(8) Condition G is that when the product is supplied or (as the case may be) administered **[**F730, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F731or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F728 Words in reg. 230(6)(a) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(4)** (with Sch. 3 para. 28)

F729 Reg. 230(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 188** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 142**)

F730 Words in reg. 230(8) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **6** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **6**

F731 Words in reg. 230(8)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **18**

Marginal Citations

M66 1978 c.29.

Exemption for supply etc under a PGD by independent hospitals etc

231.—(1) Regulations 214, 220 and 221 do not apply to the sale or supply, or administration, of a medicinal product in accordance with the following conditions by—

(a) an independent hospital;

(b) an independent clinic;

(c) an independent medical agency; or

(d) a nursing home (in Northern Ireland).

(2) Condition A, which applies only to England, is that the registered provider at the hospital, clinic or agency is registered in compliance with section 10 of the Health and Social Care Act 2008 [M67] in respect of one or more of the following regulated activities [M68]—

(a) treatment of disease, disorder or injury;

(b) assessment or medical treatment of persons detained under the Mental Health Act 1983;

(c) surgical procedures;

(d) diagnostic and screening procedures;

(e) maternity and midwifery services; and

(f) family planning.

(3) Condition B is that the product is sold or supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition C is that the PGD—

(a) relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person by whom the medicinal product is sold or supplied or administered; and

(b) has effect at the time at which it is sold or supplied.

(5) Condition D is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(6) Condition E is that the PGD is signed—

(a) by or on behalf of the registered provider; and

(b) if there is a relevant manager for the independent hospital, clinic or medical agency, or nursing home, by that manager.

(7) Condition F is that the individual who sells or supplies or (as the case may be) administers the product—

(a) belongs to one of the classes of individual specified in Part 4 of Schedule 16; and

(b) is designated in writing for the purpose of the sale or supply or (as the case may be) administration of products under the PGD—

(i) by or on behalf of the registered provider, or

(ii) if there is a relevant manager for the independent hospital, clinic or medical agency, or nursing home, by that manager.

[F732(8) Condition G is that when the product is supplied **[**F733, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK) **[**F734or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F732 Reg. 231(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 189** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 143**)

F733 Words in reg. 231(8) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **7** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **7**

F734 Words in reg. 231(8)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **19**

Marginal Citations

M67 2008 c.14.

M68 Regulated activities for the purposes of section 10 are defined in section 8 of that Act and set out in regulation 3 of, and Schedule 1 to, S.I. 2010/781.

Exemption for supply etc under a PGD by dental practices and clinics: England and Wales

232.—(1) Regulations 214, 220 and 221 do not apply to the sale or supply, or administration, of a medicinal product in accordance with the following conditions by—

(a) a dental practice in England and Wales to which paragraph (2) applies; or

(b) a dental clinic in England and Wales to which paragraph (2) applies.

(2) This paragraph applies to a dental practice or dental clinic —

(a) in England, in respect of which the registered provider is registered in compliance with section 10 of the Health and Social Care Act 2008 in respect of one or both of the following regulated activities—

(i) treatment of disease, disorder or injury, or

(ii) diagnostic and screening procedures;

(b) in Wales, in which dental services are provided by private dentists and those dentists are registered with Healthcare Inspectorate Wales in accordance with the Private Dentistry (Wales) Regulations 2008 [M69], in relation to the services provided by those dentists.

(3) Condition A is that the product is sold or supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition B is that the PGD—

(a) relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person by whom the medicinal product is sold or supplied or administered; and

(b) has effect at the time at which it is sold or supplied.

(5) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(6) Condition D is that the PGD is signed—

(a) in England—

(i) by or on behalf of the registered provider, and

(ii) if there is a relevant manager for the practice or clinic, by that manager;

(b) in Wales—

(i) by the private dentist who is treating the person, and

(ii) if there is a manager for the practice or clinic, by that manager.

(7) Condition E is that the individual who sells or supplies or (as the case may be) administers the product—

(a) belongs to one of the classes of individual specified in Part 4 of Schedule 16; and

(b) is designated in writing for the purpose of the sale or supply or (as the case may be) administration of products under the PGD—

(i) in England—

(aa) by or on behalf of the registered provider, or

(bb) if there is a relevant manager for the practice or clinic, by that manager, or

(ii) in Wales, by the private dentist who is treating the person.

[[F735](8) Condition F is that when the product is supplied, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK) is in force in relation to it.**]**

(9) In relation to Wales, in this regulation "manager" means—

(a) a person who carries on the dental practice or dental clinic; or

(b) if there is no such person, a person who manages the practice or clinic.

Textual Amendments

F735 Reg. 232(8) substituted (31.12.2020) by S.I. 2019/775, **reg. 190** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 144**)

Marginal Citations

M69 2008 No. 1976 (W. 185).

Exemption for supply etc under a PGD by person conducting a retail pharmacy business

233.—(1) Regulation 214 does not apply to the sale or supply, or administration, of a prescription only medicine by a person lawfully conducting a retail pharmacy business where—

(a) the person sells, supplies or (as the case may be) administers the prescription only medicine pursuant to an arrangement for the supply or administration of prescription only medicines with—

(i) the Common Services Agency,

(ii) a health authority or special health authority,

(iii) an NHS trust,

(iv) an NHS foundation trust,

[F736(iva) **[**F648an integrated care board**]**,

(ivb) **[**F649NHS England**]**,

(ivc) a local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006),**]**

[F737(ivd) Public Health England,

(ive) Public Health Agency,**]**

F738(v) . . . . . .

(vi) a police force in England, Wales or Scotland,

(vii) the Police Service of Northern Ireland,

(viii) a prison service,

(ix) Her Majesty's Forces, or

(x) an authority or person carrying on the business of an independent hospital, an independent clinic, an independent medical agency or, in Northern Ireland, a nursing home;

(b) the prescription only medicine is sold or supplied for the purpose of being supplied or (as the case may be) is administered to a person in accordance with a patient group direction ("PGD"); and

(c) the following conditions are met.

(2) Condition A is that the PGD relates to the sale or supply or (as the case may be) administration of a description or class of medicinal product by the person lawfully conducting a retail pharmacy business who sells or supplies or (as the case may be) administers the prescription only medicine.

(3) Condition B is that the PGD has effect at the time at which the prescription only medicine is sold or supplied or (as the case may be) administered.

(4) Condition C is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(5) Condition D is that the PGD is signed—

(a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) **[**F739to (ive) (health bodies), by or on behalf of the person specified in column 2 of Part 2 of Schedule 16 against the entry in column 1 for that body**]**;

(b) in the case of an arrangement with a police force in England, Wales or Scotland or with the Police Service of Northern Ireland—

(i) by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body, and

(ii) by a doctor who is not employed or engaged by, and does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;

(c) in the case of an arrangement with a prison service, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body;

(d) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for Her Majesty's Forces;

(e) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—

(i) by or on behalf of the registered provider, and

(ii) if there is a relevant manager for the establishment or agency in question, by that manager.

(6) Condition E is that, where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business, the person belongs to one of the classes of individual specified in Part 4 of Schedule 16 and is designated in writing for the purpose of the administration of medicinal products under the PGD—

(a) in the case of an arrangement with a body referred to in paragraph (1)(a)(i) to (v) (health bodies), on behalf of that body;

(b) in the case of an arrangement with a body referred to in paragraph (1)(a)(vi) to (ix) (a police force, the Police Service of Northern Ireland, a prison service and Her Majesty's Forces), by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for that body; and

(c) in the case of an arrangement with an authority or person referred to in paragraph (1)(a)(x) (independent hospitals etc)—

(i) by or on behalf of the registered provider, or

(ii) if there is a relevant manager for the establishment or agency in question, by that manager.

[[F740](7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered **[**[F741], either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK) **[**[F742]or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

[[F743](8) Regulation 220 does not apply to the supply, or administration, of a prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus where paragraph (1)(a) and (b) applies and conditions A to F are met.

[F744](9) . . . . . .**]**

Textual Amendments

F648 Words in Regulations substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), reg. 1(2), **Sch. para. 1(1)(3)** (with Sch. para. 1(2))

F649 Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

F736 Reg. 233(1)(a)(iva)-(ivc) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(5)(a)(i)** (with Sch. 3 para. 28)

F737 Reg. 233(1)(a)(ivd)(ive) inserted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **7(2)** and reg. 233(1)(a)(ivd)(ive) inserted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **7(2)**

F738 Reg. 233(1)(a)(v) omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(5)(a)(ii)** (with Sch. 3 para. 28)

F739 Words in reg. 233(5)(a) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **7(3)** and words in reg. 233(5)(a) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **7(3)**

F740 Reg. 233(7) substituted (31.12.2020) by S.I. 2019/775, reg. 191 (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 145**)

F741 Words in reg. 233(7) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **8(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **8(a)**

F742 Words in reg. 233(7)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **20**

F743 Reg. 233(8)(9) inserted (19.12.2020) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(2), **8(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(2), **8(b)**

F744 Reg. 233(9) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **6**

Exemption for supply etc of products under a PGD to assist the police etc

234.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product by an individual belonging to one of the classes specified in Part 4 of Schedule 16 in accordance with the following conditions.

(2) Condition A is that the individual supplies or (as the case may be) administers the product to assist the provision of health care by, on behalf of, or under arrangements made by, one of the following bodies ("the relevant body")—

(a) a police force in England and Wales or in Scotland;

(b) the Police Service of Northern Ireland;

[[F745](c) a prison service;

(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.**]**

(3) Condition B is that the product is supplied for the purpose of being administered to a person in accordance with a patient group direction ("PGD").

(4) Condition C is that the PGD relates to the supply or (as the case may be) the administration of a description or class of medicinal product to assist the provision of health care by, on behalf of, or under arrangements made by, the relevant body.

(5) Condition D is that the PGD has effect at the time at which the product is supplied or (as the case may be) administered.

(6) Condition E is that the PGD contains the particulars specified in Part 1 of Schedule 16 (but with the omission of paragraph 4 in the case of a PGD relating to administration only).

(7) Condition F is that the PGD is signed—

(a) by or on behalf of a person specified in column 2 of Part 3 of Schedule 16 against the entry in column 1 for the relevant body; and

(b) where the relevant body is a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland.

(8) Condition G is that the individual who supplies the product is designated in writing by or on behalf of the relevant body for the purpose of the supply or (as the case may be) the administration of medicinal products under the PGD.

[F746(9) Condition H is that when the product is supplied **[**F747, either an authorisation by the licensing authority on a temporary basis under regulation 174 or**]**—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), **[**F748or, in the case of a listed NIMAR product, a UKMA(UK) or UKMA(GB),**]** or

(b) in Great Britain, a UKMA(GB), UKMA(UK), certificate of registration, THR(GB) or THR(UK),

is in force in relation to it.**]**

Textual Amendments

F745 Reg. 234(2)(c)-(e) substituted for reg. 234(2)(c)(d) (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **5(2)** and reg. 234(2)(c)-(e) substituted for reg. 234(2)(c)(d) (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **5(2)**

F746 Reg. 234(9) substituted (31.12.2020) by S.I. 2019/775, **reg. 192** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 146**)

F747 Words in reg. 234(9) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **9** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **9**

F748 Words in reg. 234(9)(a) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **21**

Exemption for sale, supply or administration by certain persons

235.—(1) Regulation 214(1) does not apply to the sale or supply by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 1 of Schedule 17;

(b) the prescription only medicine is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(2) Regulation 214(1) does not apply to the supply by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 2 of Schedule 17;

(b) the prescription only medicine is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(3) Regulation 214(1) does not apply to the administration by a person of a prescription only medicine if—

(a) the person is listed in column 1 of Part 3 of Schedule 17;

(b) the product is a prescription only medicine for parenteral administration listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(4) Regulation 220 does not apply to the sale, supply or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 4 of Schedule 17;

(b) the product is a prescription only medicine or pharmacy medicine listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(5) Regulation 220 does not apply to the supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 5 of Schedule 17;

(b) the product is a prescription only medicine or pharmacy medicine listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(6) Regulation 221 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 4 of Schedule 17;

(b) the product is a medicinal product subject to general sale that is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

(7) Regulation 221 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the person is listed in column 1 of Part 5 of Schedule 17;

(b) the product is a medicinal product subject to general sale that is listed in the corresponding paragraph in column 2 of that Part; and

(c) the condition specified in the corresponding paragraph in column 3 of that Part is met.

F749(8) . . . . . .

Textual Amendments

F749 Reg. 235(8) omitted (31.3.2022) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022 (S.I. 2022/350), regs. 1(2), **7**

Exemptions in relation to specific kinds of product

Products consisting of or containing aloxiprin, aspirin or paracetamol

236. Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(e) of Schedule 1 (non-effervescent aloxiprin, aspirin or paracetamol) if the quantity of the product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.

Products consisting of or containing pseudoephedrine salts or ephedrine base or salts

237.—(1) Regulation 214(1) does not apply to a medicinal product that is a prescription only medicine by virtue of paragraph 1(f) of Schedule 1 (products consisting of or containing pseudoephedrine salts or ephedrine base or salts) if conditions A and B are met.

(2) Condition A is that the product is not sold or supplied at the same time as another medicinal product that consists of or contains—

(a) in the case of pseudoephedrine salts, ephedrine base or salts; or

(b) in the case of ephedrine base or salts, pseudoephedrine salts.

(3) Condition B is that the medicinal products sold or supplied to a person at any one time do not in total contain more than—

(a) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts; or

(b) in the case of ephedrine base or salts, 180mg ephedrine base or salts.

Administration of certain medicines in an emergency

238. Regulation 214(2) does not apply to the administration of a prescription only medicine specified in Schedule 19 where this is for the purpose of saving life in an emergency.

Administration of smallpox vaccine

239.—(1) Regulation 214(2) does not apply to the administration of smallpox vaccine if condition A or B is met.

(2) Condition A is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by—

(i) the Secretary of State,

(ii) the Scottish Ministers,

(iii) the Welsh Ministers,

(iv) the Department of Health, Social Services and Public Safety, or

(v) an NHS body; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.

(3) Condition B is that—

(a) the vaccine has been supplied by, on behalf of, or under arrangements made by, Her Majesty's Forces; and

(b) the vaccine is administered for the purpose of providing protection against smallpox virus to members of Her Majesty's Forces or other persons employed or engaged by them.

[F750Radioactive medicinal products

240.—(1) Regulation 214(2) does not apply to—

(a) a radioactive substance, administration of which results in a medical exposure; or

(b) any other prescription only medicine if it is being administered in connection with a medical exposure,

if Conditions A to E are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to—

(a) in England and Wales and Scotland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017 which apply to the exposure;

(b) in Northern Ireland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 which apply to the exposure.

(3) Condition B is that the medical exposure has been authorised by—

(a) an IRME practitioner; or

(b) where it is not practical for an IRME practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by an IRME practitioner.

(4) Condition C is that—

(a) in England and Wales and Scotland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.

(5) Condition D is that the prescription only medicine is not a product subject to special medical prescription.

(6) Condition E is that, in the case of a prescription only medicine that is not a radioactive substance, it is specified in the protocols referred to in paragraph (2).

(7) In this regulation—

"IRME practitioner" means—

(a) in relation to a medical exposure in England and Wales and Scotland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in relation to a medical exposure in Northern Ireland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"medical exposure" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;

"radioactive substance" has the same meaning—

(a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;

(b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.**]**

Textual Amendments

F750 Reg. 240 substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322), reg. 1, **Sch. 4 para. 2(3)** (as substituted (6.2.2018) by S.I. 2018/121, regs. 1(2), **2(4)(b)(ii)**)

Exemptions in respect of certain herbal remedies

241.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("A") of a herbal medicinal product if—

(a) the product does not contain a substance listed in Part 1 of Schedule 20;

(b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—

(i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and

(ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;

(c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and

(d) the product is for administration to a person ("B") and A has been requested by or on behalf of B and in B's presence to use A's judgment as to the treatment required.

(2) A reference in this regulation to a substance listed in either Part of Schedule 20 is a reference to a substance that is obtained from any botanical source listed in either Part.

Exemption for medicinal products at high dilution

242.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a **[**F751product subject to special medical prescription**]**;

(b) paragraph (2) applies to the medicinal product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million (6x);

(b) any substance that is listed in Part 1 of Schedule 21 where the unit preparation has been diluted to at least one part in a thousand (3x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

(3) Regulation 220 does not apply to the sale, supply, or offer for sale or supply by a person of a medicinal product if—

(a) the medicinal product is neither for parenteral administration nor a **[**F752product subject to special medical prescription**]**;

(b) paragraph (4) applies to the medicinal product; and

(c) the conditions in regulation 221 are met.

(4) This paragraph applies to a medicinal product that consists solely of one or more unit preparations of—

(a) any substance where the unit preparation has been diluted to at least one part in a million million (6c);

(b) any substance that is listed in Part 2 of Schedule 21 where the unit preparation has been diluted to at least one part in a million (6x); or

(c) any substance that—

(i) is the active substance of a medicine that is subject to general sale;

(ii) is listed in Part 3 of Schedule 21; or

(iii) in the case of a medicinal product for external use only, is listed in Part 4 of Schedule 21,

where the unit preparation has been diluted to at least one part in ten (1x).

Textual Amendments

F751 Words in reg. 242(1)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(g)** and words in reg. 242(1)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(g)**

F752 Words in reg. 242(3)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(g)** and words in reg. 242(3)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(g)**

Exemption for certain homoeopathic medicinal products

243.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) P has been requested by or on behalf of a particular person and in that person's presence to use P's own judgment as to the treatment required.

(2) Regulation 220 does not apply to the sale or supply, or offer for sale or supply by a person ("P") of a medicinal product if—

(a) a certificate of registration is in force in relation to the product;

(b) the product is not an excluded product; and

(c) the conditions in regulation 221 are met.

(3) In this regulation "excluded product" means a product that is promoted, recommended or marketed—

(a) for use as an anthelmintic;

(b) for parenteral administration;

(c) for use as eye drops;

(d) for use as an eye ointment;

(e) for use as an enema;

(f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum; or

(g) for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

Other exemptions

Exemption in cases involving another's default

244.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person if the person, having exercised all due diligence, believes on reasonable grounds that the product is not a prescription only medicine.

(2) Regulation 220 does not apply to the sale or supply, or offer for sale or supply of a medicinal product by a person if—

(a) the person, having exercised all due diligence, believes on reasonable grounds that the product is subject to general sale;

(b) that belief is due to the act or default of another person; and

(c) the conditions in regulation 221 are met in relation to the sale or supply, or offer for sale or supply of the product.

Exemption in case of forged prescription

245. Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription if the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

Exemption where requirements for prescriptions not met

246. Regulation 214(1) does not apply to the sale or supply of a prescription only medicine otherwise than in accordance with a prescription given by an appropriate practitioner if—

(a) the sale or supply is otherwise than in accordance with such a prescription because a condition in regulation 217, 218**[**F753, 219 or 219A**]** is not met; and

(b) the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that the condition is met.

Textual Amendments

F753 Words in reg. 246(a) substituted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **6** and words in reg. 246(a) substituted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **6**

Exemption for supply in the event or anticipation of pandemic disease

247.—(1) Regulations 214(1), 220 and 221 do not apply to the supply of a medicinal product that meets the following conditions.

(2) Condition A is that the supply is made whilst a disease is, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk, or potentially a serious risk, to human health.

(3) Condition B is that the supply is accordance with a protocol that—

(a) is approved by the Ministers **[**[F754]or an NHS body**]**;

(b) specifies **[**[F755]how the medicinal product is to be used for the prevention of or as a**]** treatment for the disease; and

(c) contains requirements as to the recording of—

(i) the name of the person who supplies the product to the person to be treated ("the patient") or to a person acting on the patient's behalf, and

(ii) evidence that the product was supplied to the patient or to a person acting on the patient's behalf.

[[F756](4) A function of the Ministers under this regulation may be exercised by either of them acting alone or both of them acting jointly (and the reference in this regulation to "the Ministers" is to be read accordingly).**]**

Textual Amendments

F754 Words in reg. 247(3)(a) substituted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(6)(a)** (with Sch. 3 para. 28)

F755 Words in reg. 247(3)(b) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **13** and words in reg. 247(3)(b) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **13**

F756 Reg. 247(4) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(6)(b)** (with Sch. 3 para. 28)

[[F757]Protocols relating to coronavirus and influenza vaccinations and immunisations

247A.—(1) Regulations 214, 220 and 221 do not apply to the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza virus (of any type) that meets the following conditions.

(2) Condition A is that the supply is made, or the medicinal product is administered, while a disease (which may be neither coronavirus disease nor influenza) is, or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially serious risk to human health.

(3) Condition B is that the supply or administration is in accordance with the requirements of a protocol that is approved by the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland.

(4) Condition C is that the protocol specifies (amongst other matters)—

(a) the classes of persons permitted to administer medicinal products under the protocol;

(b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer medicinal products under the protocol;

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers a medicinal product under the protocol; and

(d) requirements, where appropriate, for the supervision of a person who, on any particular occasion, administers a medicinal product under the protocol.

(5) Condition D is that when the medicine is supplied, there is in force in relation to it—

(a) an authorisation by the licensing authority on a temporary basis under regulation 174;

(b) before 1st January 2021, a marketing authorisation; or

(c) on and after 1st January 2021, a UK marketing authorisation **[**F758(including in Northern Ireland if supply is in accordance with regulation 167A)**]** or, in Northern Ireland, an EU marketing authorisation.

(6) As soon as is reasonably practical after the end of one year beginning on the day on which the first protocol approved under this regulation has effect, the Secretary of State must—

(a) review the operation of this regulation with a view to evaluating whether there have been any adverse consequences for the market in prescription only medicines or for patient safety as a consequence of the operation of this regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.**]**

Textual Amendments

F757 Reg. 247A inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **14** and reg. 247A inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **14**

F758 Words in reg. 247A(5)(c) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **22**

Exemption for certain collection and delivery arrangements

248.—(1) Regulations 220 and 221 do not apply to the supply of a medicinal product on premises that are not a registered pharmacy where the supply—

(a) is in accordance with a prescription issued by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber**[**F759, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F760, paramedic independent prescriber**]** or optometrist independent prescriber; and

(b) forms part of a collection and delivery arrangement used by a person who lawfully conducts a retail pharmacy business.

(2) In this regulation "collection and delivery arrangement" means an arrangement whereby a person may—

(a) take or send a prescription given by a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber**[**F761, physiotherapist independent prescriber, podiatrist independent prescriber, therapeutic radiographer independent prescriber**][**F762, paramedic

independent prescriber**]** or optometrist independent prescriber to premises other than a registered pharmacy and which are capable of being closed by the occupier to exclude the public; and

(b) collect or have collected on his or her behalf from such premises a medicinal product prepared or dispensed in accordance with such a prescription at a registered pharmacy by or under the supervision of a pharmacist.

Textual Amendments

F759 Words in reg. 248(1)(a) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **12(2)** and words in reg. 248(1)(a) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **12(2)**

F760 Words in reg. 248(1)(a) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **10(2)** and words in reg. 248(1)(a) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **10(2)**

F761 Words in reg. 248(2)(a) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **12(3)** and words in reg. 248(2)(a) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **12(3)**

F762 Words in reg. 248(2)(a) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **10(3)** and words in reg. 248(2)(a) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **10(3)**

CHAPTER 4

Miscellaneous provisions, offences and disqualification

Miscellaneous provisions

Restrictions on persons to be supplied with medicinal products

249.—(1) The holder of an authorisation of the kind referred to in paragraph (2) may not sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(2) Those authorisations are—

(a) a **[**F763UK**]** marketing authorisation;

[F764(aa) an EU marketing authorisation;**]**

(b) a certificate of registration;

(c) a traditional herbal registration; and

(d) an Article 126a authorisation.

(3) A person may not, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing, sell a prescription only medicine or a pharmacy medicine by way of wholesale dealing to a person who does not fall within a class specified in Schedule 22.

(4) This regulation is subject to regulation 250.

Textual Amendments

F763 Word in reg. 249(2)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **194(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F764 Reg. 249(2)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 194(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 148**)

Exceptions to regulation 249

250.—(1) This regulation makes provision for exceptions to regulation 249.

(2) A person may sell by way of wholesale dealing a pharmacy medicine which is for the purpose of being administered to human beings in the course of a business to any person carrying on such a business.

(3) A person may sell by way of wholesale dealing a pharmacy medicine to which a general sale exemption applies to any person who by virtue of that exemption may sell the pharmacy medicine by retail, or supply it in circumstances corresponding to retail sale, otherwise than by or under the supervision of a pharmacist.

(4) In paragraph (3) "general sale exemption" means an exemption from regulation 220 conferred by a provision of Chapter 3.

[[F765](4A) A person may, in the course of a business consisting (wholly or partly) of manufacturing medicinal products or of selling products by way of wholesale dealing, sell by way of wholesale dealing a prescription only medicine to any person who by virtue of regulation 247 or 247A may supply or administer that medicine in accordance with a protocol of the types mentioned in those regulations.**]**

(5) A person may sell by way of wholesale dealing to a person specified in column 1 of Parts 1 to 3 of Schedule 17 a prescription only medicine specified in relation to that person in column 2 of Parts 1 to 3 of that Schedule.

(6) A person may sell by way of wholesale dealing to a registered optometrist a product that is a prescription only medicine by reason only that it contains one or more of the following substances—

(a) amethocaine hydrochloride;

(b) lidocaine hydrochloride;

(c) oxybuprocaine hydrochloride; or

(d) proxymetacaine hydrochloride.

(7) A person may sell by way of wholesale dealing to an additional supply optometrist a product that is a prescription only medicine by reason only that it contains thymoxamine hydrochloride.

(8) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

(a) is required for use by a registered optometrist or doctor attending the optician's practice; and

(b) contains one or more of the following substances—

(i) amethocaine hydrochloride,

(ii) chloramphenicol,

(iii) cyclopentolate hydrochloride,

(iv) fusidic acid,

(v) lidocaine hydrochloride,

(vi) oxybuprocaine hydrochloride,

(vii) proxymetacaine hydrochloride, and

(viii) tropicamide.

(9) A person may sell by way of wholesale dealing to a registered dispensing optician a prescription only medicine that—

(a) is required for use by the optician in the course of a professional practice as a contact lens specialist; and

(b) contains one or more of the following substances—

(i) lidocaine hydrochloride,

(ii) oxybuprocaine hydrochloride, and

(iii) proxymetacaine hydrochloride.

(10) In this regulation—

"additional supply optometrist" means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;

"contact lens specialist" means a person who is a registered dispensing optician and against whose name particulars of the contact lens speciality have been entered in—

(a) the register of dispensing opticians maintained under section 7(b) of the Opticians Act 1989; or

(b) the register of visiting dispensing opticians from relevant European States maintained under section 8B(1)(b) of that Act.

Textual Amendments

F765 Reg. 250(4A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **15** and reg. 250(4A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349)

Compliance with standards specified in certain publications

251.—(1) A person may not sell a medicinal product that has been demanded by the purchaser by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(2) A person may not sell or supply a medicinal product in pursuance of a prescription given by a doctor or dentist in which the product required is described by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(3) A person may not sell or supply a medicinal product that has been offered or exposed for sale by, or by express reference to, a particular name if—

(a) the name is a name at the head of the relevant monograph; and

(b) the product does not comply with the standard specified in that monograph.

(4) If the particular name referred to in paragraph (1), (2) or (3) is that of an active ingredient of the product, the product does not comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with that standard.

(5) See regulation 252 for the meaning of certain expressions used in this regulation.

[F766(6) In paragraph (1), (2) or (3) a product is to be treated as complying with the standard specified in the relevant monograph where—

(a) the product complies with the standard specified in a relevant marketing authorisation for the product concerned, and

(b) the standard specified in that marketing authorisation does not comply with the standard specified in the relevant monograph.

(7) In paragraph (6), "relevant marketing authorisation" means—

(a) an EU marketing authorisation;

(b) an authorisation granted by the licencing authority under Chapter 4 of Title III to the 2001 Directive; or

(c) a UKMA(GB) granted under the unfettered access route.**]**

Textual Amendments

F766 Reg. 251(6)(7) inserted (31.12.2020) by S.I. 2019/775, **reg. 194A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 149**)

Compliance with standards specified in certain publications: supplementary

252.—(1) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular edition of a particular publication, "the relevant monograph" in that paragraph means—

(a) the monograph (if any) headed by the name in that edition; or

(b) if there is no such monograph, the appropriate current monograph (if any) headed by that name.

(2) Where, together with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, there was specified a particular publication, but not an edition of that publication, "the relevant monograph" in that paragraph means—

(a) the monograph (if any) headed by the name in the current edition; or

(b) if there is no monograph of the kind mentioned in sub-paragraph (a), the appropriate current monograph (if any) headed by that name; or

(c) if there is no monograph of the kinds mentioned in sub-paragraphs (a) or (b), the monograph headed by that name in the latest edition of the specified publication that contained a monograph headed by that name.

(3) Where no publication was specified with the particular name specified as described in paragraph (1), (2) or (3) of regulation 251, "the relevant monograph" in that paragraph means the appropriate current monograph (if any).

(4) In this regulation "publication" means—

(a) the British Pharmacopoeia; or

(b) a compendium published under Part 15 (British Pharmacopoeia).

(5) In this regulation "current" means current at the time when the medicinal product is demanded, described in a prescription or offered or exposed for sale (as the case may be).

(6) In this regulation "the appropriate current monograph", in relation to a particular name, means—

(a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia; or

(b) if there is no such monograph, the monograph (if any) headed by that name in the current edition of a compendium published under Part 15 (British Pharmacopoeia).

(7) For the purposes of regulation 251 and this regulation, any monograph in an edition of a publication must be construed in accordance with any general monograph or notice, or any appendix, note or other explanatory material, that is contained in that edition and applies to that monograph.

Pharmacy records

253.—(1) A person lawfully conducting a retail pharmacy business must, in respect of every sale or supply of a prescription only medicine, make or cause to be made an entry in a written or computerised record kept for that purpose.

(2) An entry required by paragraph (1)—

(a) must state the particulars specified in Schedule 23; and

(b) subject to paragraph (3), must be made—

(i) on the day of the sale or supply, or

(ii) if that is not reasonably practicable, on the day following that day.

(3) Where the sale or supply is made under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription), the particulars specified in paragraph 2(e) and (f) of Schedule 23 may be entered on the day that the prescription is received.

(4) Paragraphs (1) to (3) do not apply if any of the following apply—

(a) the sale or supply is in pursuance of a health prescription or a prescription for oral contraceptives;

(b) a separate record of the sale or supply is made in accordance with the Misuse of Drugs Regulations 2001 or the Misuse of Drugs Regulations (Northern Ireland) 2002;

(c) the sale is by way of wholesale dealing and the order or invoice relating to the sale or a copy of the order or invoice is retained by the person lawfully conducting the retail pharmacy business who makes the sale;

(d) in Scotland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 45 of Schedule 5 to the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 [M70] (provision of drugs, medicines and appliances for immediate treatment or personal administration);

(e) in Northern Ireland, the sale or supply is to a doctor for use in the circumstances referred to in paragraph 47 of Schedule 5 to the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 [M71] (provision of drugs, medicines and appliances for immediate treatment or personal administration).

(5) A person lawfully conducting a retail pharmacy business must preserve for a period of two years beginning immediately after the relevant date—

(a) the record kept under paragraphs (1) to (3);

(b) a prescription in pursuance of which a prescription only medicine has been sold or supplied other than—

(i) a health prescription, or

(ii) a prescription for a **[**[F767]product subject to special medical prescription**]**;

(c) an order or invoice referred to in paragraph (4)(c) or a copy of the order or invoice; and

(d) orders referred to in column 3 of Parts 1 to 3 of Schedule 17, except orders referred to in paragraph 3 of Part 1 of that Schedule.

(6) In paragraph (5) "the relevant date" means—

(a) in relation to sub-paragraph (a), the date on which the last entry is made in the record;

(b) in relation to sub-paragraphs (b), (c) and (d)—

(i) where the prescription only medicine was sold or supplied in accordance with a repeatable prescription, the date of the final sale or supply pursuant to that prescription, and

(ii) otherwise, the date on which the prescription only medicine was sold or supplied.

Textual Amendments

F767 Words in reg. 253(5)(b)(ii) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **5(2)(h)** and words in reg. 253(5)(b)(ii) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **5(2)(h)**

Marginal Citations

M70 S.S.I. 2004/115

M71 S.R. (NI) 2004 No. 140.

Prohibitions concerning traceability of treatment with advanced therapy medicinal products

254.—(1) A person may not treat a patient with an advanced therapy medicinal product if there is not a system in place for patient and product traceability in relation to such treatment containing sufficient detail to enable the linking of the product to the patient who received it and vice versa.

(2) A person may not treat a patient with an advanced therapy medicinal product if the treatment involves a product which contains human cells or tissues and the traceability system referred to in paragraph (1) is not complementary to, and compatible with, the requirements **[**F768imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990;

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005; and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007**]**.

(3) It is a defence to an offence of breach of paragraph (1) or, as the case may be, paragraph (2) if the person who treats a patient was assured in writing before the treatment was given that a system of traceability as described in paragraph (1) or, as the case may be, paragraph (2) was in place in relation to the treatment given by that person.

(4) A person may not give an assurance in writing to a person ("P") who treats a patient with an advanced therapy medicinal product that a system of traceability as described in paragraph (1) or paragraph (2) is in place in relation to treatment with an advanced therapy medicinal product given by P if no such system is in place.

Textual Amendments

F768 Reg. 254(2)(a)-(c) and words substituted for words (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **195**; 2020 c. 1, **Sch. 5 para. 1(1)**

Offences relating to dealings with medicinal products

255.—(1) A person is guilty of an offence if the person breaches any of the following provisions of this Part—

(a) regulation 214(1) (prohibition on sale etc of prescription only medicine otherwise than in accordance with prescription from appropriate practitioner);

(b) regulation 214(2) (prohibition on parenteral administration of prescription only medicine otherwise than by or under directions of appropriate practitioner);

(c) regulation 220 (prohibition on sale etc of medicinal product not subject to general sale otherwise than by or under supervision of pharmacist);

(d) regulation 249 (prohibition on sale of prescription only medicine or pharmacy medicine by way of wholesale dealing to person not within Schedule 22);

(e) regulation 251 (compliance with standards specified in certain publications); or

(f) regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products).

(2) A person is guilty of an offence if the person—

(a) is an appropriate practitioner by virtue of regulation 214; and

(b) gives a prescription or directions in respect of a medicinal product in relation to which the person is not an appropriate practitioner.

(3) A person is guilty of an offence if the person gives a prescription or directions or administers a medicinal product without meeting the conditions for doing so that apply to that person by virtue of regulation 215 (conditions to be met by supplementary prescriber).

(4) A person ("P") is guilty of an offence if—

(a) P has in P's possession a medicinal product to which regulation 214(1) applies; and

(b) P intends to supply it otherwise than in accordance with a prescription of an appropriate practitioner.

(5) A person guilty of an offence under any of paragraphs (1) to (4) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(6) A person is guilty of an offence if the person breaches—

(a) regulation 221 (prohibition on sale of medicinal product subject to general sale otherwise than in accordance with that regulation); or

(b) regulation 222 (prohibition on sale by automatic machine of medicinal product not subject to general sale).

(7) A person guilty of an offence under paragraph (6) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(8) A person is guilty of an offence if the person breaches regulation 253 (record-keeping requirements for persons carrying on a retail pharmacy business).

(9) A person guilty of an offence under paragraph (8) is liable on summary conviction to a fine not exceeding £400.

[F769Enforcement notices relating to Commission Regulation 2016/161: persons authorised to supply medicinal products to the public

255A.—(1) This regulation applies to a person who, in the course of a business carried on by that person, sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, **[**F770in Northern Ireland,**]** a medicinal product that is required by Article 54a of the 2001 Directive to bear safety features.

(2) If an enforcement authority has objective grounds for considering that a person to whom this regulation applies has contravened a provision of Commission Regulation 2016/161 listed in paragraph (4), the enforcement authority may serve upon that person a notice in writing (referred to in this Regulation as an "enforcement notice")—

(a) informing that person of the authority's grounds for considering that the person has contravened one or more of those provisions;

(b) specifying the relevant provisions;

(c) specifying the measures which the person must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;

(d) requiring the person to take those measures, within such period as may be specified in the notice;

(e) warning the person that that a failure to comply with the enforcement notice constitutes an offence under paragraph (5) and that further action may be taken in respect of the contravention unless the requirements specified in the notice are met.

(3) An enforcement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(4) The provisions mentioned in paragraph (2) are—

(a) Article 10 (verification of the safety features) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(c) Article 12 (unique identifiers which have been decommissioned);

(d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to persons authorised or entitled to supply medicinal products to the public;

(e) Article 25 (obligations of persons authorised or entitled to supply medicinal products to the public), subject to the exemptions contained in Article 26 (derogations from Article 25);

(f) Article 27 (obligations when applying the derogations);

(g) Article 28 (obligations when supplying only part of a pack);

(h) Article 29 (obligations in case of inability to verify the authenticity and decommission the unique identifier); and

(i) Article 30 (actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification).

(5) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with an enforcement notice served upon them under paragraph (2).

(6) A person guilty of an offence under paragraph (5) is liable—

(a) on summary conviction to a fine; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.**]**

Textual Amendments

F769 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

F770 Words in reg. 255A(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 196** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**)

[F769Exception to Article 25 of Commission Regulation 2016/161: health care institutions

255B. Article 25(1) of Commission Regulation 2016/161 does not apply to a person authorised or entitled to supply medicinal products to the public **[**F771in Northern Ireland**]** if—

(a) the person authorised or entitled to supply medicinal products to the public is operating within a healthcare institution;

(b) the person authorised or entitled to supply medicinal products to the public obtains the medicinal product bearing the unique identifier through a wholesaler belonging to the same legal entity as the healthcare institution;

(c) the wholesaler that supplies the product to the healthcare institution has verified the safety features and decommissioned the unique identifier in accordance with the requirements laid down in Commission Regulation 2016/161;

(d) no sale of the medicinal product takes place between the wholesaler supplying the product and that healthcare institution; and

(e) the medicinal product is supplied to the public within that healthcare institution.**]**

Textual Amendments

F769 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

F771 Words in reg. 255B inserted (31.12.2020) by S.I. 2019/775, **reg. 196A** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**)

[F769Offences relating to Commission Regulation 2016/161: management of the repository system

255C.—(1) A legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161 is guilty of an offence if the legal entity fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).

(2) The provisions mentioned in paragraph (1) are—

(a) Article 31 (establishment of the repositories system);

(b) Article 32 (structure of the repositories system);

(c) Article 33 (uploading of information in the repositories system);

(d) Article 34 (functioning of the hub);

(e) Article 35 (characteristics of the repositories system);

(f) Article 36 (operations of the repositories system);

(b) Article 37 (obligations of legal entities establishing and managing a repository which is part of the repositories system);

(c) Article 38 (data protection and data ownership); and

(d) Article 39 (access by national competent authorities).

(3) A legal entity guilty of an offence under paragraph (1) is liable on summary conviction, or on conviction on indictment, to a fine.

(4) A person guilty of an offence under paragraph (1) by virtue of regulation 338 is liable—

(a) on summary conviction to a fine; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.**]**

Textual Amendments

F769 Regs. 255A-255C inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **10** and regs. 255A-255C inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **10**

Disqualification

Disqualification on conviction

256.—(1) A court before which a person ("P") is convicted of any offence under regulation 255(8) may order that P is disqualified from using the premises where that offence was committed for a period not exceeding 2 years if the following conditions are met.

(2) Condition A is that the offence was committed in a retail pharmacy business.

(3) Condition B is that the period of disqualification relates to the future use of the premises as a retail pharmacy business.

(4) Condition C is that the enforcement authority has made an application to the court for such an order.

(5) Condition D is that the court thinks it appropriate to grant an order having regard—

(a) to the gravity of the offence of which P has been convicted as mentioned in the preceding subsection;

(b) to the unsatisfactory nature of the premises; or

(c) to any offences under regulation 255(8) of which P has previously been convicted.

(6) Condition E is that the enforcement authority has not less than 14 days before the date of the hearing given P notice in writing of their intention to apply for such an order.

(7) If P uses the premises in respect of which an order under this regulation is in force for the purposes of a retail pharmacy business, P shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(8) At any time after the end of the period of six months beginning with the date on which an order under this regulation comes into force, P may apply to the court to revoke the order or to vary it by reducing the period of disqualification.

(9) On any application made under paragraph (8) of this regulation the court may—

(a) revoke or vary the order if it thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the applicant and any improvement in the state of the premises to which the order relates; or

(b) refuse to revoke or vary the order.

(10) If an application made by P under paragraph (8) is refused, no further application under that paragraph may be made within the period of three months beginning with the date of the refusal.

(11) The court determining an application under this regulation shall have power to order the applicant to pay the whole or any part of the costs of the application.

(12) In the application of this regulation to Scotland, for reference to an enforcement authority and to costs there shall be substituted respectively references to the procurator fiscal and to expenses.

[F772PART 12A

Sale of medicines to the public at a distance

Textual Amendments

F772 Pt. 12A inserted (coming into force in accordance with reg. 1(2) of the amending S.I.) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(2), **28**

[F773Application of Part

256ZA. This part applies to Northern Ireland only.**]**

Textual Amendments

F773 Reg. 256ZA inserted (31.12.2020) by S.I. 2019/775, regs. 1, **197(1)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Interpretation

256A.—[F774(1)**]** In this Part—

"common logo" means the common logo that is required to be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with the requirements laid down in the implementing acts adopted by the Commission under Article 85c(3) of the 2001 Directive;

"information society services" means information society services as defined in Article 1(2) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;

"the list" means the list of persons who are entitled to supply medicinal products by information society services that is maintained on the website of the **[**F775licensing authority**]**;

F776...

"website of the EMA" means the website of the EMA that—

(a) gives explicit information to the viewer on the **[**F777website of the licensing authority**]** containing information on persons authorised or entitled to supply medicinal products at a distance in **[**F778Northern Ireland**]**;

(b) provides information on the purpose of the common logo;

(c) provides background information about the risks related to medicinal products supplied illegally to the public by means of information society services;

(d) provides information on Community legislation applicable to falsified medicinal products;

(e) contains **[**[F779]a hyperlink to the website of the licensing authority**]**.

[[F780]"website of the licensing authority" means a website of the licensing authority providing information on—

(a) the national legislation applicable to the offering of medicinal products for sale at a distance to the public by information society services;

(b) the differences between Northern Ireland and EEA States regarding classification of medicinal products and the conditions for their supply;

(c) the purpose of the common logo;

(d) the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses;

(e) background information about the risks related to medicinal products supplied illegally to the public by means of information society services;

(f) a hyperlink to the website of the EMA;**]**

[
[F781](2) In this Part, references to selling a medicinal product at a distance to the public by means of information society services, however expressed, include supplying and offering to sell or supply a medicinal product at a distance to the public by means of information society services (and related expressions are to be interpreted accordingly).**]**

Textual Amendments

F774 Reg. 256A renumbered as reg. 256A(1) (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **13(a)** and reg. 256A renumbered as 256A(1) (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **13(a)**

F775 Words in reg. 256A(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(2)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F776 Words in reg. 256A(1) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 197(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F777 Words in reg. 256A(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(2)(d)(i)(aa)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F778 Words in reg. 256A(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(2)(d)(i)(bb)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F779 Words in reg. 256A(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(2)(d)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F780 Words in reg. 256A(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 197(2)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F781 Reg. 256A(2) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **13(b)** and reg. 256A(2) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **13(b)**

Person who may sell medicinal products by information society services

256B.—[

F782(A1) This regulation applies to a person who is an established service provider (as defined in regulation 2(1) of the Electronic Commerce (EC Directive) Regulations 2002) in Northern Ireland.**]**

(1) A person may not sell a medicinal product at a distance to the public by means of information society services unless that person satisfies the following conditions.

(2) Condition A is that the person is included on the list F783....

[F784(3) Condition B is that the product to be sold by information society services is covered by a UK marketing authorisation or an authorisation granted—

(a) under Regulation (EC) No 726/2004; or

(b) by a competent authority of the member State in which that product is destined to be sold.

(3A) Condition B does not apply to—

(a) a special medicinal product;

(b) a medicinal product where the product is the result of a process of manufacture to which regulation 17(1) does not apply by virtue of any provision of section 10 of the Medicines Act 1968; or

(c) a medicinal product where—

(i) the product is a result of a process of assembly of a medicinal product that is an authorised medicinal product within the meaning of regulation 3(15);

(ii) regulation 17(1) does not apply to the process of assembly by virtue of any provision of section 10 of the Medicines Act 1968;

(iii) the process of assembly results in a change in the presentation of the authorised medicinal product; and

(iv) by reason of the change in paragraph (iii) the product does not comply with condition B.**]**

(4) Condition C is that the person selling the medicinal product is authorised or entitled to sell to the public, including by information society services, medicinal products of that type or classification F785....

(5) Condition D is that where the sale is to a member of the public in the United Kingdom, it is in accordance with regulations 214 (sale or supply of prescription only medicines), 220 (sale or supply of medicinal products not subject to general sale) and 221 (sale or supply of medicinal products subject to general sale).

(6) Condition E is that the person selling the medicinal product has given a valid notification to **[**F786the licensing authority**]**.

(7) Condition F is that the person selling medicinal products at a distance complies with the relevant provisions of the Electronic Commerce (EC Directive) Regulations 2002.

(8) A person has not given a valid notification for the purposes of paragraph (6) if—

(a) that person is not included on the list;

(b) **[**F787that person's entry on the list**]** is suspended by **[**F788the licensing authority**]**; or

(c) **[**F789the licensing authority**]** has been notified under regulation 256E(b) to remove that person from the list.

Textual Amendments

F782 Reg. 256B(A1) inserted (31.12.2020) by S.I. 2019/775, **reg. 197(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F783 Words in reg. 256B(2) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 197(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F784 Reg. 256B(3)(3A) substituted for reg. 256B(3) (31.12.2020) by S.I. 2019/775, **reg. 197(3)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F785 Words in reg. 256B(4) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 197(3)(d)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F786 Words in reg. 256B(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(3)(e)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F787 Words in reg. 256B(8)(b) substituted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **14** and words in reg. 256B(8)(b) substituted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **14**

F788 Words in reg. 256B(8)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(3)(f)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F789 Words in reg. 256B(8)(c) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(3)(f)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Notification requirements for sellers of medicinal products at a distance

256C.—(1) The **[**F790licensing authority**]** may not enter a person's details on the list unless it has been notified in accordance with paragraphs to (5).

(2) The notification must include—

(a) the name or corporate name of the person to be listed;

(b) information about—

(i) that person's permanent address from which the activity of selling medicinal products by information society services is to be carried out,

(ii) the commencement date of the activity of selling medicinal products by information society services,

(iii) the address of the website used for the purposes of selling medicinal products by information society services,

(iv) all relevant **[**F791information**]** necessary to identify the website, and

(v) information about the classification of all the medicinal products offered for sale at a distance.

(3) The notification shall—

(a) be in English; and

(b) unless paragraph (4) applies, in relation to the person whose details are to be entered on the list—

(i) be signed by that person, and

(ii) contain that person's telephone number and e-mail address if this is available.

(4) Where the notification is made by another person ("A") on behalf of the person whose details are to be entered on the list, the notification shall—

(a) contain the name and address of A;

(b) be signed by A; and

(c) contain the telephone number and e-mail address for A if this is available.

(5) The notification shall contain contact details for the site from which the activity of selling medicinal products by information society services is to be carried out including the—

(a) site address;

(b) name of person who may be contacted; and

(c) the telephone number and e-mail address of the person who may be contacted.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F791 Word in reg. 256C(2)(b)(iv) substituted (31.12.2020) by S.I. 2019/775, **reg. 197(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Procedure for listing persons who may supply medicinal products at a distance

256D.—(1) If the **[**F790licensing authority**]** receives a notification under regulation 256C it must accept or refuse to include that person on the list within the period of 90 days beginning immediately after the day on which the notification is received by the authority.

(2) Paragraph (1) applies only if the requirements of regulation 256C(2) have been met.

(3) Before determining if a person can be included on the list, the **[**F790licensing authority**]** may require the person giving the notification to provide such information as **[**F792the licensing authority**]** thinks necessary, within the period specified by **[**F792the licensing authority**]**.

(4) If a notice under paragraph (3) requires the person giving the notification to provide the **[**F790licensing authority**]** with information, the information period is not to be counted for the purposes of paragraph (1).

(5) In paragraph (4), the "information period" means the period—

(a) beginning with the day on which the notice is given, and

(b) ending with the day on which—

(i) the **[**F790licensing authority**]** receives the information; or

(ii) the person from whom the information is requested shows to the satisfaction of the **[**F790licensing authority**]** that the information cannot be provided.

(6) The **[**F790licensing authority**]** must give the person giving the notification a notice stating reasons for its decision in any case where—

(a) the **[**F790licensing authority**]** refuses to include the person giving the notification on the list; or

(b) if the **[**F790licensing authority**]** lists the person giving the notification otherwise that in accordance with the information supplied in the notification.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F792 Words in reg. 256D(3) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(6)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Removal of a person's entry from the list

256E. The **[**F790licensing authority**]** may remove a person's entry from the list if—

(a) regulation **[**F793256I(1)(c)**]** applies; or

(b) a notification to remove the entry is received from the person on the list.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F793 Word in reg. 256E(a) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **8** and word in reg. 256E(a) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **8**

Provision of information to the **[**F790licensing authority**]**

256F.—(1) A person on the list must immediately inform the **[**F790licensing authority**]** and, where applicable, the marketing authorisation holder, of medicinal products which that person—

(a) identifies as;

(b) knows or suspects; or

(c) has reasonable grounds for knowing or suspecting,

to be falsified.

(2) The person entered on the list must notify the **[**F790licensing authority**]** of any change of circumstances which is material as regards that person's entry on the list.

(3) The **[**F790licensing authority**]** may give a notice to a person on the list, requiring that person to provide information of a kind specified in the notice within the period specified in the notice.

(4) A notice under paragraph (3) may not be given to a person on the list unless it appears to the **[**F790licensing authority**]** that it is necessary for that competent authority to consider whether that person's entry on the list should be varied, suspended or removed.

(5) A notice under paragraph (4) may specify information which the **[**[F790]licensing authority**]** thinks necessary for considering whether the person's entry on the list should be varied, suspended or removed.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

Grant or refusal to list a person

256G.—(1) On receipt of a notification from a person to be included in the list—

(a) the **[**[F790]licensing authority**]** must include that person on the list if that person complies with the requirements in regulation 256C(2) to (5); or

(b) if it considers necessary or appropriate to do so, the **[**[F790]licensing authority**]** must refuse to include that person on the list having had regard to—

(i) the provisions of these Regulations, and

(ii) any EU obligation.

(2) The **[**[F790]licensing authority**]** must give a notice stating the reasons for its decision in any case where **[**[F794]the licensing authority**]**—

(a) refuses to include a person on the list; or

(b) includes a person in the list otherwise than in accordance with the notification and that person requests a statement of its reasons.

(3) Where the **[**[F790]licensing authority**]** decides to include a person on the list **[**[F795]the licensing authority**]** must ensure that the **[**[F796]website of the licensing authority**]** includes—

(a) the name or corporate name of the person that is listed; and

(b) the person's website address in the United Kingdom.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F794 Words in reg. 256G(2) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(7)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F795 Words in reg. 256G(3) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(7)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**)

F796 Words in reg. 256G(3) substituted (31.12.2020) S.I. 2019/775, regs. 1, **197(7)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**)

Conditions to be met by a person entered on the list

256H.—(1) A person entered on the list shall not sell a medicinal product at a distance by information society services unless the following conditions are satisfied.

(2) Condition A is that the person entered on the list must comply with regulation 256B.

(3) Condition B is that without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, (Directive on electronic commerce), the website used to sell medicinal products at a distance must contain—

(a) the contact details of the **[**F790licensing authority**]**F797...;

(b) a hyperlink to the **[**F798website of the licensing authority**]**.

(4) Condition C is that without prejudice to any implementing Acts adopted by the Commission under Article 85c(3) of the 2001 Directive the website used to sell medicinal products at a distance must contain the common logo which—

(a) is clearly displayed on every page of the listed person's website that relates to medicinal products offered for sale at a distance; and

(b) contains a hyperlink to the entry of that person in the list.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F797 Words in reg. 256H(3)(a) omitted (31.12.2020) by S.I. 2019/775, regs. 1, **197(8)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F798 Words in reg. 256H(3)(b) substituted (31.12.2020) S.I. 2019/775, regs. 1, **197(8)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Power to suspend, vary or remove a person's entry on the list

256I.—(1) The **[**F790licensing authority**]** may in accordance with regulation 256J—

(a) suspend a person's entry on the list for such period as the authority thinks fit;

(b) vary a person's entry on the list; or

(c) remove a person's entry from the list.

(2) The suspension of person from the list may be—

(a) total;

(b) limited to medicinal products of one or more descriptions; or

(c) limited to medicinal products sold at a distance from specified premises or a specified part of any premises.

(3) The power conferred by this regulation may only be exercised on one or more of the following grounds—

(a) in relation to any information notified to the **[**F790licensing authority**]** under regulation 256C as a result of which the person was included in the list—

(i) the information so supplied was false or incomplete in a material respect,

(ii) a material change of circumstances has occurred in relation to any of the matters stated in the notification;

(b) the person on the list has materially contravened a condition required to be met by a person entered on the list under regulation 256H; or

(c) the person on the list has without reasonable excuse failed to supply information to the **[**F790licensing authority**]** with respect to their notification when required to do so under regulation 256F(3).

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

Procedure where the [F790licensing authority] proposes to suspend, vary or remove a person's entry on the list

256J.—(1) This regulation applies where—

(a) the provisions of regulation 256K do not apply; and

(b) the **[**F790licensing authority**]** proposes to exercise the power in regulation 256I.

(2) The **[**F790licensing authority**]** must notify the person on the list in writing of—

(a) its proposal;

(b) the reasons for it; and

(c) a specified date on which it is proposed that the suspension, variation or revocation should take effect.

(3) The specified date in paragraph (2)(c) must be no earlier than 28 days following the date of the notice given by the **[**F790licensing authority**]**.

(4) The person to whom notice is given under paragraph (2) may before the date specified in the notice—

(a) make written representations to the **[**F790licensing authority**]** with respect to the proposal; or

(b) notify the **[**F790licensing authority**]** that the person wishes that competent authority to submit the proposal to review upon oral representations.

(5) If person on the list makes written representations in accordance with sub-paragraph (4)(a) the **[**F790licensing authority**]** must take those representations into account before making a decision in the matter.

(6) If the person on the list gives notice of the proposal to review upon oral representation in accordance with paragraph (4)(b)—

(a) Schedule 5 has effect; F799...

F799(b) . . . . . .

(7) If the **[**F790licensing authority**]** proceeds to suspend, vary or remove a person's entry on the list in accordance with the provisions of regulation 256I it must give a notice to that person.

(8) The notice must—

(a) give particulars of the suspension, variation or removal; and

(b) give reasons for the decision to suspend, vary or remove the person's entry on the list.

(9) Paragraphs (7) and (8) are without prejudice to any requirement of Schedule 5 as to notification.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F799 Reg. 256J(6)(b) and word omitted (31.12.2020) by S.I. 2019/775, regs. 1, **197(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Suspension of a person's entry on the list in cases of urgency

256K.—(1) The **[**F790licensing authority**]** may immediately suspend a person's entry on the list for a period not exceeding three months where it appears to **[**F800the licensing authority**]** that in the interests of safety it is appropriate to do so.

(2) This paragraph applies where—

(a) a person's entry on the list has been suspended under paragraph (1); and

(b) it appears to the **[**F790licensing authority**]** that it is necessary to consider whether the person's entry on the list should be—

(i) further suspended or varied, or

(ii) removed from the list.

(3) Where paragraph (2) applies, the **[**F790licensing authority**]** must proceed as set out in regulation 256I (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the **[**F790licensing authority**]** proceeds as set out in regulation 256I and any proceedings under that regulation have not been finally disposed of before the end of the period for which the person's entry was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the **[**F790licensing authority**]** to be necessary in the interests of safety to do so, the authority may further suspend the person's entry on the list for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 256I to suspend, vary or remove a person's entry on the list is made on an application under regulation 322(4) (validity of decisions and proceedings), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (interim order of the High Court).

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F800 Words in reg. 256K(1) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(10)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Variation of a person's entry on the list on the application of that person

256L.—(1) This regulation applies if a person entered on the list applies to the **[**[F790]licensing authority**]** for a variation of the person's entry on the list.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant; and

(d) be accompanied by such information as may be required to enable the **[**[F790]licensing authority**]** to consider the application.

(3) The **[**[F790]licensing authority**]** must vary a person's entry on the list or refuse to vary it within 30 days beginning with the day after the date when **[**[F801]the licensing authority**]** receives the application.

(4) The **[**[F790]licensing authority**]** may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the **[**[F790]licensing authority**]** with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which notice under paragraph (4) is given; and

(b) ending with the day on which the **[**[F790]licensing authority**]** receives the information or the applicant shows to **[**[F802]the licensing authority's**]** satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 256I and 256K.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

F801 Words in reg. 256L(3) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(11)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

F802 Words in reg. 256L(6)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **197(11)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**)

Offences: breach of regulations and false information

256M.—(1) A person is guilty of an offence if the person—

(a) contravenes regulation 256B(1); or

(b) offers medicinal products for sale at a distance otherwise than in accordance with the conditions in regulation 256H.

(2) A person is guilty of an offence if the person knowingly gives false information in—

(a) an application to be entered on the list in accordance with regulation 256C(2);

(b) an application for a variation in accordance with regulation 256L(2); or

(c) response to a notice under regulation 256L(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 256F(3) or 256L(4).

(4) A person is guilty of an offence if that person fails to inform the **[**F790licensing authority**]**—

(a) of a falsified medicinal product in accordance with regulation 256F(1); or

(b) about a material change of circumstances in accordance with regulation 256F(2).

(5) It is a defence for a person charged with an offence under paragraph (4) to show that the person exercised all due diligence to avoid committing the offence.

Textual Amendments

F790 Words in regs. 256C-256M substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **197(4)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 151**); 2020 c. 1, **Sch. 5 para. 1(1)**

Penalties

256N.—(1) A person guilty of an offence under regulation 256M(1), (2) or (4) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 256M(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.**]**

PART 13

Packaging and leaflets

CHAPTER 1

Requirements for packaging and package leaflets relating to medicinal products

Packaging requirements: general

257.—(1) The information specified in Part 1 of Schedule 24 must appear—

(a) on the outer packaging of a medicinal product; and

(b) on the immediate packaging of the product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 1 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 1 of Schedule 24.

(4) The information specified in Part 2 of Schedule 24 must appear on immediate packaging to which paragraph (2) applies.

(5) The information specified in Part 3 of Schedule 24 must appear on immediate packaging to which paragraph (3) applies.

(6) Information included on the packaging of a product in accordance with this regulation, **[**[F803]regulation 257C where the product is for sale or supply in Great Britain only,**]** regulation 261 and Schedule 24 must be easily legible, comprehensible and indelible.

(7) Nothing in this regulation or Schedule 24 applies to a registrable homoeopathic medicinal product.

[[F804](8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product for sale or supply in Great Britain only.**]**

Textual Amendments

F803 Words in reg. 257(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F804 Reg. 257(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F805]Packaging Requirements: medicinal products required to bear safety features

257A.—(1) The information specified in paragraph 18A of Schedule 24 must not be removed or covered, either fully or partially, **[**[F806]from a product to which Article 54a of the 2001 Directive applies**]** unless the following conditions are met—

(a) a person who is the holder of a manufacturer's licence verifies, prior to partially or fully removing or covering the features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) the holder of the manufacturer's licence replaces the features with ones which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product; and

(c) the replacement of the features is conducted in accordance with the applicable principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(2) For the purposes of paragraph (1)(b), the features shall be considered equivalent if they—

(a) comply with the requirements set out in Commission Regulation 2016/161; and

(b) are equally effective in enabling the verification of authenticity and identification of the medicinal product and in providing evidence of tampering with the medicinal product.

(3) In performing the activities referred to in paragraph (1), the holder of a manufacturer's licence shall be regarded as a producer for the purposes of the Consumer Protection Act 1987.**]**

Textual Amendments

F805 Regs. 257A, 257B inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **11** and regs. 257A, 257B inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **11**

F806 Words in reg. 257A inserted (31.12.2020) by S.I. 2019/775, **reg. 199** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**)

[F805Transitional Arrangements

257B. The information specified in paragraph 18A of Schedule 24 does not need to appear on the packaging of a medicinal product released for sale or distribution before 9 February 2019, unless the product **[**F807is one to which Article 54a of the 2001 Directive applies and**]** has been repackaged or relabelled after that date.**]**

Textual Amendments

F805 Regs. 257A, 257B inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **11** and regs. 257A, 257B inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **11**

F807 Words in reg. 257B inserted (31.12.2020) by S.I. 2019/775, **reg. 199A** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**)

[F808Packaging requirements: advanced therapy medicinal products

257C.—(1) The information specified in Part 4 of Schedule 24 must appear—

(a) on the outer packaging of an advanced therapy medicinal product for sale or supply in Great Britain only (other than an exempt advanced therapy medicinal product); and

(b) on the immediate packaging of that product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to the immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 4 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 4 of Schedule 24.

(4) The information specified in Part 5 of Schedule 24 must appear on immediate packaging to which paragraph (2) or (3) applies.

Textual Amendments

F808 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

Guidance as to packaging and package leaflets

257D.—(1) The licensing authority may publish guidance on packaging and package leaflets applicable to products for sale or supply in the whole United Kingdom or parts of the United Kingdom, as appropriate.

(2) Guidance published under paragraph (1) may, in particular, include—

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to products that are a pharmacy medicine;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods of identification and authentication of medicinal products;

(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(3) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission pursuant to Article 65 of the 2001 Directive, insofar as that guidance was in force immediately before IP completion day, continues to apply as if it had been published by the licensing authority under paragraph (1).

Textual Amendments

F808 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

Regulation-making power as to certain forms of labelling

257E. The Ministers may by regulations require the use of certain forms of labelling of a medicinal product in order to make it possible to ascertain—

(a) the price of the medicinal product;

(b) any reimbursement conditions of the National Health Service;

(c) the legal status for supply to the patient in accordance with regulation 5 (classification), insofar as not already provided for in Schedule 25;

(d) authenticity and identification of the medicinal product in accordance with Article 54a(5) of the 2001 Directive.**]**

Textual Amendments

F808 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

Packaging requirements: specific provisions

258.—(1) In addition to other information required by this Part, the information specified in Part 1 of Schedule 25 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner for the purposes of regulation 214(3) to (6), whether or not the medicinal product in question is a prescription only medicine.

(2) The requirements of paragraph 4 or 6 of Schedule 25, as the case may be, are satisfied in relation to a package containing a number of packages of medicinal products of the same description if the information specified in paragraph 4 or 6 of that Schedule is shown on one or more of those packages.

(3) The information specified in Part 2 of that Schedule must appear on a package which contains a number of packages of medicinal products of the same description, other than special medicinal products, for the purpose of transport, delivery or storage.

(4) But paragraph (3) does not apply to a packing case, crate or other covering used solely for the purposes of transport or delivery of packages of medicinal products, each of which is labelled in accordance with the other requirements of this Part.

(5) In addition to the other information required by this Part, the information specified in Parts 3 and 4 of Schedule 25 must appear on the outer packaging and the immediate packaging of products of the kind specified in those Parts of that Schedule.

(6) Nothing in this regulation or Schedule 25 requires information to appear on—

(a) a package containing a medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;

(b) a paper bag or similar wrapping in which a package that contains a medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;

(c) a package enclosing a package of a medicinal product for export;

(d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or

(e) a blister pack or similar packaging enclosed in a package on which information appears in accordance with the requirements of Parts 3 and 4 of Schedule 25.

(7) Nothing in this regulation or Schedule 25 applies to a medicinal product—

(a) which is an anti-viral medicine in the form of a solution to be used for the treatment of a child under the age of one year;

(b) on the container of which appears—

(i) the name of the person to whom the product is to be administered,

(ii) the date on which the product is sold or supplied, and

(iii) the necessary instructions for proper use; and

(c) which is sold or supplied for the purpose of treating a disease which is—

(i) a serious risk to human health, or potentially a serious risk to human health, and

(ii) pandemic or imminently pandemic.

(8) Nothing in this regulation or Schedule 25 applies to a traditional herbal medicinal product or a registrable homoeopathic medicinal product.

Packaging requirements: information for blind and partially sighted patients

259.—(1) The name of a medicinal product must also be expressed in Braille format on the outer packaging of the product (or, if there is no outer packaging, on the immediate packaging of the product).

(2) The holder of a **[**F809UK marketing authorisation, EU marketing authorisation**]**, Article 126a authorisation or traditional herbal registration for a medicinal product must ensure that the package leaflet is made available on request in formats suitable for blind and partially-sighted persons.

(3) Nothing in this regulation applies to a registrable homoeopathic medicinal product.

Textual Amendments

F809 Words in reg. 259(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 202** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 156**)

Package leaflets

260.—(1) A package leaflet for a medicinal product must—

(a) be drawn up in accordance with the summary of the product characteristics; and

(b) contain all the information specified in Schedule 27 in the order specified in that Schedule.

[[F810](1A) If the medicinal product is an advanced therapy medicinal product for sale or supply in Great Britain only (other than an exempt advanced therapy medicinal product), the package leaflet must contain the information specified in Part 3 of Schedule 27 in the order specified in that Part.**]**

(2) A package leaflet must be included in the packaging of a medicinal product unless all the information required by Part 1 of Schedule 27 (and, where the product contains paracetamol, the information required by Part 2 of that Schedule) **[**[F811], or where the product is an advanced therapy medicinal product for sale or supply in Great Britain only, the information specified in Part 3 of that Schedule,**]** is conveyed on the outer packaging or the immediate packaging of the product.

(3) A package leaflet relating to a medicinal product must be legible, clear and easy to use, and the applicant for, or holder of, a **[**[F812]UK marketing authorisation, EU marketing authorisation,**]** Article 126a authorisation or traditional herbal registration relating to the product must ensure that target patient groups are consulted in order to achieve this.

(4) Regulation (5) applies in a case where a package leaflet is not provided under paragraph (2) because all the information required by Schedule 27 is conveyed on the outer packaging or the immediate packaging of the product.

(5) Where this paragraph applies, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to the outer packaging or, as the case may be, the immediate packaging of the product.

(6) Nothing in this regulation or Schedule 27 applies to a registrable homoeopathic medicinal product.

Textual Amendments

F810 Reg. 260(1A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F811 Words in reg. 260(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F812 Words in reg. 260(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Use of pictures and symbols etc

261.—(1) The outer packaging and the package leaflet of a medicinal product may include—

(a) symbols, diagrams or pictures designed to clarify information mentioned in Part 1 of Schedule 24 or in Schedule 27; and

(b) other information, compatible with the summary of the product characteristics, which is useful to the patient.

(2) Symbols, diagrams, pictures or additional information included in accordance with this regulation must not include any element of a promotional nature.

(3) Nothing in this regulation applies to a registrable homoeopathic product.

Labelling requirements for radionuclides

262.—(1) Where a medicinal product contains radionuclides—

(a) the carton and the container of the product must be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency; and

(b) the labelling on the shielding and the vial must comply with the remaining provisions of this regulation.

(2) The label on the shielding must—

(a) include the information specified in Part 1 of Schedule 24;

(b) explain in full the codings used on the vial;

(c) indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial; and

(d) indicate the number of capsules or, for liquids, the number of millilitres per container.

(3) The label on the vial must include—

(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;

(b) the batch identification and expiry date of the product;

(c) the international symbol for radioactivity;

(d) the name and address of the manufacturer; and

(e) the amount of radioactivity; as mentioned in paragraph 2(c).

Leaflets relating to radionuclides

263.—(1) The licensing authority must ensure that a detailed instruction leaflet is enclosed with—

(a) radiopharmaceuticals;

(b) radionuclide generators;

(c) radionuclide kits; or

(d) radionuclide precursors.

(2) The leaflet must include the information specified in Schedule 27.

(3) The leaflet must also include—

(a) any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product; and

(b) special precautions for the disposal of the packaging and its unused contents.

Homoeopathic medicines

264.—(1) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a homoeopathic medicinal product must clearly include the words "homoeopathic medicinal product".

(2) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a registrable homoeopathic medicinal product must also include the information specified in paragraph (1) and Part 1 of Schedule 28 and no other information (unless paragraph (5) or (6) applies).

(3) Regulation (4) applies in a case where a package leaflet is not included with a registrable homoeopathic medicinal product.

(4) Unless the context requires otherwise, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to—

(a) the outer packaging or the immediate packaging of the product; or

(b) in a case to which paragraph (5) or paragraph (6) applies, the outer packaging of the product.

(5) Where the immediate packaging of a registrable homoeopathic medicinal product is in the form of a blister pack and is placed in outer packaging which complies with the requirements of this regulation and Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 2 of Schedule 28.

(6) Where the immediate packaging of a registrable homoeopathic medicinal product is too small to display the information required by Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 3 of Schedule 28.

Additional requirements for traditional herbal medicinal products

265.—(1) Schedule 29 imposes additional requirements in relation to traditional herbal medicinal products.

(2) Nothing in this regulation or Schedule 29 requires information to appear on—

(a) a package containing a traditional herbal medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;

(b) a paper bag or similar wrapping in which a package that contains a traditional herbal medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;

(c) a package enclosing a package of a traditional herbal medicinal product for export;

(d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or

(e) a blister pack or similar packaging, enclosed in a package labelled in accordance with the requirements of this regulation and that Schedule.

Language requirements etc

266.—(1) Information given in accordance with the requirements of this Part must be given in English unless either or both of paragraphs (2) and (3) applies.

(2) This paragraph applies in the case of a medicinal product that has been designated as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [M72] where—

(a) any information specified in paragraph (1) is given in a language of an EEA State other than English; and

(b) the licensing authority accedes to a reasoned request that the information need not be given in English.

(3) This paragraph applies in the case of a product for which the licensing authority grants an Article 126a authorisation where the licensing authority decides that the information need not be given in English.

(4) In a case where paragraph (5) applies, the licensing authority may grant either or both of—

(a) an exemption from the obligation that certain particulars should appear on the outer and immediate packaging and in the package leaflet of the medicinal product in accordance with this Part; and

(b) a full or partial exemption from the obligation that the information included on the outer and immediate packaging and in the package leaflet for the product must be given in English in accordance with paragraph (1).

(5) This paragraph applies—

(a) when a medicinal product is not intended to be delivered directly to the patient; or

(b) where there are severe problems in respect of the availability of the medicinal product.

(6) The licensing authority may make the grant of an exemption in accordance with paragraph (4) subject to measures that it considers necessary to safeguard human health

(7) Information given in English in accordance with this regulation may be given in several languages in addition to English, provided that the same particulars appear in all the languages used.

Marginal Citations

M72 OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.

Submission of mock-ups of packaging and leaflets to licensing authority

267.—(1) At the time when a person applies for a **[**F813UK**]** marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, the person must submit to the licensing authority—

(a) one or more mock-ups of the outer packaging and immediate packaging proposed for the product; and

(b) a draft package leaflet.

(2) If the application is for a **[**F813UK**]** marketing authorisation, Article 126a authorisation or traditional herbal registration, the person must also provide to the licensing authority the results of assessments of the packaging and package leaflet carried out in co-operation with target patient groups.

(3) The licensing authority must refuse the application for a **[**F813UK**]** marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration if—

(a) the packaging or the package leaflet does not comply with the requirements of this Part; or

(b) (in relation to an application for a **[**F813UK**]** marketing authorisation, Article 126a authorisation or traditional herbal registration) the information on the packaging or the package leaflet does not accord with the particulars listed in the summary of the product characteristics.

(4) If the holder of a **[**F813UK**]** marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a product wishes to make changes to the packaging or the package leaflet (other than a change connected with the summary of the product characteristics), the proposed change must be submitted to the licensing authority in accordance with paragraph (5).

(5) In the circumstances in paragraph (4) the holder must submit to the licensing authority such of the following as are affected by the proposed change—

(a) one or more mock-ups of the outer packaging and immediate packaging of the product showing the proposed change; and

(b) a draft package leaflet showing the proposed change.

(6) If the licensing authority has not refused a proposed change within the period of 90 days beginning with the date of the submission, the applicant may make the change.

Textual Amendments

F813 Word in reg. 267 inserted (31.12.2020) by S.I. 2019/775, **reg. 206** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 160**)

Enforcement and offences

Offence relating to packaging and package leaflets [F814in Great Britain]: holder of authorisation etc

268.—(1) This regulation applies to the holder of a **[**F815UKMA(UK), UKMA(GB)**]**, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply **[**F816, in Northern Ireland**]**, a medicinal product to which the authorisation, certificate or registration relates.

(2) A person to whom this regulation applies is guilty of an offence if—

(a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part F817... or **[**F818regulation 50C(4), 50D(8) or 58A(2)(b)**]**; or

(b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Textual Amendments

F814 Words in reg. 268 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(1A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F815 Words in reg. 268(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F816 Words in reg. 268(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(2)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F817 Words in reg. 268(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F818 Words in reg. 268(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F819Offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc

268A.—(1) This regulation applies to the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, in Northern Ireland, a medicinal product to which the authorisation, certificate or registration relates.

(2) A person to whom this regulation applies is guilty of an offence if—

(a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or

(b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.**]**

Textual Amendments

F819 Reg. 268A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207A** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 162**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences relating to packaging and package leaflets [F820in Great Britain]: other persons

269.—(1) This regulation applies to a person, other than the holder of a **[**F821UKMA(UK), UKMA(GB)**]**, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business **[**F822carried on by that person,**]** sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply **[**F823, in Great Britain**]**.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, **[**F824in Great Britain**]** knowing or having reasonable cause to believe—

(a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part F825... or **[**F826regulation 50C(4), 50D(8) or 58A(2)(b)**]**; or

(b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Textual Amendments

F820 Words in reg. 269 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(1A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F821 Words in reg. 269(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F822 Words in reg. 269(1) inserted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, 7 and words in reg. 269(1) inserted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **7**

F823 Words in reg. 269(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(2)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(b)**); ; 2020 c. 1, **Sch. 5 para. 1(1)**

F824 Words in eg. 269(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(2A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F825 Words in reg. 269(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F826 Words in reg. 269(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F827Offences relating to packaging and package leaflets in Northern Ireland: other persons

269A.—(1) This regulation applies to a person, other than the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply in Northern Ireland.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, in Northern Ireland knowing or having reasonable cause to believe—

(a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or

(b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.**]**

Textual Amendments

F827 Reg. 269A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **208A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 164**)

Non-compliance with requirements of this Part

270.—(1) If the holder of a **[**F828UK marketing authorisation, EU marketing authorisation,**]** Article 126a authorisation, certificate of registration or traditional herbal registration fails to comply with a requirement imposed by this Part in relation to a medicinal product, the licensing authority may give a notice to the holder requiring compliance within three months or such other period (which may be less than three months) as may be specified in the notice.

(2) If the holder fails to comply with the notice, the licensing authority may suspend the **[**F829UK marketing authorisation, EU marketing authorisation,**]** Article 126a authorisation, certificate of registration or traditional herbal registration until the holder complies with the requirements of this Part.

(3) A person who fails to comply with a notice under this regulation is guilty of an offence.

Textual Amendments

F828 Words in reg. 270(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **209** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 165**); 2020 c. 1, **Sch. 5 para. 1(1)**

F829 Words in reg. 270(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **209** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 165**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences: penalties

271. A person who is guilty of an offence under regulation **[**F830268, 268A, 269, 269A**]** or 270 is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years, or to both.

Textual Amendments

F830 Words in reg. 271 substituted (31.12.2020) by S.I. 2019/775, **reg. 209A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 166**)

CHAPTER 2

Requirements relating to child safety

Interpretation

272. In this Chapter—

"appropriate practitioner" means any of the persons described as appropriate practitioners in relation to any prescription only medicine in regulation 214(3), (5) and (6);

"regulated medicinal product" means a medicinal product containing aspirin, paracetamol or more than 24mg of elemental iron, in the form of tablets, capsules, pills, lozenges, pastilles, suppositories or oral liquids, but does not include—

(a) effervescent tablets containing not more than 25% of aspirin or paracetamol by weight;

(b) medicinal products in sachets or other sealed containers which hold only one dose;

(c) medicinal products which are not intended for retail sale or for supply in circumstances corresponding to retail sale; or

(d) medicinal products which are for export only.

Child resistant containers for regulated medicinal products

273.—(1) Regulated medicinal products sold or supplied otherwise than in accordance with regulation 274 may be sold only in containers which are—

(a) opaque or dark tinted; and

(b) child resistant.

(2) For the purposes of these Regulations, containers which are not reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

(a) British Standard EN 14375:2003 published by the British Standards Institution on 18th April 2005; or

[[F831](b) any specification for non-reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).**]**

(3) For the purposes of these Regulations, containers which are reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

(a) British Standard EN ISO 8317:2004 published by the British Standards Institution on 11th May 2005; or

[[F832](b) any specification for reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).**]**

Textual Amendments

F831 Reg. 273(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **210(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F832 Reg. 273(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **210(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Exemptions from regulation 273

274.—(1) Regulation 273 does not apply to the retail sale, or supply in circumstances corresponding to retail sale, of regulated medicinal products in accordance with paragraph (2).

(2) Sale or supply is in accordance with this paragraph if the sale or supply is carried out—

(a) by or under the supervision of a pharmacist;

(b) on premises which are a registered pharmacy; and

(c) either—

(i) in accordance with a prescription given by an appropriate practitioner where it is not reasonably practicable to provide the regulated medicinal products in containers that are both opaque or dark tinted and child resistant, or

(ii) at the request of a person who is aged 16 or over and specifically requests that the regulated medicinal products not be contained in a child resistant container.

(3) Regulation 273 also does not apply to the sale or supply of regulated medicinal products—

(a) by a doctor or dentist to a patient, or the patient's carer, for the patient's use;

(b) by a doctor or dentist to a person who is an appropriate practitioner, at the request of that person, for administration to a patient of that person; or

(c) in the course of the business of a hospital or health centre, where the sale or supply is for the purposes of administration, whether in the hospital or health centre or elsewhere, in accordance with the directions of an appropriate practitioner.

Colouring of aspirin and paracetamol products for children

275. The sale or supply of a medicinal product containing aspirin or paracetamol of any colour other than white is prohibited if—

(a) it is a product for children aged 12 or under; and

(b) in the case of paracetamol, it is in a solid form (including tablets, capsules, pills, lozenges, pastilles or suppositories).

Offences

276.—(1) A person is guilty of an offence if, in the course of a business, the person sells or supplies, or possesses for the purposes of sale or supply—

(a) a regulated medicinal product in a container which does not comply with the requirements of regulation 273, unless the sale or supply is or would be exempt from those requirements under regulation 274; or

(b) a medicinal product containing aspirin or paracetamol the sale or supply of which is prohibited under regulation 275.

(2) A person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding 2 years, or to both.

PART 14

Advertising

CHAPTER 1

General

Interpretation

277.—(1) In this Part—

"court" means the High Court or, in Scotland, the Court of Session;

[[F833]"holder of a temporary authorisation" means, where there is in force in relation to a medicinal product an authorisation by the licensing authority on a temporary basis under regulation 174 (but not an authorisation, certificate or registration as mentioned in regulation **[**[F834]281(1)(a) to (e)**]**), the person who is responsible for placing that product on the market in the United Kingdom;**]**

"injunction" (except in regulation 313) includes an interim injunction;

"OFCOM" means the Office of Communications;

"person qualified to prescribe or supply medicinal products" includes—

(a) persons who, in the course of their profession or in the course of a business, may lawfully—

(i) prescribe medicinal products,

(ii) sell medicinal products by retail, or

(iii) supply medicinal products in circumstances corresponding to retail sale; and

(b) employees of such persons;

"publication", in relation to an advertisement, means the dissemination or issue of that advertisement—

(a) orally;

(b) in writing;

(c) by means of an electronic communications network within the meaning of the Communications Act 2003 [M73]; or

(d) in any other way,

and includes causing or procuring such publication by or on behalf of another person, and "publish" has a corresponding meaning.

(2) In the application of this Part to Scotland—

(a) references to an injunction are to be read as references to an interdict; and

(b) references to an interim injunction are to be read as references to an interim interdict.

Textual Amendments

F833 Words in reg. 277(1) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **16** and words in reg. 277(1) inserted

(N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **16**

F834 Words in reg. 277(1) substituted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **10** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **10**

Marginal Citations

M73 2003 c.21.

Functions of the Ministers

278. A function of the Ministers under this Part may be exercised by either of them acting alone or both of them acting jointly (and references in this Part to "the Ministers" are to be read accordingly).

CHAPTER 2

Requirements relating to advertising

General

Products without a marketing authorisation etc

[[F835]**279.**—(1) A person may not publish an advertisement in Great Britain for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(GB) or UKMA(UK);

[[F836](aa) an authorisation by the licensing authority on a temporary basis under regulation 174;**]**

(b) a COR(GB) or COR(UK); or

(c) a THR(GB) or THR(UK).

(2) A person may not publish an advertisement in Northern Ireland for a medicinal product unless one of the following is in force for the product—

(a) a UKMA(NI) or UKMA(UK);

[[F837](aa) an authorisation by the licensing authority on a temporary basis under regulation 174;**]**

(b) a COR(NI) or COR(UK);

(c) a THR(NI) or THR(UK);

(d) an EU marketing authorisation; or

(e) an Article 126a authorisation.

(3) A person may not publish an advertisement in the whole United Kingdom for a medicinal product unless, in relation to that product—

(a) one of the authorisations or registrations specified in paragraph (1) is in force in Great Britain; and

(b) one of the authorisations or registrations specified in paragraph (2) is in force in Northern Ireland.**]**

Textual Amendments

F835 Reg. 279 substituted (31.12.2020) by S.I. 2019/775, **reg. 211** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 167**)

F836 Reg. 279(1)(aa) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **11(a)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350, regs. 1(3), **11(a)**

F837 Reg. 279(2)(aa) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **11(b)** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **11(b)**

General principles

280.—(1) A person may not publish an advertisement for a medicinal product with a **[**[F838]UK marketing authorisation, EU marketing authorisation,**]** traditional herbal registration or Article 126a authorisation unless the advertisement complies with the particulars listed in the summary of the product characteristics.

[[F839](1A) Where an advertisement mentioned in paragraph (1) relates to a product in relation to which there is a separate authorisation or registration in force in Great Britain and in Northern Ireland, it may not be published in the whole United Kingdom unless it complies with the particulars listed in the summary of the product characteristics in each of those authorisations or registrations (as the case may be).**]**

(2) A person may not publish an advertisement for a medicinal product unless the advertisement encourages the rational use of the product by presenting it objectively and without exaggerating its properties.

(3) A person may not publish an advertisement for a medicinal product that is misleading.

[[F840](4) A person may not publish an advertisement for a medicinal product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174 (but not an authorisation, certificate or registration as mentioned in regulation **[**[F841]281(1)(a) to (e)**]**), unless it is published as part of a campaign that has been approved by the Ministers.**]**

Textual Amendments

F838 Words in reg. 280(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 212(a)** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(b)**)

F839 Reg. 280(1A) inserted (31.12.2020) by S.I. 2019/775, **reg. 212(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(c)**)

F840 Reg. 280(4) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **18** and reg. 280(4) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **18**

F841 Words in reg. 280(4) substituted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **12** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **12**

Duties of authorisation holders and registration holders

281.—(1) This regulation applies to a person who holds—

(a) a **[**F842UK**]** marketing authorisation for a medicinal product;

(b) a certificate of registration for a medicinal product;

(c) a traditional herbal registration for a medicinal product; F843...

(d) an Article 126a authorisation for a medicinal product **[**F844; or

(e) an EU marketing authorisation for a medicinal product.**]**

[F845(1A) Paragraphs (3) to (5) apply to the holder of a temporary authorisation in relation to a medicinal product.**]**

(2) The person must establish a scientific service to compile and collate all information relating to the product (whether received from medical sales representatives employed by that person or from any other source).

(3) The person must ensure that any medical sales representative who promotes the product is given sufficient training, and has sufficient scientific knowledge, to enable the representative to provide information about the product that is as precise and complete as possible.

(4) The person must retain—

(a) a sample of any advertisement for which the person is responsible relating to the product; and

(b) a statement indicating the persons to whom the advertisement is addressed, the method of its publication and the date when it was first published.

(5) The person must, if required to do so by notice given to the person by the Ministers, within the period specified in that notice—

(a) provide a copy of the sample and statement mentioned in paragraph (4) to the Ministers;

(b) supply such other information as the Ministers may request for the purposes of their functions under this Part; or

(c) provide such assistance as the Ministers may request for those purposes.

Textual Amendments

F842 Word in reg. 281(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **213(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F843 Word in reg. 281(1)(c) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 213(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 169**)

F844 Reg. 281(1)(e) and word inserted (31.12.2020) by S.I. 2019/775, **reg. 213(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 169**)

F845 Reg. 281(1A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **19** and reg. 281(1A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **19**

Advertising to the public

Application of regulations 283 to 292

282. Regulations 283 (products for the purpose of inducing abortions) to 292 (exception for approved vaccination campaigns) apply to advertisements wholly or mainly directed at members of the public

Products for the purpose of inducing abortions

283. A person may not publish an advertisement that is likely to lead to the use of a medicinal product for the purpose of inducing an abortion.

Prescription only medicines

284.—(1) A person may not publish an advertisement that is likely to lead to the use of a prescription only medicine.

(2) This regulation is subject to **[**F846regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F846 Words in reg. 284(2) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **20** and words in reg. 284(2) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **20**

[F847Medicines with differing classification status in Great Britain and Northern Ireland

284A. In the case of a medicinal product for sale or supply in Great Britain where the product concerned is not a prescription only medicine in Great Britain but is either—

(a) a prescription only medicine in Northern Ireland; or

(b) not authorised for sale or supply in Northern Ireland,

any advertisement to the public must include a statement that the medicinal product is not available without a prescription, or is not available for sale or supply, in Northern Ireland (as the case may be).**]**

Textual Amendments

F847 Reg. 284A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **213A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 170**)

Narcotic and psychotropic substances

285.—(1) A person may not publish an advertisement relating to a medicinal product that—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(2) This regulation is subject to **[**F848regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F848 Words in reg. 285(2) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **21** and words in reg. 285(2) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **21**

Material relating to diagnosis

286.—(1) A person may not publish an advertisement relating to a medicinal product that states, or implies, that a medical consultation or surgical operation is unnecessary.

(2) A person may not, in particular, publish an advertisement relating to a medicinal product that offers to provide a diagnosis or suggest a treatment by post or by means of an electronic communications network within the meaning of the Communications Act 2003.

(3) A person may not publish an advertisement relating to a medicinal product that might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.

Material about effects of medicinal product

287.—(1) A person may not publish an advertisement relating to a medicinal product that suggests that the effects of taking the medicinal product—

(a) are guaranteed;

(b) are better than or equivalent to those of another identifiable treatment or medicinal product; or

(c) are not accompanied by any adverse reaction.

(2) A person may not publish an advertisement relating to a medicinal product that uses in terms that are misleading or likely to cause alarm pictorial representations of—

(a) changes in the human body caused by disease or injury; or

(b) the action of the medicinal product on the human body.

(3) A person may not publish an advertisement relating to a medicinal product that refers in terms that are misleading or likely to cause alarm to claims of recovery.

(4) A person may not publish an advertisement relating to a medicinal product that suggests that—

(a) the health of a person who is not suffering from any disease or injury could be enhanced by taking the medicinal product; or

(b) the health of a person could be affected by not taking the medicinal product.

(5) Paragraph (4)(b) is subject to **[**F849regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.) and**]** regulation 292 (exception for approved vaccination campaigns).

Textual Amendments

F849 Words in reg. 287(5) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **22** and words in reg. 287(5) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **22**

Material about status of medicinal product

288. A person may not publish an advertisement relating to a medicinal product that suggests that—

(a) it is a foodstuff, cosmetic or other consumer product that is not a medicinal product; or

(b) its safety or efficacy is due to the fact that it is natural.

Recommendations by scientists etc

289. A person may not publish an advertisement relating to a medicinal product that refers to a recommendation by—

(a) scientists;

(b) health care professionals; or

(c) persons who because of their celebrity could encourage use of the medicinal product.

Advertisements directed at children

290. A person may not publish an advertisement relating to a medicinal product that contains any material that is directed principally at children.

Form and content of advertisement

291.—(1) A person may not publish an advertisement relating to a medicinal product unless it is presented so that—

(a) it is clear that it is an advertisement; and

(b) the product is clearly identified as a medicinal product.

(2) A person may not publish an advertisement relating to a medicinal product unless it includes—

(a) the name of the medicinal product;

(b) if the medicinal product contains only one active ingredient, the common name of the active ingredient;

(c) the information necessary for the correct use of the medicinal product; and

(d) an express and clear invitation to read carefully the instructions on the package or in the package leaflet (as the case may be).

(3) This regulation is subject to regulation 296 (exception for advertisements intended as a reminder).

(4) Paragraph (2) is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

[[F850](5) Paragraph (2)(d) is subject to regulation 291A (campaigns relating to the suspected or confirmed spread of pathogenic agents etc.).**]**

Textual Amendments

F850 Reg. 291(5) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **23** and reg. 291(5) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **23**

[F851Campaigns relating to the suspected or confirmed spread of pathogenic agents etc.

291A.—(1) Regulations 284 (prescription only medicines), 285 (narcotic and psychotropic substances), 287(4)(b) (material about effects of a medicinal product) and 291(2)(d) (form and content of advertisement) do not apply to an advertisement as part of a campaign that—

(a) relates to the use of a medicinal product in response to the suspected or confirmed spread of—

(i) pathogenic agents,

(ii) toxins,

(iii) chemical agents, or

(iv) nuclear radiation; and

(b) has been approved by the Ministers.

(2) Before approving a campaign that relates to—

(a) all or any area of Scotland, the Ministers must consult the Scottish Ministers;

(b) all or any areas of Wales, the Ministers must consult the Welsh Ministers.**]**

Textual Amendments

F851 Reg. 291A inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **24** and reg. 291A inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **24**

Exception for approved vaccination campaigns

292. Regulations 284 (prescription only medicines), 285 (narcotic and psychotropic substances) and 287(4)(b) (material about effects of medicinal products) do not apply to an advertisement as part of a vaccination campaign that—

(a) relates to a medicinal product that is a vaccine or serum; and

(b) has been approved by the Ministers.

Prohibition of supply to the public for promotional purposes

Prohibition of supply to the public for promotional purposes

293.—**[**F852(1) The holder of **[**F853either a temporary authorisation or**]**—

(a) in the case of a medicinal product for sale or supply in Great Britain, a UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK); or

(b) in the case of a medicinal product for sale or supply in Northern Ireland, a UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation or Article 126a authorisation,

may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.**]**

(2) A person who carries on a medicines business may not sell or supply a medicinal product for a promotional purpose to a person who is not qualified to prescribe medicinal products.

(3) This regulation applies regardless of whether the promotional purpose is that of the seller or supplier or of a third party.

(4) In this regulation "medicines business" means a business that consists in whole or in part of manufacturing, selling or supplying medicinal products.

Textual Amendments

F852 Reg. 293(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 214** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 171**)

F853 Words in reg. 293(1) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **13** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **13**

Advertising to persons qualified to prescribe or supply etc

General requirements

294.—(1) This regulation applies to an advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not publish an advertisement to which this regulation applies unless—

(a) subject to **[**[F854]paragraphs (2C) and (3),**]** it contains the particulars set out in paragraphs 1 to 8 of Schedule 30; and

(b) in the case of a written advertisement, it is in accordance with paragraph 9 of that Schedule.

[[F855](2A) By way of an exception to paragraph (2), in the case of an advertisement that relates to a pharmacy medicine or a medicinal product subject to general sale, a person may publish the advertisement if it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30; and

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a website address that corresponds to that statement.

(2B) The website at the address mentioned in paragraph (2A)(c) must make available—

(a) the particulars set out in paragraphs 1 to 8 of Schedule 30; or

(b) a copy of the summary of the product characteristics.**]**

[[F856](2C) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(3) In the case of an advertisement that is not a written advertisement, those particulars may alternatively be made available in written form to all persons to whom the advertisement is made available.

(4) This regulation—

(a) does not apply to an advertisement to which regulation 295 (abbreviated advertisements) applies;

(b) does not apply to oral representations made by medical sales representatives to which regulation 299 (medical sales representatives) applies; and

(c) is subject to regulations 296 (exception for advertisements intended as a reminder) and 301 (advertisements for registered homoeopathic medicinal products).

[F857(5) In the case of an advertisement which relates to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

Textual Amendments

F854 Words in reg. 294(2)(a) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(2)** and words in reg. 294(2)(a) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(2)**

F855 Reg. 294(2A)(2B) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **24(2)** and reg. 294(2A)(2B) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **24(2)**

F856 Reg. 294(2C) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **26(3)** and reg. 294(2C) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **26(3)**

F857 Reg. 294(5) inserted (31.12.20200 by S.I. 2019/775, **reg. 214A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 172**)

Abbreviated advertisements

295.—(1) This regulation applies to an abbreviated advertisement that—

(a) relates to a medicinal product; and

(b) is wholly or mainly directed at persons qualified to prescribe or supply such products.

(2) A person may not issue an abbreviated advertisement to which this regulation applies unless it contains—

(a) the particulars set out in paragraphs 2 to 6 of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply);

(b) the statement "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"; accompanied by

(c) a web site address that corresponds to that statement; and

[F858(d) the name and address of the holder **[**F859of either the temporary authorisation or**]**—

(i) in the case of a medicinal product for sale or supply in Great Britain, of the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK) for the medicinal product, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, the name and address of the holder of the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisation, or Article 126a authorisation for the medicinal product,

or the business name and address of the part of the holder's business that is responsible for the sale or supply of the medicinal product.**]**

(3) The web site at the address mentioned in sub-paragraph (2)(c) must make available—

(a) the particulars set out in Schedule 30; or

(b) a copy of the summary of the product characteristics.

(4) In this regulation, "abbreviated advertisement" means an advertisement, other than a loose insert, that—

(a) does not exceed 420 square centimetres in size; and

(b) appears in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products.

[F860(4A) In the application of this regulation to a medicinal product for sale or supply—

(a) in Northern Ireland only, the requirements of this regulation must be met in relation to the product for sale or supply in Northern Ireland,

(b) in Great Britain only, the requirements of this regulation must be met in relation to the product for sale or supply in Great Britain, and

(c) in the whole of the United Kingdom, the requirements of this regulation must be met in relation to both—

(i) the product for sale or supply in Great Britain, and

(ii) the product for sale or supply in Northern Ireland.**]**

(5) This regulation is subject to regulation 301 (advertisements for registered homoeopathic medicinal products).

Textual Amendments

F858 Reg. 295(2)(d) substituted (31.12.2020) by S.I. 2019/775, **reg. 215(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

F859 Words in reg. 295(2)(d) inserted (31.12.2020 immediately after S.I. 2019/775 comes into force) by The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.I. 2020/1594), regs. 1(3), **14** and The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (S.R. 2020/350), regs. 1(3), **14**

F860 Reg. 295(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 215(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**)

Exception for advertisements intended as a reminder

296. Regulations 291 (form and content of advertisement) and 294 (general requirements) do not apply to an advertisement relating to a medicinal product if the advertisement is intended solely as a reminder of the product and consists solely of—

(a) in the case of a product other than a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name or trademark; and

(b) in the case of a homoeopathic medicinal product to which a certificate of registration relates, its name, international non-proprietary name, invented name or trademark or the scientific name of the stock or stocks from which it is derived.

Written material accompanying promotions

297.—(1) A person may not as part of the promotion of a medicinal product send or deliver any written material to a person qualified to prescribe or supply medicinal products unless the material—

(a) **[**[F861]subject to paragraph (1A),**]** contains particulars in accordance with all the paragraphs of Schedule 30; and

(b) states the date on which it was drawn up or last revised.

[[F862](1A) Paragraph 1 of Schedule 30 does not apply in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis under regulation 174.**]**

(2) A person may not include any information in written material to which paragraph (1) applies unless it—

(a) is accurate;

(b) is up-to-date;

(c) can be verified; and

(d) is sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product to which it relates.

(3) A person may not include any illustrative material in written material to which paragraph (1) applies unless—

(a) the illustrative material is accurately reproduced; and

(b) the written material indicates the precise source of the illustrative material.

(4) In this regulation "illustrative material" means a quotation, table or any other illustrative material taken from a medical journal or other scientific work.

Textual Amendments

F861 Words in reg. 297(1)(a) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(2)** and words in reg. 297(1)(a) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(2)**

F862 Reg. 297(1A) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **28(3)** and reg. 297(1A) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **28(3)**

Free samples for persons qualified to prescribe or supply medicinal products

298.—(1) A person ("the supplier") may not supply a free sample of a medicinal product to another person ("the recipient") unless the following conditions are met.

(2) Condition A is that the recipient—

(a) is qualified to prescribe medicinal products; and

(b) receives the sample for the purpose of acquiring experience in dealing with the product in question.

(3) Condition B is that the sample is supplied to the recipient—

(a) on an exceptional basis; and

(b) in response to a request from, and signed and dated by, the recipient.

(4) Condition C is that, taking the year in which the sample is supplied as a whole, only a limited number of samples of the product in question are supplied to the recipient in that year.

(5) Condition D is that the sample—

[F863(a) is no larger than the smallest presentation of the product that is available for sale—

(i) in the case of a medicinal product for sale or supply in Great Britain, in Great Britain, or

(ii) in the case of a medicinal product for sale or supply in Northern Ireland, in Northern Ireland;**]**

(b) is marked "free medical sample – not for resale" or bears a similar description; and

(c) is accompanied by a copy of the summary of the product characteristics.

(6) Condition E is that the sample does not contain—

(a) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

(7) Condition F is that the supplier maintains an adequate system of control and accountability in relation to the supply of free samples.

Textual Amendments

F863 Reg. 298(5)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 215A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 174**)

Medical sales representatives

299.—(1) This regulation applies in relation to the promotion by a medical sales representative of medicinal products to persons qualified to prescribe or supply such products.

(2) During each visit for promotional purposes the representative must give to, or have available for, each person visited a copy of the summary of the product characteristics for each product promoted.

(3) The representative must report all information, with particular reference to any adverse reactions, that—

(a) is received from persons visited for promotional purposes; and

(b) relates to the use of a product promoted,

to the scientific service established in accordance with regulation 281(2) by the holder of the **[**[F864]UK marketing authorisation, EU marketing authorisation**]** certificate of registration, traditional herbal registration or Article 126a authorisation for the product.

Textual Amendments

F864 Words in reg. 299(3) substituted (31.12.2020) by S.I. 2019/775, **reg. 217** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 176**); 2020 c. 1, **Sch. 5 para. 1(1)**

Inducements and hospitality

300.—(1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is—

(a) inexpensive; and

(b) relevant to the practice of medicine or pharmacy.

(2) A person may not provide hospitality at a meeting or event held for the purposes of the promotion of a medicinal product unless—

(a) the hospitality is strictly limited to the main purposes of the meeting or event; and

(b) the person to whom it is provided or offered is a health care professional.

(3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that—

(a) the hospitality is strictly limited to the main scientific objective of the event; and

(b) the person to whom it is provided or offered is a health care professional.

(4) A person qualified to prescribe or supply medicinal products may not solicit or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.

(5) In this regulation "hospitality" includes—

(a) sponsorship of a person's attendance at a meeting or event; and

(b) the payment of travelling or accommodation expenses.

(6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

Homoeopathic medicinal products

Advertisements for registered homoeopathic medicinal products

301.—(1) A person may not publish an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates unless the advertisement meets the following conditions.

(2) Condition A is that the advertisement does not mention any specific therapeutic indications.

(3) Condition B is that the advertisement does not contain any details other than those mentioned in Schedule 28 (labelling requirements for registrable homoeopathic medicinal products).

(4) Nothing in regulation 291(2) (form and content of advertisement), 294 (general requirements) or 295 (abbreviated advertisements) requires an advertisement relating to a homoeopathic medicinal product to which a certificate of registration relates to contain any detail not specified in Schedule 28.

Traditional herbal medicinal products

Advertisements for traditional herbal medicinal products

302. A person may not publish an advertisement relating to a herbal medicinal product to which a traditional herbal registration relates unless it contains—

(a) the words "Traditional herbal medicinal product for use in"; followed by

(b) a statement of one or more therapeutic indications for the product consistent with the terms of the registration; followed by

(c) the words "exclusively based on long standing use".

Offences

Offences

303.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Chapter.

(2) A breach of a provision in this Chapter includes any—

(a) contravention by any person of any prohibition in this Chapter; and

(b) failure by any person to comply with any requirement or obligation in this Chapter.

(3) A person guilty of an offence under this regulation other than one to which paragraph (4) applies is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(4) This paragraph applies to an offence consisting of a breach of—

(a) regulation 298(1) (free samples);

(b) regulation 299(2) or (3) (medical sales representatives); or

(c) regulation 300(4) (solicitation or acceptance of inducements or hospitality).

(5) A person guilty of an offence to which paragraph (4) applies is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

CHAPTER 3

Monitoring of Advertising

Scrutiny by Ministers

Requirement to provide copy advertisement

304.—(1) The Ministers may give a notice in writing under paragraph (2) or (3) to any person appearing to them to be concerned or likely to be concerned with the publication of advertisements relating to medicinal products.

(2) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers within a specified period with a copy of any advertisement that, as at the date of service of the notice, the person has published or proposes to publish and that relates to—

(a) a specified medicinal product; or

(b) medicinal products of a specified class or description.

(3) A notice under this paragraph is a notice that requires the person to whom it is given to provide the Ministers with a copy of any advertisement that the person proposes to publish during a specified period and that relates to—

(a) a specified medicinal product; or

(b) medicinal products of a specified class or description.

(4) The period specified in a notice under paragraph (3) must not exceed 12 months.

(5) A notice under paragraph (3) must specify the number of days before the proposed publication date of any advertisement by which a copy of the advertisement must be provided to the Ministers.

(6) A notice under paragraph (3) may be withdrawn by the Ministers before the expiry of the specified period.

(7) A notice under paragraph (2) or (3) may require the person to whom it is given not to publish, or further publish, during a specified period any advertisement a copy of which the person is required by the notice to provide to the Ministers.

(8) A notice under paragraph (2) or (3) must give the Ministers' reasons for giving the notice and (if appropriate) for imposing a requirement under paragraph (7).

(9) In this regulation "specified" means specified in the notice.

Invitation to make representations about compatibility

305.—(1) This regulation applies if, having considered an advertisement a copy of which is obtained by them pursuant to a notice given under regulation 304 or by some other means, the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2.

(2) The Ministers may give a notice in writing under this regulation to any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) A notice under this regulation must—

[[F865](a) state that the Ministers are minded to make a determination under regulation 306 that the advertisement is incompatible with the prohibitions imposed by Chapter 2 and specify whether the incompatibility is insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland;**]**

(b) give the reasons why they are minded to make the determination;

(c) state that the person to whom it is given may make written representations to the Ministers within the period of 21 days beginning immediately after the date of the notice as to why the advertisement is compatible with the prohibitions imposed by Chapter 2; and

(d) refer to the action that may be taken by the Ministers under regulation 306.

(4) A notice under this regulation may require the person to whom it is given not to publish, or to cease to publish, the advertisement

[[F866](a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

Textual Amendments

F865 Reg. 305(3)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 217A(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F866 Reg. 305(4)(a)-(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 217A(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

Decision about compatibility

306.—(1) This regulation applies if the Ministers have given a notice under regulation 305 ("the original notice") to a person.

(2) After the end of the period of 21 days referred to in that regulation, the Ministers must give a further notice in writing ("the new notice") to that person of their determination whether the advertisement is compatible with the prohibitions imposed by Chapter 2 **[**F867and specify whether the incompatibility is insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

(3) In making that determination, the Ministers must take account of any representations made in accordance with that regulation.

(4) If—

(a) the Ministers make a determination that the advertisement is compatible with the prohibitions imposed by Chapter 2 **[**F868insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland**]**; and

(b) the original notice imposed a requirement under regulation 305(4),

the new notice must provide that the requirement no longer applies **[**F869 in Great Britain, Northern Ireland, or both Great Britain and Northern Ireland (as appropriate)**]**.

(5) The following provisions apply if the Ministers make a determination that the advertisement is incompatible with the prohibitions imposed by Chapter 2 **[**F870insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

(6) The new notice must give the Ministers' reasons for the determination.

(7) If the original notice imposed a requirement under regulation 305(4), the new notice may provide—

(a) that the requirement is to continue to apply; or

(b) that the requirement no longer applies **[**F871,

and where that original notice related to both Great Britain and Northern Ireland, the new notice may be expressed to apply in relation to either of or both Great Britain and Northern Ireland**]**.

(8) If the original notice did not impose a requirement under regulation 305(4), the new notice may require the person to whom it is given not to publish, or to cease to publish, the advertisement

[F872(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland**]**.

Textual Amendments

F867 Reg. 306(2)(a)-(c) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F868 Reg. 306(4)(a)(i)-(iii) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(b)(i)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F869 Words in reg. 306(4) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(b)(ii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F870 Reg. 306(5)(a)-(c) and words inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F871 Words in reg. 306(7)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(d)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F872 Reg. 306(8)(a)-(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 217B(e)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

Corrective statement

307.—(1) This regulation applies if the new notice—

(a) maintains the application of a requirement imposed under regulation 305(4) to cease to publish the advertisement that is the subject of the notice **[**F873in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland**]**; or

(b) imposes a requirement to cease to publish that advertisement **[**F874in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland**]**.

(2) The new notice may require the person to whom it is given to publish—

(a) the Ministers' reasons for making the determination that the advertisement was incompatible with the prohibitions imposed by Chapter 2 **[**F875in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

either in full or in part; and**]**

(b) a corrective statement concerning the advertisement.

(3) A requirement imposed under paragraph (2)—

(a) must specify the time within which publication must take place; and

(b) may specify the form of publication.

Textual Amendments

F873 Reg. 307(1)(a)(i)-(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217C(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F874 Reg. 307(1)(b)(i)-(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217C(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F875 Reg. 307(2)(a)(i)-(iii) and words substituted for words (31.12.2020) by S.I. 2019/775, **reg. 217C(c)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

Offences

308.—(1) A person is guilty of an offence if that person fails to comply with a requirement imposed by a notice given to that person under—

(a) regulation 304(2) or (3);

(b) regulation 305(4) (including such a notice as maintained under regulation 306(7)); or

(c) regulation 306(8).

(2) A person guilty of an offence under paragraph (1) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.

(3) A person is guilty of an offence if that person fails to comply with a requirement imposed on that person under regulation 307(2).

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Complaints to Ministers

Complaints to Ministers: duty to consider

309.—(1) This regulation applies if a person makes a complaint to the Ministers that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by Chapter 2.

(2) Subject to the following provisions of this regulation and to regulation 310, the Ministers must consider the complaint unless it appears to the Ministers to be frivolous or vexatious.

(3) The Ministers are not under any duty to consider a complaint if either OFCOM or a body that appears to the Ministers to be a self-regulatory body that deals with complaints about advertisements of the type in question is already dealing with the same complaint.

(4) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) they—

(a) may consider the complaint; but

(b) are not under any duty to do so.

(5) If the complaint is one that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314) the Ministers must—

(a) investigate the complaint; or

(b) seek the agreement of the complainant to the complaint being referred to OFCOM.

(6) If, within a reasonable time of being approached by the Ministers, the complainant agrees to the complaint being referred to OFCOM the Ministers must refer the complaint to OFCOM.

(7) If, within a reasonable time of being approached by the Ministers, the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.

(8) The Ministers must also consider the complaint if, having referred it to OFCOM, OFCOM—

(a) decides not to consider the complaint because it appears to OFCOM to be frivolous or vexatious; or

(b) fails to deal adequately with the complaint within a reasonable time of the referral being made.

Complaints to Ministers: power to refer

310.—(1) This regulation applies if—

(a) a person ("the complainant") makes a complaint within paragraph (2) to the Ministers that an advertisement that has been published, or that it is proposed be published, is incompatible with the prohibitions imposed by Chapter 2; and

(b) the complaint does not appear to the Ministers to be frivolous or vexatious.

(2) A complaint is within this paragraph if—

(a) it is a complaint that the advertisement contains material prohibited by any of regulations 286 to 290, but is not a complaint that OFCOM would be under a duty to consider if it had been made to OFCOM (see regulation 314); or

(b) it is a complaint that the advertisement is incompatible with any of the prohibitions imposed by regulations 294 to 300.

(3) The Ministers may—

(a) select a body that appears to them to be a self-regulatory body that deals with complaints about advertisements of the type in question ("the appropriate body"); and

(b) seek the agreement of the complainant to the complaint being referred to the appropriate body.

(4) If within a reasonable time of being approached by the Ministers the complainant agrees to the complaint being referred to the appropriate body, the Ministers must refer the complaint to that body.

(5) If within a reasonable time of being approached by the Ministers the complainant does not agree to the referral of the complaint, the Ministers must consider the complaint.

(6) The Ministers must also consider the complaint if, having referred it to the appropriate body—

(a) the appropriate body decides not to consider the complaint because it appears to the body to be frivolous or vexatious; or

(b) the Ministers think that the appropriate body has failed to deal adequately with the complaint within a reasonable time of the referral being made.

(7) But if the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306)—

(a) the duties in paragraphs (4) to (6) do not apply; and

(b) each of those paragraphs has effect as if it conferred a power on the Ministers to act as mentioned in that paragraph.

Injunctions

Application for injunction

311.—(1) This regulation applies—

(a) if the Ministers consider that an advertisement that has been published, or that is proposed to be published, is incompatible with the prohibitions imposed by **[**[F876]Chapter 2 in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland; and**]**

(b) whether or not a complaint has been made to the Ministers or to any other person.

(2) The Ministers may apply to the court for an injunction against any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement.

(3) On the making of an application under paragraph (2), the court may grant an injunction prohibiting the publication, or further publication, of the advertisement **[**[F877]in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

as the case may be.**]**

(4) An injunction granted under paragraph (3) may also prohibit the publication, or further publication, of any advertisement in similar terms or likely to convey a similar impression.

(5) The court may not refuse to grant an injunction for lack of evidence that—

(a) the publication, or proposed publication, of the advertisement has given rise to loss or damage to any person; or

(b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.

(6) The court must give its detailed reasons in writing for its decision to grant or refuse an injunction.

(7) Where the court grants an injunction, the Ministers must as soon as is reasonably practicable provide the following in writing to each person against whom the injunction has been granted—

(a) the court's reasons for granting the injunction;

(b) any remedy available in the court; and

(c) the time limit to be met for any remedy to be available.

Textual Amendments

F876 Reg. 311(1)(a)(i)-(iii) substituted for words in reg. 311(1)(a) (31.12.2020) by S.I. 2019/775, **reg. 217D(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

F877 Reg. 311(3)(i)(iii) inserted (31.12.2020) by S.I. 2019/775, **reg. 217D(b)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**)

Application for injunction: accuracy of factual claim

312.—(1) This regulation applies if—

(a) an application for an injunction is made under regulation 311; and

(b) the advertisement in question makes a factual claim about the medicinal product to which it relates.

(2) The court may require any person appearing to it to be responsible for the advertisement to provide evidence as to the accuracy of the factual claim.

(3) The court may impose a requirement under paragraph (2)—

(a) on the application of any party to the proceedings for the injunction; or

(b) of its own motion.

(4) In deciding whether or not to impose a requirement under paragraph (2) the court must have regard to the interests of any person who would be subject to, or affected by, the requirement.

(5) A requirement imposed under paragraph (2) must specify the time within which the evidence must be provided.

(6) If the person on whom a requirement is imposed under paragraph (2) fails to comply with it the court may infer that the factual claim is inaccurate.

(7) A person may fail to comply with a requirement imposed under paragraph (2) by—

(a) not providing any evidence; or

(b) providing evidence that the court considers inadequate.

Grant of injunction: publication of decision and corrective statement

313.—(1) This regulation applies if the court grants an injunction under regulation 311, other than an interim injunction, in respect of an advertisement that has been published.

(2) The Ministers may by notice in writing require any person against whom the injunction has been granted to publish—

(a) all or part of the court's decision; and

(b) a corrective statement concerning the advertisement in respect of which the application for the injunction was made.

(3) A requirement imposed under paragraph (2)—

(a) must specify the time within which publication must take place; and

(b) may specify the form of publication.

(4) If a person ("P") fails to comply with a requirement imposed under paragraph (2) the Ministers may certify that failure to the court and the court may enquire into the matter.

(5) If the court enquires into the matter it must as part of its enquiry—

(a) hear any witnesses produced against or on behalf of P; and

(b) consider any statement offered in P's defence.

(6) If having conducted its enquiry the court is satisfied that P failed without reasonable excuse to comply with a requirement imposed under paragraph (2) it may deal with P as if P were in contempt of court.

Complaints to OFCOM

Complaints to OFCOM

314.—(1) This regulation applies if OFCOM—

(a) receives from a person a complaint that an advertisement that contains material prohibited by any of regulations 286 to 290 ("prohibited material") has been included in—

(i) a licensed service, or

(ii) S4C Digital or a service provided by the Welsh Authority under section 205 of the Communications Act 2003 [M74] ("the 2003 Act"); or

(b) has a complaint as described in sub-paragraph (a) referred to it by the Ministers under regulation 309(5) and (6).

(2) OFCOM must consider the complaint unless—

(a) the complaint appears to it to be frivolous or vexatious; or

(b) paragraph (3) applies.

(3) If the Ministers have served a notice in respect of the advertisement under regulation 305 (whether or not they have taken action in respect of it under regulation 306) OFCOM—

(a) may consider the complaint; but

(b) is not subject to any duty to do so.

(4) If, having considered the complaint, OFCOM considers that the advertisement contains prohibited material it may—

(a) in the case of an advertisement that has been included in a licensed service, give to the person who is the holder of the licence in respect of that service a direction to exclude the advertisement from the licensed service; and

(b) in the case of an advertisement that has been included in S4C Digital or a service provided by the Welsh Authority under section 205 of the 2003 Act, give to the Welsh Authority a direction to exclude the advertisement from S4C Digital or the service provided under section 205 of the 2003 Act.

(5) If OFCOM gives a direction under paragraph (4), it may also give a direction to the licence holder or (as the case may be) the Welsh Authority to exclude from the service any advertisement in similar terms or likely to convey a similar impression.

(6) In deciding whether or not to exercise its power to give a direction under paragraph (4), OFCOM must disregard any lack of evidence that—

(a) the publication of the advertisement has given rise to loss or damage to any person; or

(b) the person responsible for the advertisement intended it to be incompatible with the prohibitions imposed by Chapter 2 or failed to exercise proper care to prevent it from being so incompatible.

(7) A direction given under this regulation to a licence holder is to be treated for the purposes of the 2003 Act as a direction with respect to a matter mentioned in section 325(5) of that Act.

(8) A direction given under this regulation to the Welsh Authority is to be treated for the purposes of the Communications Act 2003 Act as a direction with respect to a matter mentioned in paragraph 14(2) of Schedule 12 to that Act.

(9) If OFCOM gives a direction under this regulation, it must inform the licence holder or (as the case may be) the Welsh Authority in writing of its reasons for doing so.

(10) In this regulation—

"licensed service" means a service in respect of which OFCOM has granted a licence under Part 1 or 3 of the Broadcasting Act 1990 [M75] or Part 1 or 2 of the Broadcasting Act 1996 [M76];

"S4C Digital" means the television service provided in digital form and known as S4C Digital; and

"Welsh Authority" means the authority whose name is, by virtue of section 56(1) of the Broadcasting Act 1990 [M77], Sianel Pedwar Cymru.

Marginal Citations

M74 2003 c.21.

M75 1990 c.42.

M76 1996 c.55.

M77 Section 56(1) was amended by section 406(7) of and Schedule 19(1) to the Communications Act 2003.

General

Public interest etc

315. In exercising the functions conferred on them by this Chapter, the Ministers, the court and OFCOM must have regard, in particular, to the public interest.

Civil proceedings

316. In exercising the functions conferred on them by this Chapter, the Ministers may institute civil proceedings in their own name.

PART 15

British Pharmacopoeia

British Pharmacopoeia and compendia

317.—(1) The British Pharmacopoeia Commission (in this Part referred to as "the BPC") must, at such intervals as it thinks appropriate, prepare or cause to be prepared editions of the British Pharmacopoeia, containing such relevant information relating to substances, combinations of substances and articles falling within paragraph (2) as the BPC thinks appropriate.

(2) The substances, combinations of substances, and articles falling within this paragraph are—

(a) substances, combinations of substances and articles (whether medicinal products or not) which are or may be used in the practice of medicine or surgery (other than veterinary medicine or veterinary surgery), dentistry or midwifery; and

(b) substances, combinations of substances and articles used in the manufacture of anything falling within paragraph (a).

(3) The BPC may also, at such intervals as it thinks appropriate, prepare or cause to be prepared—

(a) a compendium (other than the British Pharmacopoeia) containing such relevant information relating to substances, combinations of substances and articles within paragraph (2) as the BPC thinks appropriate; and

(b) a compendium containing such relevant information as the BPC thinks appropriate in relation to—

(i) substances, combinations of substances and articles (whether veterinary medicinal products or not) which are or may be used in the practice of veterinary medicine or veterinary surgery; and

(ii) substances, combinations of substances and articles used in the manufacture of anything falling within sub-paragraph (i).

(4) The Ministers must arrange for the publication of anything prepared or caused to be prepared by the BPC under this regulation.

(5) In this Part—

(a) a reference to preparing a thing or causing it to be prepared includes amending it, or causing it to be amended;

(b) a reference to publication includes publication by electronic means; and

(c) "relevant information", in relation to a substance, combination of substances or article, means information consisting of descriptions of, standards for, or notes or other matter relating to the substance, combination of substances or article.

Lists of names

318.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared a list of names which appear to it to be suitable—

(a) to be used as the names of substances, combinations of substances or articles falling within regulation 317(2) or (3)(b); and

(b) to be placed at the head of monographs relating to those substances, combinations of substances or articles in any edition of the British Pharmacopoeia or in a compendium prepared under that regulation.

(2) Where a list has been prepared in accordance with paragraph (1), the Ministers must cause it to be published.

Other documents

319.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared other documents (in addition to those falling within regulation 317 or 318) containing such relevant information relating to substances, combinations of substances or articles falling within regulation 317(2) or (3)(b) as the BPC thinks appropriate.

(2) Where a document has been prepared in accordance with paragraph (1), the Ministers may cause it to be published.

Supplementary provisions

320.—(1) Anything published in accordance with a provision of this Part (other than regulation 319 ("a publication") must specify the date on which it is to take effect.

(2) The Ministers must give notice of the date mentioned in paragraph (1) by notices published in the London, Edinburgh and Belfast Gazettes not less than 21 days before that date.

(3) Where in any proceedings an enforcement authority produces a copy of a publication, it shall be presumed that the copy is a true copy of the edition of that publication that was in force at the time when the events that are the subject of the proceedings took place, unless evidence is adduced to the contrary.

Specified publications

321.—(1) In this regulation "specified publication" means any of the following—

(a) the European Pharmacopoeia;

(b) the British Pharmacopoeia;

(c) the Cumulative List of Recommended International Nonproprietary Names;

(d) a compendium prepared and published under regulation 317; or

(e) a list of names prepared and published under regulation 318.

(2) Paragraph (3) applies if an authorisation refers to a specified publication, but not to a particular edition of the publication.

(3) Where this paragraph applies, in order to determine whether anything done at a time when the authorisation is in force is done in accordance with the authorisation, the reference to a specified publication is to be construed as a reference to the edition of the specified publication in force at that time, unless the authorisation expressly provides otherwise.

(4) In paragraph (3) the reference to the edition of a specified publication in force at a particular time is a reference to the edition of that publication in force, under whatever title, at that time.

(5) In this regulation "authorisation" means any of the following—

(a) a manufacturer's licence;

(b) a wholesale dealer's licence;

(c) a **[**F878UK**]** marketing authorisation;

[F879(ca) an EU marketing authorisation;**]**

(d) an Article 126a authorisation;

(e) a certificate of registration; or

(f) a traditional herbal registration.

Textual Amendments

F878 Word in reg. 321(5)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **218(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F879 Reg. 321(5)(ca) inserted (31.12.2020) by S.I. 2019/775, **reg. 218(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 178**)

PART 16

Enforcement

Validity of decisions and proceedings

322.—(1) The validity of a decision of the licensing authority under Parts 3 (manufacturing and wholesale dealing), 5 (UK marketing authorisations), 6 (certification of homoeopathic medicinal products), 7 (traditional herbal medicinal products) or 8 (Article 126a authorisations) is not to be questioned in any legal proceedings.

(2) The validity of a licence, authorisation, certificate or registration granted or issued, or other thing done, in pursuance of a decision of a kind mentioned in paragraph (1) is not to be questioned in any legal proceedings.

(3) Paragraphs (1) and (2) are subject to the following provisions of this regulation.

(4) A person to whom notice of the decision is given may make an application to the High Court to challenge the validity of the decision on the grounds that—

(a) the decision is not within the powers conferred on the licensing authority; or

(b) a requirement of these Regulations in connection with the matter to which the decision relates has not been complied with.

(5) An application under paragraph (4) must be made within the period of three months beginning immediately after the day on which notice of the decision is given to the applicant.

(6) On an application under paragraph (4) the High Court may—

(a) make an interim order suspending the operation of the decision to which the application relates until the final determination of proceedings; or

(b) quash the decision, if satisfied that—

(i) the decision is not within the powers conferred by these Regulations, or

(ii) the interests of the applicant have been substantially prejudiced by a failure to comply with a requirement under these Regulations.

(7) If a decision to grant a licence, authorisation, certificate or registration is quashed under this regulation—

(a) a licence, authorisation, certificate or registration granted in pursuance of the decision is void; and

(b) the application process for the grant of the licence, authorisation, certificate or registration may be continued as if the decision had not been made.

(8) In the application of this regulation to Scotland, references to the High Court are to be construed as references to the Court of Session.

Modifications etc. (not altering text)

C5 Reg. 322 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Enforcement in England, Wales and Scotland

323.—(1) The Secretary of State must enforce or secure the enforcement of these Regulations [F880]... in England, Wales and Scotland.

(2) The Secretary of State may make arrangements for either or both of—

(a) the General Pharmaceutical Council; or

(b) in respect of each area for which there is a drugs authority, the drugs authority for the area,

to enforce the provisions of these Regulations listed in paragraph (3) to the extent specified in the arrangements.

(3) The provisions referred to in paragraph (2) are—

(a) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (offences relating to dealings with medicinal products: compliance with standards specified in certain publications);

(b) Part 13 (packaging and leaflets); [F881]... **[**[F882]and**]**

(c) Part 14 Chapter 2 (requirements relating to advertising); **[**[F883]and

F884(d) . . . . . .]

(4) Arrangements made with the General Pharmaceutical Council under paragraph (2)(a) in relation to Part 14 Chapter 2 are to be limited to the enforcement of those provisions in respect of—

(a) advertisements displayed or representations made on or in any premises where medicinal products are sold by retail or supplied in circumstances corresponding to retail sale;

(b) advertisements displayed on any web site associated with such premises; and

(c) advertisements displayed on, or in close proximity to, a vending machine in which medicinal products are offered or exposed for sale.

F885(4A) . . . . . .

(5) The General Pharmaceutical Council must continue to enforce—

(a) regulations 214 (sale or supply of prescription only medicines) and 220 (sale or supply of medicines not subject to general sale); and

(b) in their application to or in relation to premises that are registered pharmacies, the provisions of these Regulations to which paragraph (7) applies.

(6) In each area for which there is a drugs authority, that drugs authority must continue to enforce the provisions of these Regulations to which paragraph (7) applies in their application to or in relation to premises that are not registered pharmacies.

(7) This paragraph applies to regulations 221 (sale or supply of medicinal products subject to general sale) and 222 (sale of medicinal products from automatic machines).

(8) Functions conferred by virtue of paragraphs (2), (5) and (6) are to be exercised concurrently with the Secretary of State.

(9) Nothing in this regulation confers a function on a person in relation to—

(a) a hospital (except so much of the hospital as is a registered pharmacy); or

(b) so much of any premises as is used as a doctor's or dentist's practice.

(10) In this regulation "drugs authority" means—

(a) in England—

(i) in relation to a non-metropolitan county, metropolitan district or London borough, the council of that county, district or borough, and

(ii) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London;

(b) in Wales, the council of a county or county borough; and

(c) in Scotland, a council constituted in relation to a local government area under section 2 of the Local Government etc (Scotland) Act 1994 M78.

(11) In this Part "premises" includes—

(a) any place; and

(b) a ship, aircraft, hovercraft or vehicle.

(12) Nothing in this regulation is to be construed as authorising any person other than the Lord Advocate or a procurator fiscal to institute proceedings in Scotland for an offence.

Textual Amendments

F880 Words in reg. 323(1) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **220(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F881 Word in reg. 323(3)(b) omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **14(a)(i)** and word in reg. 323(3)(b) omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **14(a)(i)**

F882 Word in reg. 323(3)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **220(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F883 Reg. 323(3)(d) and preceding word inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **14(a)(ii)** and reg. 323(3)(d) and preceding word inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **14(a)(ii)**

F884 Reg. 323(3)(d) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **220(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F885 Reg. 323(4A) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **220(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

C6 Reg. 323(1) applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M78 1994 c.39. There is an amendment to section 2(1) that is not relevant to this regulation.

Enforcement in Northern Ireland

324.—(1) The Minister for Health, Social Services and Public Safety (in this regulation referred to as "the Minister") must enforce or secure the enforcement of these Regulations and the relevant EU provisions in Northern Ireland.

(2) The Minister may make arrangements for a district council to enforce the provisions of these Regulations listed in paragraph (3) in its district to the extent specified in the arrangements.

(3) Those provisions are—

(a) regulations 221 (sale or supply of medicinal products subject to general sale), 222 (sale of medicinal products from automatic machines) and 255(6) (certain offences relating to dealings with medicinal products);

(b) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (certain offences relating to dealings with medicinal products);

(c) Part 13 (packaging and leaflets); and

(d) Part 14 Chapter 2 (requirements relating to advertising).

(4) Functions conferred by virtue of paragraph (2) are to be exercised concurrently with the Minister.

(5) Regulation 323(9) has effect in relation to functions conferred by this regulation as it has effect in relation to functions conferred by regulation 323.

(6) In this regulation, "district council" means a council established under the Local Government Act (Northern Ireland) 1972 [M79].

Modifications etc. (not altering text)

C7 Reg. 324(1) applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M79 1972 c.9 (N.I.).

Rights of entry

325.—(1) An inspector may at any reasonable time enter premises—

(a) in order to determine whether there has been a contravention of a provision of these Regulations which the enforcement authority is required or empowered to enforce by virtue of regulations 323 and 324;

(b) in order to verify whether the data submitted in respect of an active substance used as a starting material in order to obtain a conformity certificate issued by the European Directorate for the Quality of Medicines and Healthcare ("EDQM") comply with the monographs of the European Pharmacopoeia, if the EDQM asks the enforcement authority to do so; and

(c) for the purposes of any other function of the enforcement authority under these Regulations.

(2) A person may not exercise a right of entry under this regulation in relation to premises used only as a private dwelling unless 24 hours' notice has been given to the occupier.

(3) A person exercising, or attempting to exercise, a right of entry under this regulation must produce identification on request.

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Application for warrant

326.—(1) In a case where this regulation applies, a justice of the peace may issue a warrant authorising an inspector to enter premises, by force if necessary.

(2) This regulation applies if, on sworn information in writing, the justice of the peace is satisfied that—

(a) there are reasonable grounds for entering the premises by virtue of the enforcement authority's functions under these Regulations;

(b) an inspector has a right to enter them by virtue of regulation 325; and

(c) a condition specified in paragraph (3) is satisfied.

(3) Those conditions are—

(a) that—

(i) admission to the premises has been refused or is expected to be refused, and

(ii) notice of the intention to apply for a warrant has been given to the occupier;

(b) that a request for admission, or the giving of notice, would defeat the object of the entry;

(c) that the case is one of urgency; or

(d) that the premises are unoccupied or the occupier is temporarily absent.

(4) In relation to a ship, aircraft, hovercraft or vehicle, references in this Part to the occupier of premises are to be read as references to the master, commander or other person in charge of the ship, aircraft, hovercraft or vehicle.

(5) A warrant granted under this regulation continues in force for a period of 30 days beginning with the day on which the warrant is granted.

(6) In the application of this regulation to England, references to a justice of the peace include a reference to a district judge (magistrates' courts).

(7) In the application of this regulation to Scotland, references to a justice of the peace are to be read as references to a sheriff, stipendiary magistrate or justice of the peace.

(8) In the application of this regulation to Northern Ireland, references to a justice of the peace are to be read as references to a lay magistrate or a district judge (magistrates' courts).

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Powers of inspection, sampling and seizure

327.—(1) An inspector may inspect anything mentioned in paragraph (2)—

(a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority must or may enforce by virtue of regulations 323 and 324;

(b) for the purpose described in regulation 325(1)(b) (verification of data at the request of the European Directorate for the Quality of Medicines and Healthcare); or

[[F886](c) in relation to an application under Parts 3 or 5 to 8 in order to verify any statement made by an applicant for—

(i) a manufacturer's licence,

(ii) a wholesale dealer's licence,

(iii) a brokering registration,

(iv) registration as an importer, manufacturer or distributor of active substances,

(v) a **[**[F887]UK**]** marketing authorisation,

[[F888](va) an EU marketing authorisation;**]**

(vi) a certificate of registration,

(vii) a traditional herbal registration, or

(viii) an Article 126a authorisation;

(d) in relation to a person's notification to sell medicinal products at a distance under Part 12A.**]**

[[F889](2) The things mentioned in paragraph (1) are—

(a) a substance or article appearing to the inspector to be a medicinal product or an active substance;

(b) an article appearing to the inspector to be—

(i) a container or package used or intended to be used to contain a medicinal product or an active substance, or

(ii) a label or leaflet used or intended to be used in connection with a medicinal product or an active substance;

(c) plant or equipment, including computer equipment, appearing to the inspector to be used or intended to be used in connection with the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;

(d) any process of manufacture or assembly of medicinal products or active substances;

(e) the way in which medicinal products or active substances, or the materials used in the manufacture of medicinal products or active substances, are tested at any stage in the process of manufacture or assembly;

(f) information and documents relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;

(g) information and documents relating to the safety of medicinal products or active substances, including information and documents relating to compliance with—

(i) conditions imposed under any of regulations 59 (conditions of UK marketing authorisation: general), 60 (conditions of UK marketing authorisation: exceptional circumstances), 61 (conditions of UK marketing authorisation: new obligations post-authorisation) or 105 (conditions of certificate of registration),

(ii) the requirements of Part 11 (pharmacovigilance),

(iii) obligations and conditions under Articles 10a(1), 14(7), 14(8), 16 or 57(2) of Regulation (EC) No 726/2004,

(iv) the requirements of Chapter 3 (pharmacovigilance) of Title II of Regulation (EC) No 726/2004,

[[F890](iva) the requirements of Schedule 12A (further provision as to the performance of pharmacovigilance activities);**]**

(v) the requirements of the Implementing Regulation as defined in regulation 177(5) (pharmacovigilance: interpreting provision), and

(vi) obligations under regulations 75 (obligation to provide information relating to safety) and 76 (obligation in relation to product information);

[[F891](h) information and documents relating to compliance with the requirements of Commission Regulation 2016/161C.**]**

(3) The inspector may for the purposes specified in paragraph (1) take or purchase a sample of a substance or article which appears to the inspector to be—

(a) a medicinal product or an active substance which is, or is intended to be, sold or supplied; or

(b) a substance or article used, or intended to be used, in the manufacture of a medicinal product or an active substance.

(4) The inspector may for the purposes specified in paragraph (1) require a person carrying on a business which consists of or includes the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances, or a person employed in connection with such a business, to produce information or documents relating to the business which are in the person's possession or under the person's control.**]**

[[F892](4A) The inspector may for the purposes specified in paragraph (1) require a legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161, or a person employed in connection with such a entity, to produce information or documents relating to the repositories system which are in the entity's possession or under the entity's control.**]**

(5) The inspector may take copies of information or documents—

(a) inspected under sub-paragraph (2)(f)**[**F893, (g) or (h);**]** or

(b) produced under paragraph (4) **[**F894or (4A)**]**.

[F895(6) The inspector may seize and retain a substance or article appearing to the inspector to be a medicinal product or an active substance if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that substance or article.**]**

(7) The inspector may, if the inspector reasonably believes that it may be required as evidence in proceedings, seize and retain—

(a) any document; or

(b) anything inspected, or discovered in the course of an inspection, under paragraph (1).

(8) The inspector may, if necessary, require a person who has the authority to do so—

(a) to open a container or package;

(b) to open a vending machine; or

(c) to allow the inspector to open a container, package or vending machine,

for the purpose of enabling the inspector to seize a substance, article, document or other thing under paragraph (6) or (7).

(9) The information and documents referred to in this regulation include any that are stored electronically.

Textual Amendments

F886 Reg. 327(4)(c)(d) substituted for reg. 327(4)(c) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **29(2)**

F887 Word in reg. 327(1)(c)(v) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **221(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F888 Reg. 327(1)(c)(va) inserted (31.12.2020) by S.I. 2019/775, **reg. 221(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(a)**)

F889 Reg. 327(2)-(4) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **29(3)**

F890 Reg. 327(2)(g)(iva) inserted (31.12.2020) by S.I. 2019/775, **reg. 221(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(b)**)

F891 Reg. 327(2)(h) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **15(a)** and reg. 327(2)(h) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **15(a)**

F892 Reg. 327(4A) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **15(b)** and reg. 327(4A) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **15(b)**

F893 Words in reg. 327(5)(a) substituted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **15(c)** and words in reg. 327(5)(a) substituted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **15(c)**

F894 Words in reg. 327(5)(b) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **15(d)** and words in reg. 327(5)(b) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **15(d)**

F895 Reg. 327(6) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **29(4)**

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Regulation 327: supplementary

328.—(1) Where an inspector seizes a substance, article, document or other thing under regulation 327(6) or (7) (powers of inspection, sampling and seizure) the inspector—

(a) must, where practicable, inform—

(i) the person, if any, from whom it was seized, and

(ii) the occupier of the premises from which it was seized; or

(b) in relation to anything seized from a vending machine, must inform—

(i) the person whose name and address are stated on the machine to be those of the machine's owner, or

(ii) if no name and address are stated, the occupier of the premises on which the machine stands or to which it is affixed.

(2) An inspector exercising, or attempting to exercise, a right under regulation 327 must produce identification on request.

(3) The provisions of Schedule 31 have effect in relation to samples obtained by inspectors on behalf of enforcement authorities.

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Application of sampling procedure to substance or article seized under this Part

329.—(1) This regulation applies where an inspector seizes a substance or article under regulation 327 (powers of inspection, sampling and seizure).

(2) On request in accordance with paragraph (3), the inspector must either—

(a) set aside a sample of the substance or article seized; or

(b) treat the substance or article as a sample,

whichever seems more appropriate having regard to the nature of the substance or article.

(3) A request is made in accordance with this paragraph if—

(a) it is made by a person ("P") who is entitled to be informed of the seizure under regulation 328; and

(b) it is made either at the time of the seizure or within the period of 21 days beginning with the day immediately after the day on which P is informed of the seizure.

(4) An inspector is not required by paragraph (2) to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

(5) An inspector must—

(a) divide a sample under paragraph (2) into three parts;

(b) mark each part;

(c) seal or fasten each part; and

(d) supply one part to P.

(6) Paragraphs 10 to 12 and 15 to 26 of Schedule 31 apply to a sample under this regulation as they apply to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if—

(a) references to the preceding provisions of that Schedule were references to the preceding provisions of this regulation;

(b) references to a sampling officer were references to an inspector who seized a substance or article under regulation 327 (powers of inspection, sampling and seizure); and

(c) a reference to the relevant enforcement authority were a reference to the authority by which the inspector is authorised.

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Analysis of samples: other cases

330.—[F896(1) This regulation applies where a person other than an inspector or a person authorised by an enforcement authority has purchased an active substance or a medicinal product.

(2) The person may submit a sample of the active substance or medicinal product for analysis to the public analyst for the area in which the active substance or medicinal product was purchased or, if for the time being there is no public analyst for the area, to the public analyst for another area.]

(3) Paragraphs 2 to 13 of Schedule 31 have effect, in relation to a person proposing to submit a sample in pursuance of paragraph (2), as if in that Schedule references to the sampling officer were references to that person.

(4) A public analyst to whom a sample is submitted under this regulation must analyse the sample, or cause it to be analysed, as soon as practicable (but this is subject to the following provisions of this regulation).

(5) If the public analyst to whom a sample is submitted thinks that a proper analysis cannot be carried out for any reason, the public analyst must send it to the public analyst for some other area, who must as soon as practicable analyse the sample, or cause it to be analysed (subject to paragraph 6).

(6) A public analyst to whom a sample is submitted or sent under this regulation may demand payment in advance of the required fee, and if payment in advance is demanded may refuse to carry out the analysis until the fee is paid.

(7) A public analyst who has analysed a sample or caused it to be analysed must issue a certificate specifying the result of the analysis to the person by whom the sample was submitted under paragraph (2).

(8) Paragraphs 21 to 23 of Schedule 31 have effect in relation to a certificate issued under this regulation as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) In this regulation "public analyst"—

(a) in relation to England and Wales and Scotland has the meaning given by section 27 of the Food Safety Act 1990 M80; and

(b) in relation to Northern Ireland has the meaning given by Article 27(1) of the Food Safety (Northern Ireland) Order 1991 [M81].

Textual Amendments

F896 Reg. 330(1)(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **30**

Modifications etc. (not altering text)

C8 Regs. 325-330 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M80 1990 c.16. Section 27 was amended by the Local Government etc (Scotland) Act 1994 section 180(1) and Schedule 18 paragraph 163(3), the Food Standards Act 1999 section 40(1) and Schedule 5 paragraphs 7 and 8, the Local Government (Wales) Act 1994 section 22(3) and Schedule 9 paragraph 16(2), S.I. 1994/865 regulation 24, and the Local Government and Public Involvement in Health Act 2007 sections 22 and 241, Schedule 1 Part 2 paragraph 17, and Schedule 18 Part 1.

M81 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.

Findings and reports of inspections

331.—(1) If the outcome of the inspection of things referred to in regulation 327(2)(g) (powers of inspection, sampling and seizure: information and documents relating to safety etc) is that the holder of a **[**[F897]UK marketing authorisation, EU marketing authorisation**]** or traditional herbal registration does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file, or any provision of Part 11 (pharmacovigilance), the enforcement authority must—

(a) bring the deficiencies to the attention of the holder;

(b) give the holder the opportunity to submit comments; and

(c) **[**[F898]in the case of a product authorised under a UKMA(NI) or UKMA(UK),**]** inform the other EEA States, the EMA and the European Commission.

(2) Paragraph (1) is without prejudice to paragraphs (3) and (5).

(3) After every inspection carried out in accordance with regulations 325 (rights of entry) and 327 (powers of inspection, sampling and seizure) in connection with medicinal products other than registrable homoeopathic medicinal products, the enforcement authority must report on whether the activities to which the inspection relates comply with such of the provisions mentioned in paragraph (4) as apply to those activities.

(4) Those provisions are—

(a) the Good Manufacturing Practice Directive and any principles or guidelines of good manufacturing practice referred to in Article 47 of the 2001 Directive;

[[F899](b) the guidelines on good distribution practice—

(i) in the case of Great Britain, published under, or that apply by virtue of, regulation C17;

(ii) in the case of Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive;**]**

(c) in the case of the holder of a marketing authorisation or traditional herbal registration—

(i) Part 11 (pharmacovigilance), and

(ii) Chapter 3 (pharmacovigilance) of Title II (authorisation and supervision of medicinal products for human use) of Regulation (EC) No 726/2004.

[[F900](d) Schedule 12A; and

(e) the Implementing Regulation (as defined in regulation 177(5)).**]**

(5) The enforcement authority must before adopting the report —

(a) communicate the content of the report to the person to whose activities the inspection relates; and

(b) give that person the opportunity to submit comments.

Textual Amendments

F897 Words in reg. 331(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 222(2)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(a)**)

F898 Words in reg. 331(1)(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 222(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(a)**)

F899 Reg. 331(4)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 222(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(b)**)

F900 Reg. 331(4)(d)(e) inserted (31.12.2020) by S.I. 2019/775, **reg. 222(3)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(b)**)

[[F901]Guidelines on inspections

331A.—(1) The licensing authority may publish guidelines specifying the principles applicable to inspections referred to in this Part.

(2) Guidelines under paragraph (1) may include the form and content of reports under regulation 331 and of certificates of good manufacturing practice or good distribution practice.

(3) Until the licensing authority exercises its power under paragraph (1), the guidelines adopted by the European Commission under Article 111a of the 2001 Directive, as they had effect immediately before IP completion day, are to continue to apply.**]**

Textual Amendments

F901 Reg. 331A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **223** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 182**); 2020 c. 1, **Sch. 5 para. 1(1)**

Restrictions on disclosure of information

332.—(1) A person ("P") must not disclose to another person, otherwise than in the performance of P's functions—

(a) any information relating to a manufacturing process or trade secret obtained by P on premises which P has entered by virtue of regulation 325 or of a warrant under regulation 326; or

(b) any information obtained by P or given to P in pursuance of these Regulations.

(2) Paragraph (1) does not apply if—

(a) P is, or is acting on behalf of, a public authority for the purposes of the Freedom of Information Act 2000 [M82]; and

(b) the information is not held by the authority on behalf of another person.

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M82 2000 c.36.

Protection for inspectors

333.—(1) An inspector is not personally liable in respect of any act done in the execution, or purported execution, of a function under these Regulations and within the scope of the inspector's employment by an enforcement authority (or, where the inspector is not employed by the authority, the scope of the inspector's authorisation), provided that the act was done in the honest belief that these Regulations required or permitted it.

(2) Where an action is brought against an inspector in respect of an act falling within paragraph (1), the enforcement authority may indemnify the inspector against any damages, costs or expenses incurred, if the authority is satisfied that the inspector honestly believed that these Regulations required or permitted the act.

(3) Paragraph (2) applies in a case where the person is not legally entitled to require an indemnity from the enforcement authority.

(4) A reference to an inspector in this regulation includes a reference to an employee of the licensing authority who accompanies an inspector pursuant to regulation 334(1).

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Supplementary provisions and offences

334.—(1) An inspector entering any premises by virtue of regulation 325 or of a warrant under regulation 326 may be accompanied by such persons, and take such equipment, as the inspector thinks appropriate.

(2) Where an inspector enters premises in pursuance of a warrant under regulation 326, the inspector must, if the property is unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespass as they were before the inspector entered.

(3) It is an offence for a person—

(a) intentionally to obstruct an inspector;

(b) intentionally to fail to comply with a requirement properly made under regulation 327 by an inspector; or

(c) without reasonable cause, to fail to give an inspector any other assistance or information which the inspector may reasonably require in order to perform a function under these Regulations.

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(5) A person who knowingly makes a false statement in giving information as mentioned in paragraph (3)(c) is guilty of an offence.

(6) A person who breaches the prohibition in regulation 332(1) (restrictions on disclosure of information) is guilty of an offence.

(7) A person who is guilty of an offence under paragraph (5) or (6) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

(8) Nothing in this regulation is to be read as requiring a person to answer a question or to give information if doing so might incriminate that person or the spouse or civil partner of that person.

(9) In this regulation "occupier", in relation to a ship, aircraft, or vehicle, is to be read in accordance with regulation 326(4).

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

PART 17

Miscellaneous and general

Provisions relating to offences

Contravention due to fault of another person

335.—(1) This regulation applies where—

(a) a contravention of a provision referred to in paragraph (6) constitutes an offence; and

(b) a person ("A") contravenes the provision by reason of the act or omission of another person ("B").

(2) B may be charged with and convicted of the offence, whether or not proceedings are also brought against A.

(3) If B is convicted B is liable to the same punishment as would have been imposed on A if A had been convicted of the offence.

(4) If A is charged with the offence it is a defence for A to prove on the balance of probabilities that—

(a) A exercised all due diligence to avoid contravening the provision; and

(b) the contravention was due to the act or omission of B.

(5) A may not rely on the defence in paragraph (4) unless not later than seven clear days before the date of the hearing A serves on the prosecutor a notice in writing of any information held by A which identifies, or assists in identifying, B.

(6) The provisions mentioned in paragraph (1) are—

(a) regulation 251 (compliance with standards specified in certain publications);

(b) regulations **[**F902268, 268A, 269 and 269A**]** (offences relating to packaging and package leaflets);

(c) regulation 273 (child resistant containers for regulated medicinal products);

(d) regulation 275 (colouring of aspirin and paracetamol products for children);

(e) any prohibition or requirement in Chapter 2 of Part 14 (advertising); and

(f) regulations 305(4) and 306(7) and (8) (notices not to publish, or to cease to publish, an advertisement.

Textual Amendments

F902 Words in reg. 335(6)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZA** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Warranty as defence

336.—(1) This regulation applies where proceedings are brought against a person ("the defendant") for an offence under these Regulations in respect of a contravention of a provision mentioned in paragraph (3).

(2) It is a defence for the defendant to prove that—

(a) the substance or article to which the contravention relates (the "relevant substance or article") was sold to the defendant in the United Kingdom as—

(i) a substance or article which could be lawfully sold, supplied or offered for sale or supply, or

(ii) a substance or article which could be lawfully sold, supplied or offered for sale or supply under the name or description or for the purpose under or for which it was sold;

(b) the relevant substance or article was sold with a written warranty certifying a matter specified in paragraph (a), and that if the warranty were true the alleged offence would not have been committed;

(c) at the time of the commission of the alleged offence the defendant had no reason to believe that the matter certified in the warranty was otherwise; and

(d) at the time of the commission of the alleged offence the relevant substance or article was in the same state as when the defendant purchased it.

(3) The provisions are—

(a) regulation 251 (compliance with standards specified in certain publications);

(b) regulations **[**F903268, 268A, 269 and 269A**]** (offences relating to packaging and package leaflets);

(c) regulation 273 (child resistant containers for regulated medicinal products); and

(d) regulation 275 (colouring of aspirin and paracetamol products for children).

(4) A warranty is not to be a defence under this regulation unless, no later than three clear days before the date of the hearing, the defendant sends to the prosecutor, and to the person who gave the warranty to the defendant—

(a) a copy of the warranty;

(b) a notice stating that the defendant intends to rely on it; and

(c) the name and address of the person from whom the defendant received the warranty.

(5) Where the defendant is an employee of the person who purchased the substance or article under the warranty, the defendant is entitled to rely on the provisions of this regulation in the same way as the employer.

(6) The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and to give evidence.

(7) The court may adjourn the hearing in order to enable a person to appear and give evidence in accordance with paragraph (6).

(8) For the purposes of this regulation, a name or description entered in an invoice is to be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description without contravening a provision mentioned in paragraph (3).

(9) In the application of this regulation and regulation 337 to Scotland, references to the defendant are to be construed as references to the accused.

Textual Amendments

F903 Words in reg. 336(3)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZB** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Offences in relation to warranties and certificates

337.—(1) It is an offence for a defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336 (3)—

(a) intentionally to apply a warranty given in relation to one substance or article to a different substance or article; or

(b) intentionally to apply to one substance or article a certificate issued under regulation 330 or paragraph 19 of Schedule 31 in relation to a sample of a different substance or article.

(2) A person who intentionally or recklessly gives a purchaser a false warranty certifying a matter specified in regulation 336(2)(a) is guilty of an offence.

(3) If the defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336(3) relies successfully on a warranty given

to the defendant or to the defendant's employer, proceedings for an offence under paragraph (2) may be brought in accordance with paragraph (4).

(4) Proceedings may be brought, as the prosecutor chooses—

(a) before a court which has jurisdiction in the place where a sample of the substance or article to which the warranty relates was taken; or

(b) before a court which has jurisdiction in the place where the warranty was given.

(5) A person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Offences by bodies corporate and partnerships

338.—(1) If an offence under these Regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, an officer of the body corporate, or a person purporting to act as an officer of the body corporate, that officer or person (as well as the body corporate) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(2) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and omissions of a member in connection with the member's functions of management as it applies to an officer of the body corporate.

(3) If an offence under these Regulations is—

(a) committed by a Scottish partnership; and

(b) proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, a partner of the partnership,

the partner (as well as the partnership) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(4) In this regulation "officer" in relation to a body corporate means a director, secretary or other similar officer of the body corporate.

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Prosecutions

Prosecutions

339.—(1) A magistrates' court in England or Wales may try an information for an offence under these Regulations that is triable only summarily if the information was laid at any time within the period of twelve months beginning with the commission of the offence.

(2) Summary proceedings in Scotland for an offence triable only summarily under these Regulations may be commenced at any time within the period of twelve months beginning with the commission of the offence (and section 136(3) of the Criminal Procedure (Scotland) Act 1995 [M83] applies for the purposes of this paragraph as it applies for the purposes of that section).

(3) A magistrates' court in Northern Ireland may hear and determine a complaint for an offence punishable on summary conviction under these Regulations, other than an offence which is also triable on indictment, if the complaint was made at any time within the period of twelve months beginning with the commission of the offence.

(4) A body referred to in regulation 323(2) (enforcement in England, Wales and Scotland) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under that regulation unless it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Secretary of State.

(5) A district council (as defined in regulation 324 (enforcement in Northern Ireland)) may not institute proceedings for an offence under these Regulations in relation to a contravention of a provision which it may or must enforce by virtue of arrangements made under regulation 324(2) unless it has given no less than 28 days' notice of its intention to do so, together with a summary of the facts on which the charges are founded, to the Minister for Health, Social Services and Public Safety.

(6) A certificate of the Secretary of State or of the Minister for Health, Social Services and Public Safety that the requirements of paragraph (4) or, as the case may be, (5) have been complied with is to be conclusive evidence that the requirements have been complied with, and a document purporting to be such a certificate is to be presumed to be such a certificate unless the contrary is proved.

Modifications etc. (not altering text)

C9 Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M83 1995 c. 46.

General

Presumptions

340.—(1) Paragraph (2) applies for the purposes of proceedings under these Regulations for an offence consisting of offering a medicinal product for sale by retail in contravention of regulation 220 (sale or supply of products not subject to general sale) or 221 (sale or supply of products subject to general sale).

(2) If it is proved that the medicinal product in question was found on a vehicle from which medicinal products are sold, it is to be presumed, unless the contrary is proved, that the person in charge of the vehicle offered the medicinal product for sale.

(3) Paragraph (4) applies for the purposes of proceedings under these Regulations for an offence consisting of a contravention of a provision within paragraph (5), where it is proved that the medicinal product in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products.

(4) It is to be presumed, unless the contrary is proved, that the person charged possessed the medicinal product for the purpose of sale or supply.

(5) The provisions within this paragraph are regulations **[**F904268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**]** and 276 (offences: requirements relating to child safety) to the extent that they establish an offence based on possession of a medicinal product for the purpose of sale or supply.

Textual Amendments

F904 Words in reg. 340(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZC** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

Decisions under these Regulations

341.—(1) Where the licensing authority notifies a person of a decision under these Regulations, it must—

(a) state its reasons for the decision; and

(b) inform the person of any action the person may take under these Regulations to challenge that decision and of the time for taking that action.

(2) Paragraph (1) is without prejudice to any other provision of these Regulations concerning notification by the licensing authority.

(3) The licensing authority must publicise any decision under these Regulations to which paragraph (4) applies in such manner as it thinks fit.

(4) Those decisions are—

(a) a decision to grant or revoke a **[**F905UK**]** marketing authorisation;

[F906(aa) a decision to grant or revoke an EU marketing authorisation;**]**

(b) a decision to grant or revoke a certificate of registration; and

(c) a decision to grant or revoke a traditional herbal registration.

Textual Amendments

F905 Word in reg. 341(4)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 224(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 184**)

F906 Reg. 341(4)(aa) inserted (31.12.2020) by S.I. 2019/775, **reg. 224(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 184**)

Time limits for provision of information etc

342.—(1) This regulation applies if—

(a) by any provision of these Regulations a person is required to provide—

(i) any information or document to the licensing authority or to the Ministers, or

(ii) any assistance to the licensing authority or to the Ministers; and

(b) no time is specified in that provision within which the obligation must be performed.

(2) The obligation must be performed within such time as may be specified in a written notice given to the person by the licensing authority or the Ministers (as the case may be).

Service of documents

343.—(1) A notice or other document required or authorised by any provision of these Regulations to be served on a person, or to be given or sent to a person, may be served, given or sent—

(a) by delivering it to the person;

(b) by sending it by post to the person's usual or last known residence or place of business in the United Kingdom;

(c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it by post to the secretary or clerk of the body corporate at that office; or

(d) in the case of a Scottish partnership by delivering it to a partner or by sending it by post to the address of the principal office of the partnership; or

(e) if the person consents in writing to the use of electronic communication, by a means of electronic communication.

(2) Where a notice or other document is sent by means of electronic communication it is treated for the purposes of these Regulations as received on the day on which it is sent, unless the contrary is proved.

Modifications etc. (not altering text)

C10 Reg. 343 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Payment of expenses by Ministers

344.—(1) If a person enforces a provision of these Regulations in accordance with functions conferred under Part 16 (enforcement), the relevant Minister must pay such amounts as the person may reasonably require in respect of expenses incurred in the course of enforcement.

(2) In paragraph (1) "the relevant Minister" means—

(a) in relation to enforcement in England, Wales, and Scotland, the Secretary of State; and

(b) in relation to enforcement in Northern Ireland, the Minister for Health, Social Services and Public Safety.

[F907Modifications to deal with serious shortages

344A.—(1) The Ministers may by regulations modify the application of any of the specified provisions in circumstances where the United Kingdom, or any part of the United Kingdom, is experiencing or may experience a serious shortage of medicinal products, or of medicinal products of a specified description, arising from the withdrawal of the United Kingdom from the European Union.

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that is being or may be experienced.

(3) For the purposes of paragraph (1), the "specified provisions" are the provisions of Parts 1, 3 to 5, 10 to 13 and 16, and of the associated Schedules.

(4) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where the withdrawal of the United Kingdom from the European Union is one but not the only significant factor contributing to the shortage.

(5) No regulations under paragraph (1) may be made, or have effect, after the end of the period of two years beginning with IP completion day.

Textual Amendments

F907 Regs. 344A, 344B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **225** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 185**); 2020 c. 1, **Sch. 5 para. 1(1)**

Regulation making powers

344B.—(1) Regulations made under a power in the regulations listed in paragraph (2)—

(a) are to be made by statutory instrument;

(b) may make different provision for different purposes and different areas; and

(c) may include incidental, supplemental, consequential, transitional, transitory or saving provisions, including consequential amendments to these Regulations.

(2) The regulations referred to in paragraph (1) are—

(a) regulation B17(1) and (4) (good manufacturing practice);

(b) regulation 50(5A) (Annex I to the 2001 Directive);

(c) regulation 50G(5) (orphan criteria etc);

(d) regulations 59(3A) and 61(7A) (post-authorisation efficacy studies);

(e) regulation 65C(7) (variations of UK marketing authorisations);

(f) regulation 102(7) (homoeopathic medicinal products);

(g) regulation 205A(2) (further obligations in respect of pharmacovigilance activities);

(h) regulation 257E (certain forms of labelling); and

(i) regulation 344A (modifications to deal with serious shortages).

(3) A statutory instrument containing regulations made under the powers listed in paragraph (2) is subject to annulment in pursuance of a resolution of either House of Parliament.**]**

Textual Amendments

F907 Regs. 344A, 344B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **225** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 185**); 2020 c. 1, **Sch. 5 para. 1(1)**

Immunity from civil liability

Immunity from civil liability

345.—(1) This regulation applies where the licensing authority makes a recommendation or requirement to which paragraph (2) applies in response to the suspected or confirmed spread of—

(a) pathogenic agents;

(b) toxins;

(c) chemical agents; or

(d) nuclear radiation,

which may cause harm to human beings.

(2) This paragraph applies to a recommendation or requirement—

(a) for the use of a medicinal product without an authorisation; or

(b) for the use of a medicinal product with an authorisation, but for a therapeutic indication that is not permitted under the authorisation.

(3) None of the following are to be subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement—

(a) any holder of an authorisation for the product;

[F908(aa) if there is no holder of an authorisation for the product but the sale or supply of the product is authorised by the licensing authority on a temporary basis under regulation 174, the person responsible for placing the product on the market in the United Kingdom;**]**

(b) any manufacturer of the product;

(c) any officer, servant, employee or agent of a person within **[**F909sub-paragraph (a), (aa) or (b);**]**

(d) any health care professional**[**F910; or**]**

[F911(e) any person, not being a health care professional, who administers the product in accordance with a protocol of the type mentioned in regulation 247A.**]**

(4) This regulation does not apply in relation to liability under section 2 (liability for defective products) of the Consumer Protection Act 1987M84 or article 5 of the Consumer Protection (Northern Ireland) Order 1987M85.

(5) In this regulation "authorisation" means a **[**F912UK marketing authorisation, EU marketing authorisation**]**, certificate of registration, traditional herbal registration or Article 126a authorisation.

Textual Amendments

F908 Reg. 345(3)(aa) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(a)** and reg. 345(3)(aa) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(a)**

F909 Words in reg. 345(3)(c) substituted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(b)** and words in reg. 345(3)(c) substituted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(b)**

F910 Word in reg. 345(3)(d) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(c)** and word in reg. 345(3)(d) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(c)**

F911 Reg. 345(3)(e) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **29(d)** and inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **29(d)**

F912 Words in reg. 345(5) substituted (31.12.2020) by S.I. 2019/775, **reg. 226** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 186**)

Marginal Citations

M84 1987 c.43. Section 2(4) was repealed in relation to England and Wales by S.I. 2000/2771 article 2(1) and (3) and in relation to Scotland by S.S.I. 2001/265 article 2(1) and (3).

M85 S.I. 1987/2049 (N.I. 20), as amended by 2001 c.13 (NI).

[F913Obligation on licensing authority to maintain list of medicinal products to which derogations have applied

345A.—(1) The licensing authority must publish a list of medicinal products to which the derogations described in Articles 5a, 8(2a) and (2b), 18a, 20 (second paragraph), 40(1a) and (3a), 48(3) and 104(3) of the 2001 Directive have applied.

(2) The licensing authority must update the list referred to in paragraph (1) at least every six months.**]**

Textual Amendments

F913 Reg. 345A inserted (17.5.2023) by The Human Medicines (Amendment) Regulations 2023 (S.I. 2023/437), regs. 1(1), **5**

Review

[F914Review

346.—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

(a) Chapters 1, 3 and 4 of Part 3;

(b) Parts 11 and 12A;

(c) regulations—

(i) **[**F915 18(6)**]**,

(ii) 20(1),

[F916(iia) 36(4) to (7),**]**

(iii) 37(4)(b), (5), (6), (11) and (12),

[F917(iiia) 42(4) and (5),**]**

(iv) 43(5), (6)(a) **[**F918and (d)**]**, 7(c)(iii) and (vii), (8) and (10) to (14),

[F919(iva) 43A,**]**

(v) 44(1) to (6),

(vi) 59,

(vii) 60(3)(b), (9) and (10),

(viii) 61,

(ix) 63,

(x) 64(4)(b), (d) and (e), (5)(a) and (6)(c),

(xi) 65(2),

(xii) 66(5) and (6),

(xiii) 68(2)(a) and (b), (5) and (12A),

(xiv) 69(2)(a) and (b), (5) and (10),

[F920(xiva) 73(5A) to (5C),**]**

(xv) 75(2)(b) and (c),

(xvi) 76,

(xvii) 79,

[F921(xviia) 82(1)(c),**]**

(xviii) 85,

(xix) 86,

F922(xixa) . . . . . .

(xx) 97,

(xxi) 105(3)(b),

(xxii) 107(2),

(xxiii) 108(5),

(xxiv) 110(8A),

[F923(xxiva) 113(3A),**]**

(xxv) 115(2)(b) and (c),

(xxvi) 132(2),

(xxvii) 133(5) and (6),

(xxviii) 135(10A),

[F924(xxviiia) 142(5A) to (5C),**]**

[F925(xxviiiaza) regulations 167A **[**F926to 167H**]**,**]**

[F927(xxviiiaa) regulation 174A,**]**

[F928(xxviiib) 213(3),**]**

[F929(xxviiiba) 214(5C) **[**F930and (5D)**]**,**]**

[F928(xxviiic) 217A,**]**

[F928(xxviiid) 218(2)(b) and (c), (3) and (5),**]**

[F931(xxviiie) 219 and 219A,**]**

[F932(xxviiiea) 223(3)(b),**]**

[F933(xxviiieb) 226A,**]**

[F934(xxviiieb) 228(2)(d)(iv),**]**

[F935(xxviiif) 229(1)(db) and (dc) **[**F936and (2)**]**,

[233(1)(a)(ivd) and (ive),**]**
F937(xxviiifa)

(xxviiig) 234(2)(e),**]**

[F938(xxviiiga) regulation 247A,**]**

[F939(xxviiih) 248(1)(a) and (2)(a),**]**

[F940(xxviiii) 255A to 255C,

(xxviiij) 257A,**]**

(xxix) 266(4) and (5),

(xxx) 327(2)(g) and insofar as the provision relates to active substances paragraphs (1)(c)(iii), (iv) and (viii), (2)(a) to (f), (3), (4) and (6),

(xxxi) 330(1) and (2),

(xxxii) 331, and

(xxxiii) regulation 349 insofar as it repeals section 10(7) of the Medicines Act 1968; and

(d) Schedules—

(i) 5 paragraphs 1(1)(b) to (d), (2)(b) to (d), 3(11)(b)(vi) to (viii), 5(2)(f) to (h),

F941(ia) . . . . . .

(ii) 7A,

(iii) 8 paragraphs 9A, 12, 13, 19 and 23,

(iv) 12 paragraph 21,

[F942(ivza) 16, Part 2 entries relating to "Public Health England" and "Public Health Agency" and Part 3 entries relating to "search and rescue operations",**]**

[F943(iva) 17, Part 1 items 12 and 13, Part 2 items 4a, 11 and 12, **[**F944Part 3 item 11,**]** Part 4 items 11 to 13 and Part 5 items 7a and 18 **[**F945to 20**]**,

(ivaa) 23, paragraph 1(a)(vii) to **[**F946(x)**]**,**]**

[F947(ivab) 24 paragraph 18A,**]**

[F948(ivb) 22, entries relating to "Public Health England", "Public Health Agency" and "search and rescue operations", and**]**

(v) 27 paragraphs 14 and 15.

(3) The Secretary of State must—

(a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and

(b) publish the report.

[F949(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how—

(a) the 2001 Directive;

(b) Directive 2010/84/EU of the European Parliament and of the Council of 15 October 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use;

(c) Article 11 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare;

(d) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products; and

(e) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State,

are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).**]**

(5) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b), (c)(i) to **[**[F950](xxxii)**]** and (d);

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.**]**

Textual Amendments

F914 Reg. 346 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **31**

F915 Word in reg. 346(2)(c)(i) substituted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(i)** and word in reg. 346(2)(c)(i) substituted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(i)**

F916 Reg. 346(2)(c)(iia) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(i)** and reg. 346(2)(c)(iia) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(i)**

F917 Reg. 346(2)(c)(iiia) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(ii)** and reg. 346(2)(c)(iiia) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(ii)**

F918 Words in reg. 346(2)(c)(iv) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(ii)** and words in reg. 346(2)(c)(iv) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(ii)**

F919 Reg. 346(2)(c)(iva) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(iii)** and reg. 346(2)(c)(iva) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(iii)**

F920 Reg. 346(2)(b)(xiva) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **8**

F921 Reg. 346(2)(b)(xviia) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **8**

F922 Reg. 346(2)(c)(xixa) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **227(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 187(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F923 Reg. 346(2)(b)(xxiva) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **8**

F924 Reg. 346(2)(b)(xxviiia) inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **8**

F925 Reg. 346(2)(c)(xxviiiaza) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **23**

F926 Words in reg. 346(2)(c)(xxviiiaza) substituted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **11** (with reg. 19)

F927 Reg. 346(2)(c)(xxviiiaa) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **30(a)** and reg. 346(2)(c)(xxviiiaa) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **30(a)**

F928 Reg. 346(2)(c)(xxviiib)-(xxviiie) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **9(2)(a)** and reg. 346(2)(c)(xxviiib)-(xxviiie) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **9(2)(a)**

F929 Reg. 346(2)(c)(xxviiiba) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(iii)** and reg. 346(2)(c)(xxviiiba) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(iii)**

F930 Words in reg. 346(2)(c)(xxviiiba) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(a)(i)** and words in reg. 346(2)(c)(xxviiiba) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(a)(i)**

F931 Reg. 346(2)(c)(xxviiie) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **8** and reg. 346(2)(c)(xxviiie) substituted (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **8**

F932 Reg. 346(2)(c)(xxviiiea) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(iv)** and reg. 346(2)(c)(xxviiiea) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(iv)**

F933 Reg. 346(2)(c)(xxviiieb) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(v)** and reg. 346(2)(c)(xxviiieb) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(v)**

F934 Reg. 346(2)(c)(xxviiieb) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(a)(ii)** and reg. 346(2)(c)(xxviiieb) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(a)(ii)**

F935 Reg. 346(2)(c)(xxviiif)(xxviiig) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **6(2)(a)** and reg. 346(2)(c)(xxviiif)(xxviiig) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **6(2)(a)**

F936 Words in reg. 346(2)(c)(xxviiif) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(v)** and words in reg. 346(2)(c)(xxviiif) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(v)**

F937 Reg. 346(2)(c)(xxviiifa) inserted (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **9(2)(a)** and reg. 346(2)(c)(xxviiifa) inserted (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **9(2)(a)**

F938 Reg. 346(2)(c)(xxviiiga) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **30(b)** and reg. 346(2)(c)(xxviiiga) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **30(b)**

F939 Reg. 346(2)(c)(xxviiih) inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(a)(vi)** and reg. 346(2)(c)(xxviiih) inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(a)(vi)**

F940 Reg. 346(2)(c)(xxviiii)(xxviiij) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(a)(vi)** and reg. 346(2)(c)(xxviiii)(xxviiij) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(a)(vi)**

F941 Reg. 346(2)(d)(ia) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **227(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 187(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F942 Reg. 346(2)(d)(ivza) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **6(2)(b)(i)** and reg. 346(2)(d)(ivza) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **6(2)(b)(i)**

F943 Reg. 346(2)(d)(iva)(ivaa) substituted for reg. 346(2)(d)(iva) (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **15(2)(b)(i)** and reg. 346(2)(d)(iva)(ivaa) substituted for reg. 346(2)(d)(iva) (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **15(2)(b)(i)**

F944 Words in reg. 346(2)(d)(iva) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **7** and words in reg. 346(2)(d)(iva) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **7**

F945 Words in reg. 346(2)(d)(iva) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(b)(i)** and words in reg. 346(2)(d)(iva) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(b)(i)**

F946 Word in reg. 346(2)(d)(ivaa) substituted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **11(2)(b)(ii)** and word in reg. 346(2)(d)(ivaa) substituted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **11(2)(b)(ii)**

F947 Reg. 346(2)(d)(ivab) inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **16(b)(ii)** and reg. 346(2)(d)(ivab) inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **16(b)(ii)**

F948 Reg. 346(2)(d)(ivb) inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **6(2)(b)(iii)** and reg. 346(2)(d)(ivb) inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **6(2)(b)(iii)**

F949 Reg. 346(4) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **9(3)** and reg. 346(4) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **9(3)**

F950 Word in reg. 346(5)(a) substituted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **9(4)** and word in reg. 346(5)(a) substituted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **9(4)**

Transitional provisions, savings, amendments, repeals and revocations

Transitional provisions and savings

347. Schedule 32 contains transitional provisions and savings.

[F951Transitional provision in relation to EU exit

347A. Schedule 33A contains transitional provision in relation to the EU Exit Regulations.**]**

Textual Amendments

F951 Reg. 347A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **228(1)**; 2020 c. 1, Sch. 5 para. 1(1)

Amendments to existing law

348. Schedule 34 contains amendments to existing law.

Repeals and revocations

349. Schedule 35 contains repeals and revocations.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State

Department of Health

Edwin Poots
Minister for Health, Social Services and Public Safety

SCHEDULES

SCHEDULE 1

Regulation 5

Further provisions for classification of medicinal products

PART 1

Descriptions of certain medicinal products to be available only on prescription

1. The following medicinal products shall be available only on prescription—

(a) a product for parenteral administration;

(b) a product that is a controlled drug **[**F952as defined in section 2(1)(a) of the Misuse of Drugs Act 1971**]**, unless it is covered by a **[**F953UK**]** marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale;

(c) cyanogenic substances, other than preparations for external use;

(d) medicinal substances that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;

(e) a product that—

(i) is covered by a **[**F954UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence**]** in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and

(ii) consists of or contains aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules;

(f) a product that—

(i) is covered by a **[**F955UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence**]** in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and

(ii) consists of or contains (in any pharmaceutical form) pseudoephedrine salts or ephedrine base or salts; F956...

(g) a product that—

(i) is not covered by a **[**F957UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence**]**, and

(ii) is a prescription only medicine by virtue of articles 5 and 10 of, and Schedules 1 and 2 to, the Prescription Only Medicines (Human Use) Order 1997 M86**[**F958; F959...**]**

[F960(h) a product which is authorised by the licensing authority on a temporary basis under regulation 174, in circumstances where the licensing authority has attached a condition to that authorisation to the effect that, for the duration of the temporary authorisation, the product is classified as a prescription only medicine **[**F961; and**]]**

[[F962](i) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, the product is classified as a prescription only medicine.**]**

Textual Amendments

F952 Words in Sch. 1 para. 1(b) inserted (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), **regs. 1(2)**, 10 and words in Sch. 1 para. 1(b) inserted (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **10**

F953 Word in Sch. 1 para. 1(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 8(a)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**)

F954 Words in Sch. 1 para. 1(e)(i) substituted (31.12.2020) by S.I. 2019/775, **reg. 8(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**)

F955 Words in Sch. 1 para. 1(f)(i) substituted (31.12.2020) by S.I. 2019/775, **reg. 8(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**)

F956 Word in Sch. 1 para. 1(f) omitted (6.11.2020) by virtue of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(a)** and word in Sch. 1 para. 1(f) omitted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(a)**

F957 Words in Sch. 1 para. 1(g)(i) substituted (31.12.2020) by S.I. 2019/775, **reg. 8(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**)

F958 Word in Sch. 1 para. 1(g) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(b)** and word in Sch. 1 para. 1(g) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(b)**

F959 Word in Sch. 1 para. 1(g) omitted (15.4.2022) by virtue of The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(2)(a)** (with reg. 19)

F960 Sch. 1 para. 1(h) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(2)(c)** and Sch. 1 para. 1(h) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(2)(c)**

F961 Word in Sch. 1 para. 1(h) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(2)(b)** (with reg. 19)

F962 Sch. 1 para. 1(i) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(2)(c)** (with reg. 19)

Marginal Citations

M86 S.I. 1997/1830, as amended by S.I. 1997/2044, S.I. 1998/108, S.I. 1998/1178, S.I. 1998/2081, S.I. 1999/1044, S.I. 1999/3463, S.I. 2000/1917, S.I. 2000/2899, S.I. 2000/3231, S.I. 2001/2777, S.I. 2001/3942, S.I. 2003/696 and S.I. 2006/915 and these Regulations. There are other amendments, but none is relevant.

2. In this Part "cyanogenic substances" means preparations which—

(a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17; or

(b) contain more than 0.1 per cent by weight of any substance having the formula either—

(i) alpha-Cyanobenzyl -6-O-Beta-d-glucopyranosyl -Beta-d-glucopyranoside, or

(ii) alpha-Cyanobenzyl -Beta-d-glucopyranosiduronic acid.

PART 2

Descriptions of certain medicinal products to be available only from a pharmacy

3. The following medicinal products shall be available only from a pharmacy—

(a) a product comprising eye ointment;

(b) a product that contains Vitamin A, Vitamin A acetate or Vitamin A palmitate, in each case with a maximum daily dose equivalent to more than 7500 international units of Vitamin A or 2250 micrograms of retinol;

(c) a product that contains Vitamin D with a maximum daily dose of more than 400 units of antirachitic activity **[**F963; F964...**]**

[F965(d) a product which is authorised by the licensing authority on a temporary basis under regulation 174, in circumstances where the licensing authority has attached a condition to that authorisation to the effect that, for the duration of the temporary authorisation, it is only to be available from a pharmacy **[**F966; and**]]**

[F967(e) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, it is only to be available from a pharmacy.**]**

Textual Amendments

F963 Word in Sch. 1 para. 3(c) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(3)(a)** and word in Sch. 1 para. 3(c) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(3)(a)**

F964 Word in Sch. 1 para. 3(c) omitted (15.4.2022) by virtue of The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(3)(a)** (with reg. 19)

F965 Sch. 1 para. 3(d) inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **31(3)(b)** and Sch. 1 para. 3(d) inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **31(3)(b)**

F966 Word in Sch. 1 para. 3(d) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(3)(b)** (with reg. 19)

F967 Sch. 1 para. 3(e) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **12(3)(c)** (with reg. 19)

4. The following medicinal products shall be available only from a pharmacy unless they are the subject of a **[**F968UK marketing authorisation, EU marketing authorisation, Article 126a authorisation, parallel import licence**]** or traditional herbal registration that classifies them as medicinal products subject to general sale—

(a) a product that is for use as an anthelmintic;

(b) a product that is for parenteral administration;

(c) a product that is for use as an enema;

(d) a product that is for use wholly or mainly for irrigation of—

(i) wounds, or

(ii) the bladder, vagina or rectum;

(e) a product that is for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

Textual Amendments

F968 Words in Sch. 1 para. 4 substituted (31.12.2020) by S.I. 2019/775, **reg. 8(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**)

5. A medicinal product shall be available only from a pharmacy if it is a medicinal product of a kind specified in Schedule 15 but is not presented for sale in accordance with the requirements specified in that Schedule for a product of that kind to be subject to general sale.

SCHEDULE 2

Regulation 16

Supplementary provision relating to advisory bodies and expert advisory groups

Terms of appointment

1.—(1) The person appointed to chair an advisory body is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The person's term of office as chair of the advisory body is not to exceed the person's term of office as a member of the body.

(3) The person may resign from chairing the advisory body at any time by notice in writing to the Ministers.

2.—(1) A member of an advisory body, other than its chair, is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The term of an appointment may not exceed four years (but an appointment may be renewed).

(3) A member of an advisory body may resign from it at any time by notice in writing to the Ministers.

(4) Where a person ceases to be a member of an advisory body, the person also ceases to be a member of any expert advisory group appointed by the advisory body (including an expert advisory group appointed jointly with the other advisory body).

(5) But sub-paragraph (4) does not apply if—

(a) the person was a member of the advisory body only by virtue of being co-opted under regulation 13; or

(b) the person is immediately re-appointed to the advisory body.

3.—(1) The person appointed to chair an expert advisory group is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (2) and (3)).

(2) The person's term of office as chair of the expert advisory group is not to exceed the person's term of office as a member of the group.

(3) The person may resign from chairing the group at any time by notice in writing to the advisory body or bodies which appointed the group.

4.—(1) This paragraph applies to a member of an expert advisory group, other than a person appointed to chair an expert advisory group.

(2) The member is to hold and vacate office in accordance with the written terms of the appointment (but this is subject to sub-paragraphs (3) and (4)).

(3) The term of an appointment may not exceed four years (but an appointment may be renewed).

(4) The member may resign office at any time by notice in writing to the advisory body or bodies which appointed the group.

Facilities and proceedings

5. The Ministers must provide each advisory body with such staff, accommodation, services and other facilities as the Ministers think necessary or expedient for the proper performance of its functions.

6. The validity of any proceedings of an advisory body or expert advisory group is not affected by—

(a) a vacancy among its members; or

(b) a defect in the appointment of any member.

7.—(1) An advisory body may, subject to approval by the Secretary of State, make such provision as it thinks fit for the regulation of its own proceedings.

(2) The licensing authority may make provision for the regulation of the proceedings of an expert advisory group.

Payment and expenses

8. The Ministers may pay to the members of each advisory body and expert advisory group such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.

9. The Ministers must defray any expenses incurred with their approval by each advisory body and expert advisory group.

10. If an action is brought against a person arising out of an act performed as a member of an advisory body or expert advisory group, the Ministers may indemnify that person against any damages, costs or expenses incurred in that action.

11. Paragraphs 8 to 10 shall have effect in relation to an expert committee appointed by the licensing authority and to its members as if they were an advisory body or expert advisory group and its members.

Status

12. An advisory body or expert advisory group is not to be regarded—

(a) as a servant or agent of the Crown; or

(b) as enjoying any status, immunity or privilege of the Crown.

[F969SCHEDULE 2A

Regulations 8(1) and B17(3)

Modifications of Commission Directive 2003/94/EC

Textual Amendments

F969 Sch. 2A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 3**; 2020 c. 1, Sch. 5 para. 1(1)

Provision of Commission Directive 2003/94/EC	***Modification subject to which that provision is to be read***
Article 1 (scope)	The reference to— (a) "Article 40 of Directive 2001/83/EC" is to be read as a reference to "regulation 17 of the Human Medicines Regulations 2012"; and (b) "Article 13 of Directive 2001/20/EC" is to be read as a reference to "regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004".
Article 2 (definitions)	In the definition of— (a) "medicinal product", the reference to "Article 1(2) of Directive 2001/83/EC" is to be read as a reference to "regulation 2 of the Human Medicines Regulations 2012"; (b) "investigational medicinal product", the reference to "Article 2(d) of Directive 2001/20/EC" is to be read as a reference to "regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004"; (c) "manufacturer" the reference to "Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC" is to be read as a reference to "regulation 17(1) of the Human Medicines Regulations 2012 or the authorisation referred to in regulation 36(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004"; (d) "qualified person" the reference to "Article 48 of Directive 2001/83/EC or in Article 13(2) of Directive 2001/20/EC" is to be read as a reference to "regulation 41 of the Human Medicines Regulations 2012 or regulation 43 of the Medicines for Human Use (Clinical Trials) Regulations 2004".
Article 3(1) (inspections)	The reference to— (a) "for Article 111(1) of Directive 2001/83/EC" is to be read as a reference to "Part 16 of the Human Medicines Regulations 2012 (enforcement)";

	(b) "Article 15(1) of Directive 2001/20/EC" is to be read as a reference to "Part 8 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (enforcement)"; (c) "the Member States", is to be read as a reference to "the licensing authority"; (d) "Member States shall" is to be read as a reference to "The licensing authority may"; (e) "published by the Commission, of Community procedures on inspections and exchanges of information" is to be read as if after it there were inserted "or any guidance published by the licensing authority to replace that Commission guidance".
Article 3(2) (inspections)	The reference to— (a) "competent authorities" is to be read as a reference to "licensing authority"; (b) "the second paragraph of Article 47 of Directive 2001/83/EC" to the end is to be read as a reference to "regulation C17(1)(a) of the Human Medicines Regulations 2012, or which applies by virtue of regulation C17(2) of those Regulations".
Article 4(2) (conformity with good manufacturing practice)	The reference to— (a) "third countries" is to be read as a reference to "country other than the United Kingdom"; (b) "Community" is to be read as a reference to "licensing authority".
Article 5 (compliance with marketing authorisation)	The reference to— (a) "Article 9(2) of Directive 2001/20/EC" in both places it appears is to be read as a reference to "regulation 17 of the Medicines for Human Use (Clinical Trials) Regulations 2004"; (b) "competent authorities" in both places it appears is to be read as a reference to "licensing authority".
Article 9 (documentation)	The reference in— (a) paragraph (1) to "Article 51(3) of Directive 2001/83/EC" is to be read as a reference to "paragraph 15(1) of Schedule 7 to the Human Medicines Regulations 2012"; (b) paragraph (2) to "competent authorities" is to be read as a reference to "licensing authority".
Article 11 (quality control)	The reference in paragraph (2)— (a) to "point (b) of Article 20 of Directive 2001/83/EC" is to be read as a reference to "paragraph 3 or 17 of Schedule 4 to the Human Medicines Regulations 2012"; (b) to "Article 9(2) of Directive 2001/20/EC" is to be read as a reference to "regulation 17 of

	the Medicines for Human Use (Clinical Trials) Regulations 2004"; The reference in paragraph (4)— (a) to "Member State" is to be read as a reference to "United Kingdom"; (b) to "competent authority" is to be read as a reference to "licensing authority";
Article 12(4) (work contracted out)	The reference to— (a) "competent authorities" is to be read as a reference to "licensing authority"; (b) "for Article 111 of Directive 2001/83/EC and Article 15(1) of Directive 2001/20/EC" is to be read as a reference to "Part 16 of the Human Medicines Regulations 2012 or Part 8 of the Medicines for Human Use (Clinical Trials) Regulations 2004".
Article 13 (complaints, product recall and emergency unblinding)	The reference to "Article 123 of Directive 2001/83/EC" is to be read as a reference to "Part 5 of the Human Medicines Regulations 2012".**]**

SCHEDULE 3

Regulation 21(1)

Applications for licences under Part 3

Manufacturer's licences

1.—(1) This paragraph applies to an application for a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the address of each of the premises where any operations to which the licence relates are to be carried out;

(d) the address of any premises not mentioned by virtue of paragraph (c) where—

(i) the applicant proposes to keep any living animals, from which a substance used in the production of the medicinal product to which the application relates is to be derived, or

(ii) materials of animal origin, from which a substance is to be derived as mentioned in sub-paragraph (i), are to be kept;

(e) the address of each of the premises where medicinal products are to be stored, or from which medicinal products are to be distributed;

(f) the name, address, qualifications and experience of the person ("S") whose duty it will be to supervise the manufacturing or assembling operations, and the name and job title of the person to whom S reports;

[[F970](g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of—

(i) in the case of a product for sale or supply in Great Britain, the UK marketing authorisation, certificate of registration or traditional herbal registration relating to the products, or

(ii) in the case of a product for sale or supply in Northern Ireland, the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products,

a statement of that fact);**]**

(h) the name, address and qualifications of the person to be responsible for any animals kept as mentioned in sub-paragraph (d)(i);

(i) the name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of medicinal products;

(j) the name, address and qualifications of the qualified person.

(3) The application must also contain—

(a) the pharmaceutical form of each medicinal product to be manufactured or assembled;

(b) details of the manufacturing or assembling operations to which the licence is to relate, including a statement of whether they include—

(i) the manufacture of medicinal products, or

(ii) the assembly of medicinal products;

(c) a statement of whether the medicinal products are to be manufactured or assembled for the purpose of—

(i) being administered to human beings in that form, or

(ii) as an ingredient in the preparation of another medicinal product;

(d) a statement of the facilities and equipment available at each of the premises where medicinal products are to be stored, or from which medicinal products are to be distributed;

(e) a separate statement, in respect of each of the premises mentioned in the application, of—

(i) the manufacturing or assembling operations capable of being carried out at those premises, and the class of medicinal products to which those operations relate, and

(ii) the equipment available at those premises for carrying out each stage of those operations;

(f) a statement of the authority conferred on the person mentioned in sub-paragraph (2)(g) to reject unsatisfactory medicinal products;

(g) a description of the arrangements for the identification and storage of materials and ingredients before and during manufacture or assembly and for the storage of medicinal products after manufacture or assembly;

(h) a description of the arrangements, at each of the premises where the applicant proposes to store medicinal products, for ensuring, so far as practicable, the turn-over of stocks of medicinal products;

(i) a description of the arrangements for maintaining—

(i) production records, and

(ii) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials used in manufacture, or of medicinal products, with the specification for such materials or medicinal products;

(j) a description of the arrangements for keeping reference samples of—

(i) materials used in the manufacture of medicinal products, and

(ii) medicinal products;

(k) where the application relates to an exempt advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow product traceability containing sufficient detail to enable the linking of a product to the patient who received it and vice versa; and

(l) details of—

(i) any manufacturing operations, other than those to which the licence is to relate, carried on by the proposed licence holder on or near the premises mentioned in sub-paragraph (2)(c), and

(ii) the substances or articles to which those operations relate.

Textual Amendments

F970 Sch. 3 para. 1(2)(g) substituted (31.12.2020) by S.I. 2019/775, **reg. 18(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(a)**)

Manufacturers' licence relating to import

2.—**[**[F971](1) This paragraph applies to an application for a manufacturer's licence relating to the import from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State,

of medicinal products.**]**

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the name, pharmaceutical form, country of origin and marketing authorisation number of each imported medicinal product;

(d) the address of each set of premises where the importation operation is to take place;

(e) the address of each set of premises where any testing associated with the importation is to take place;

(f) the address of each set of premises where medicinal products are to be stored, or from which they are to be distributed;

(g) the name, address and qualifications of the qualified person; and

(h) the name, address, qualifications and experience of the person in charge of quality control.

(3) The application must also contain—

(a) details of the importation operations to which the licence is to relate;

(b) a statement of the facilities and equipment available at each set of premises where medicinal products are to be stored, or from which they are to be distributed;

(c) details of—

(i) any manufacturing of medicinal products carried on by the applicant on or near the premises mentioned in sub-paragraph (2)(d) to (f), and

(ii) the substances or articles manufactured or used in the manufacturing;

(d) a description of the arrangements for storage of the medicinal products after importation;

(e) a description of the arrangements at each set of premises for ensuring, so far as practicable, the turn-over of stocks of medicinal products;

(f) a description of the arrangements for maintaining—

(i) records of importation, and

(ii) records of analytical and other procedures applied in the course of importation; and

(g) a description of the arrangements for keeping reference samples of the medicinal products.

Textual Amendments

F971 Sch. 3 para. 2(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 18(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(b)**)

Wholesale dealer's licences

3.—(1) This paragraph applies to an application for a wholesale dealer's licence.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the address of each of the premises where medicinal products are to be stored, or from which they are to be distributed; and

(d) the name, address and qualifications of the responsible person **[**F972or the responsible person (import)**]**.

(3) The application must also contain—

(a) details of the distribution by way of wholesale dealing to which the licence is to relate;

(b) a statement of whether the medicinal products to which the distribution relates are the subject of—

[F973(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,**]**

(ii) a certificate of registration,

(iii) a traditional herbal registration, or

(iv) **[**F974in the case of a product for sale or supply in Northern Ireland,**]** an Article 126a authorisation;

[F975(v) an authorisation granted by an authority in a country other than the United Kingdom to sell or supply the medicinal product in that other country;**]**

(c) a statement of whether the medicinal products to which the distribution relates are—

(i) prescription only medicines,

(ii) pharmacy medicines, or

(iii) medicines subject to general sale;

(d) a statement of whether the medicinal products to which the distribution relates are—

(i) special medicinal products, [F976]...

[[F977](ia) EAMS medicinal products,**]**

(ii) sold or supplied pursuant to regulation 174 (supply in response to spread of pathogenic agents **[**[F978]etc), or**]**

[[F979](iii) to be distributed by means of export from Great Britain to an approved country for import;**]**

(e) a statement of whether the medicinal products dealt in under the licence are to be used—

(i) for administration to human beings, or

(ii) as ingredients in the preparation of medicinal products for administration to human beings;

(f) an indication of the range of medicinal products to be stored at each of the premises mentioned in the application;

(g) a statement of the facilities and equipment available at those premises for storing and distributing medicinal products;

(h) a description of the arrangements at those premises for ensuring, so far as practicable, the turn-over of stocks of medicinal products (whether by the maintenance of records or by other means);

(i) details of an emergency plan which satisfies the requirements of regulation 43(7)(b), and

(j) a description of the arrangements for keeping records relating to products received or dispatched.

[[F980](4) In sub-paragraph (2)(d)—

"the responsible person" means the person who has the functions described in regulation 45(2);

"the responsible person (import)" means the person who has the functions described in regulation 45AA(4).**]**

Textual Amendments

F972 Words in Sch. 3 para. 3(2)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F973 Sch. 3 para. 3(3)(b)(i)(ia) substituted for Sch. 3 para. 3(3)(b)(i) by S.I. 2019/775, regs. 1, **18(4)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(i)**)

F974 Words in Sch. 3 para. 3(3)(b)(iv) inserted (31.12.2020) by S.I. 2019/775, **reg. 18(4)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(ii)**)

F975 Sch. 3 para. 3(3)(b)(v) inserted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F976 Word in Sch. 3 para. 3(3)(d)(i) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F977 Sch. 3 para. 3(3)(d)(ia) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **13** (with reg. 19)

F978 Words in Sch. 3 para. 3(3)(d)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F979 Sch. 3 para. 3(3)(d)(iii) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(iii)** (as amended by S.I. 2020/1488, **reg. 1 Sch. 2 para. 12(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F980 Sch. 3 para. 3(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

All licences

4.—(1) If an application does not include information or other matters required under this Schedule, the application must state—

(a) why that information is not applicable; or

(b) any other reason for not including them.

(2) An application for a licence must be in English.

(3) The pages of an application for a licence must be serially numbered.

(4) The applicant must sign the application.

(5) If the application is made by another person on behalf of the applicant, that person must also sign the application.

SCHEDULE 4 Regulation 24

Standard provisions of licences under Part 3

PART 1

Manufacturer's licence relating to manufacture and assembly

1. The provisions of this Part are standard provisions of a manufacturer's licence relating to the manufacture or assembly of medicinal products.

2. The licence holder must place the quality control system referred to in Article 11(1) of the Good Manufacturing Practice Directive under the authority of the person notified to the licensing authority in accordance with paragraph 1(2)(g) of Schedule 3.

3. The licence holder may use a contract laboratory pursuant to Article 11(2) of the Good Manufacturing Practice Directive if the laboratory is operated by a person approved by the licensing authority.

4. The licence holder must provide such information as may be requested by the licensing authority—

(a) about the products currently being manufactured or assembled by the licence holder; and

(b) about the operations being carried out in relation to such manufacture or assembly.

5. The licence holder must inform the licensing authority of any change that the licence holder proposes to make to a person named in the licence as—

(a) the person whose duty it is to supervise the manufacturing or assembling operations;

(b) in charge of the animals from which are derived substances used in the production of the medicinal products being manufactured or assembled; or

(c) responsible for the culture of living tissues used in the manufacture of the medicinal products being manufactured or assembled.

6. The licence holder must—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of the Good Manufacturing Practice Directive; and

(b) permit the authorised person to take copies or make extracts from such documentation.

7. The licence holder must keep readily available for examination by a person authorised by the licensing authority the samples in each batch of finished medicinal product referred to in Article 11(4) of the Good Manufacturing Practice Directive.

8. Where the licence holder has been informed by the licensing authority that the strength, quality or purity of a batch of a medicinal product to which the licence relates has been found not to conform with—

(a) the specification for the finished product; or

(b) the provisions of these Regulations applicable to the medicinal product,

the holder must, if so directed, withhold the batch from distribution, so far as reasonably practicable, for a period (not exceeding six weeks) specified by the licensing authority.

9. The licence holder must ensure that tests for determining conformity with the standards and specifications applying to a product used in the manufacture of a medicinal product must, except so far as the conditions of the product specification for that product otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage of the manufacture as may be approved by the licensing authority.

10. Where the manufacturer's licence relates to the assembly of a medicinal product or class of product, and the licence holder supplies the product at such a stage of assembly that does not fully comply with the provisions of the product specification which relate to labelling, the licence holder must communicate the particulars of those provisions to the person to whom that product has been supplied.

11. Where—

(a) the manufacturer's licence relates to the assembly of a medicinal product;

(b) the medicinal product is not manufactured by the licence holder; and

(c) particulars of the name and address of the manufacturer of the product, or the person who imports the product, have been given by the licence holder to the licensing authority,

the licence holder must immediately notify the licensing authority in writing of any changes in the particulars.

12. The licence holder must keep readily available for examination by a person authorised by the licensing authority durable records of the details of the manufacture of intermediate products held by the licence holder for use in the manufacture of biological medicinal products, and the records must—

(a) be in such form as to ensure that the licence holder has a comprehensive record of all matters that are relevant to an evaluation of the safety, quality and efficacy of a finished biological medicinal product manufactured using those intermediate products; and

(b) not be destroyed without the consent of the licensing authority until the records of the details of manufacture of finished medicinal products which were or may be manufactured using those intermediate products may be destroyed in accordance with the requirements of these Regulations.

13. Where—

(a) animals are used in the production of medicinal products; and

[[F981](b) in the case of a product for sale or supply—

(i) in Great Britain, a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in Northern Ireland, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

contains provisions relating to them,**]**

the manufacturer's licence holder must arrange for the animals to be housed in such premises, and managed in such a manner, as facilitates compliance with those provisions.

Textual Amendments

F981 Sch. 4 para. 13(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 20(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(a)**)

14. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided to the licensing authority is not false or misleading in any material particular if—

(a) it relates to a medicinal product which the licence holder manufactures or assembles; or

(b) it relates to any starting materials or intermediate products held by the licence holder which are for use in the manufacture of medicinal products.

[[F982]**14A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.**]**

Textual Amendments

F982 Sch. 4 para. 14A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(b)**)

[[F983]**14B.** A licence holder may only manufacture or assemble EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.**]**

Textual Amendments

F983 Sch. 4 para. 14B inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(2)** (with reg. 19)

PART 2

Manufacturer's licence relating to the import of medicinal products from a state other than an EEA State [F984/ Country other than an Approved Country for Import]

Textual Amendments

F984 Words in Sch. 4 Pt. 2 heading inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(c)**)

15. The provisions of this Part are standard provisions of a manufacturer's licence relating to the import of medicinal products [F985from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State].

Textual Amendments

F985 Sch. 4 para. 15(a)(b) substituted for words in Sch. 4 para. 15 (31.12.2020) by S.I. 2019/775, **reg. 20(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F986**15A.** The provisions of this Part are standard provisions of a manufacturer's licence relating to the supply of a listed NIMAR product from Great Britain to Northern Ireland.]

Textual Amendments

F986 Sch. 4 para. 15A inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **24**

16. The licence holder must place the quality control system referred to in Article 11(1) of the Good Manufacturing Practice Directive under the authority of the person notified to the licensing authority in accordance with paragraph 2(2)(h) of Schedule 3.

17. The licence holder may use a contract laboratory pursuant to Article 11(2) of the Good Manufacturing Practice Directive if operated by a person approved by the licensing authority.

18. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal products which the licence holder imports.

19. The licence holder must—

(a) keep readily available for inspection by a person authorised by the licensing authority the batch documentation referred to in Article 9(1) of the Good Manufacturing Practice Directive; and

(b) permit the person authorised to take copies or make extracts from such documentation.

20. Where the licence holder has been informed by the licensing authority that the strength, quality or purity of a batch of a medicinal product to which the licence relates has been found not to conform with—

(a) the specification of the medicinal product in question; or

(b) those provisions of these Regulations that are applicable to the medicinal product,

the licence holder must, if so directed, withhold the batch from distribution, so far as reasonably practicable, for such a period (not exceeding six weeks) as may be specified by the licensing authority.

21. The licence holder must ensure that any tests for determining conformity with the standards and specifications applying to any ingredient used in the manufacture of a medicinal product must, except so far as the conditions of the product specification for that ingredient otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

22.—(1) Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from **[**F987, in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]**—

(a) in response to an order which satisfies the requirements of regulation 167 (supply to fulfil special patient needs); and

(b) where the conditions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days before the day on which each importation of a special medicinal product takes place, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or the name of the manufacturer of the medicinal product;

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name, or where that constituent does not have any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in sub-paragraph (6); and

(e) the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported and, if the person who will supply the medicinal product for importation is not the manufacturer or assembler, the name and address of the supplier.

(3) The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in sub-paragraph (2), the licensing authority has notified the licence holder in writing that the product should not be imported.

(4) The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in sub-paragraph (3) that the product may be imported.

(5) Where the licence holder sells or supplies special medicinal products **[**F988or EAMS medicinal products**]**, the licence holder must, in addition to any other records which are required by the provisions of the licence, make and maintain written records relating to—

(a) the batch number of the batch of the product from which the sale or supply was made; and

(b) details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware.

(6) The licence holder must not, on any one occasion, import more than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and must not, on any one occasion, import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder must not publish any advertisement, catalogue or circular relating to a special medicinal product **[**F989or EAMS medicinal product**]** or make any representations in respect of that product.

(8) The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product **[**F990or EAMS medicinal product**]** imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(9) The licence holder must cease importing or supplying a special medicinal product **[**F991or EAMS medicinal product**]** if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

(10) In this paragraph—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia: lists of names);

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the European Pharmacopoeia or a foreign or international compendium of standards and "current" in this definition means current at the time the notice is sent to the licensing authority.

Textual Amendments

F987 Words in Sch. 4 para. 22(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 20(4A)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

F988 Words in Sch. 4 para. 22(5) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(a)** (with reg. 19)

F989 Words in Sch. 4 para. 22(7) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(b)** (with reg. 19)

F990 Words in Sch. 4 para. 22(8) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(c)** (with reg. 19)

F991 Words in Sch. 4 para. 22(9) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(3)(d)** (with reg. 19)

23. The licence holder must take all reasonable precautions and exercise due diligence to ensure that any information provided to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product for human use which is imported from **[**F992, in the case of an import into Great Britain, a country other than Northern Ireland or a country other than

an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State**]**, handled, stored or distributed under the licence is not false or misleading in a material particular.

Textual Amendments

F992 Words in Sch. 4 para. 23 substituted (31.12.2020) by S.I. 2019/775, **reg. 20(4A)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F993 23ZA. The licence holder in Great Britain must take all reasonable precautions and exercise due diligence to ensure that any information provided to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a product for human use which is supplied from Great Britain into Northern Ireland by virtue of regulation 167A handled, stored or distributed under the licence is not false or misleading in a material particular.**]**

Textual Amendments

F993 Sch. 4 para. 23ZA inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **25**

[F994 23A. A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.**]**

Textual Amendments

F994 Sch. 4 para. 23A inserted by S.I. 2019/775, regs. 1, **20(4B)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**)

[F995 23B. A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.**]**

Textual Amendments

F995 Sch. 4 para. 23B inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(4)** (with reg. 19)

PART 3

Manufacturer's licence relating to exempt advanced therapy medicinal products

24. The provisions of paragraphs 25 to 27 are incorporated as additional standard provisions of a manufacturer's licence relating to the manufacture and assembly of exempt advanced therapy medicinal products.

25. The licence holder must ensure that the immediate packaging of an exempt advanced therapy medicinal product is labelled to show the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the expiry date in clear terms including the year and month and, if applicable, the day;

(c) a description of the active substance, expressed qualitatively and quantitatively;

(d) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and of their specific origin;

(e) the pharmaceutical form and the contents by weight, volume or number of doses of the product;

(f) a list of excipients, including preservative systems;

(g) the method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated;

(h) any special storage precautions;

(i) specific precautions relating to the disposal of the unused product or waste derived from the product and, where appropriate, reference to any appropriate collection system;

(j) the name and address of the holder of the manufacturer's licence;

(k) the manufacturer's licence number;

(l) the manufacturer's batch number;

(m) the unique donation code **⌊**F996assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells**⌋**; and

(n) where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words “for autologous use only”.

Textual Amendments

F996 Words in Sch. 4 para. 25(m) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **20(5)**; 2020 c. 1, Sch. 5 para. 1(1)

26. The licence holder must ensure that the package leaflet of the exempt advanced therapy medicinal product shall include the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the intended effect of the medicinal product if correctly used, applied, administered or implanted;

(c) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and, where such cells or tissues are of animal origin, their specific origin;

(d) where the product contains a medical device or an active implantable medical device, a description of that device and, where that device contains cells or tissues of animal origin, their specific origin;

(e) any necessary instructions for use, including—

(i) the posology,

(ii) the method of use, application, administration or implantation and, if appropriate, the route of administration,

(iii) a description of symptoms of overdose,

(iv) action to be taken in the event of overdose, including any emergency procedures,

(v) action to be taken if one or more doses have been missed, and

(vi) a recommendation to consult the doctor or pharmacist for any clarification on the use of the product;

(f) where adverse reactions are known, a description of those which may occur under recommended conditions of use of the product and, if appropriate, an indication of action to be taken in such a case;

(g) an instruction that the patient report any adverse reaction not specified in the package leaflet to the doctor or pharmacist;

(h) the expiry date in clear terms and a warning against using the product after that date;

(i) any special storage precautions;

(j) a description of any visible signs of deterioration;

(k) a complete qualitative and quantitative composition;

(l) the name and address of the holder of the manufacturer's licence; and

(m) the date on which the package leaflet was last revised.

27. The licence holder must keep the data referred to in paragraph 8 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

PART 4

Wholesale dealer's licence

All wholesale dealer's licences

28. The provisions of this Part are standard provisions of a wholesale dealer's licence.

29. The licence holder must not use any premises for the handling, storage or distribution of medicinal products other than those specified in the licence or notified to the licensing authority from time to time and approved by the licensing authority.

30. The licence holder must provide such information as may be requested by the licensing authority concerning the type and quantity of medicinal products which the licence holder handles, stores or distributes.

31. The licence holder must take all reasonable precautions and exercise all due diligence to ensure that any information provided by the licence holder to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of a medicinal product which the licence holder handles, stores or distributes is not false or misleading.

Wholesale dealer's licence relating to special medicinal products

32. The provisions of paragraphs 33 to 42 are incorporated as additional standard provisions of a wholesale dealer's licence relating to special medicinal products.

33. Where and in so far as the licence relates to special medicinal products, the licence holder may only import such products from **[**F997, in the case of an import into Great Britain, an approved country for import and in the case of an import into Northern Ireland, an EEA State**]**—

(a) in response to an order which satisfies the requirements of regulation 167, and

(b) where the conditions set out in paragraphs 34 to 41 are complied with.

Textual Amendments

F997 Words in Sch. 4 para. 33 substituted (31.12.2020) by S.I. 2019/775, **reg. 20(6)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(e)**)

[F998**33A.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.**]**

Textual Amendments

F998 Sch. 4 para. 33A inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(5)** (with reg. 19)

34. No later than 28 days prior to each importation of a special medicinal product, the licence holder must give written notice to the licensing authority stating the intention to import the product and stating the following particulars—

(a) the brand name, common name or scientific name of the medicinal product and (if different) any name under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or the name of the manufacturer of the medicinal product;

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name, or where that constituent does not have any of those, the accepted scientific name or any other name descriptive of the true nature of the constituent;

(d) the quantity of medicinal product to be imported, which must not exceed the quantity specified in paragraph 38; and

(e) the name and address of the manufacturer or assembler of the medicinal product in the form in which it is to be imported and, if the person who will supply the medicinal product for importation is not the manufacturer or assembler, the name and address of the supplier.

35. The licence holder may not import the special medicinal product if, before the end of 28 days beginning immediately after the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that it has received the notice referred to in paragraph 34, the licensing authority has notified the licence holder in writing that the product should not be imported.

36. The licence holder may import the special medicinal product referred to in the notice where the licence holder has been notified in writing by the licensing authority, before the end of the 28-day period referred to in paragraph 35, that the product may be imported.

37. Where the licence holder sells or supplies special medicinal products **[**F999or EAMS medicinal products**]**, the licence holder must, in addition to any other records which are required by the provisions of the licence, make and maintain written records relating to—

(a) the batch number of the batch of the product from which the sale or supply was made; and

(b) details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware.

Textual Amendments

F999 Words in Sch. 4 para. 37 inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(6)** (with reg. 19)

38. The licence holder must not, on any one occasion, import more than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment, and must not, on any one occasion, import more than the quantity notified to the licensing authority under paragraph 34(d).

39. The licence holder must inform the licensing authority immediately of any matter coming to the licence holder's attention which might reasonably cause the licensing authority to believe that a special medicinal product **[**F1000or EAMS medicinal product**]** imported in accordance with this paragraph can no longer be regarded as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

Textual Amendments

F1000 Words in Sch. 4 para. 39 inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(7)** (with reg. 19)

40. The licence holder must not publish any advertisement, catalogue, or circular relating to a special medicinal product **[**F1001or EAMS medicinal product**]** or make any representations in respect of that product.

Textual Amendments

F1001 Words in Sch. 4 para. 40 inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(8)** (with reg. 19)

41. The licence holder must cease importing or supplying a special medicinal product **[**F1002or EAMS medicinal product**]** if the licence holder receives a notice in writing from the licensing authority directing that, from a date specified in the notice, a particular product or class of products may no longer be imported or supplied.

Textual Amendments

F1002 Words in Sch. 4 para. 41 inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **14(9)** (with reg. 19)

[F1003**41A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.**]**

Textual Amendments

F1003 Sch. 4 para. 41A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **20(7)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(f)**)

42. In this Part—

"British approved name" means the name which appears in the current edition of the list prepared by the British Pharmacopoeia Commission under regulation 318 (British Pharmacopoeia- lists of names);

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the European Pharmacopoeia or a foreign or international compendium of standards, and "current" in this definition means current at the time the notice is sent to the licensing authority.

Wholesale dealer's licence relating to exempt advanced therapy medicinal products

43. The provisions of paragraph 44 are incorporated as additional standard provisions of a wholesale dealer's licence relating to exempt advanced therapy medicinal products.

44. The licence holder shall keep the data referred to in paragraph 16 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.

SCHEDULE 5

Regulation 27; Schedule 11paragraphs 11(3), 13(3),23(4) and 30(4)

Review upon oral representations

Application of this Schedule

[F1004 1.—(1) This Schedule applies if a person ("the applicant") mentioned in sub-paragraph (2) notifies the licensing authority that the applicant wishes the licensing authority to submit the proposal or as the case may be the decision to review upon oral representations under—

(a) regulation 27(3)(b);

(b) regulation 45H(3)(b);

(c) regulation 45R(3)(b);

(d) regulation 256J(4)(b); or

(e) Part 1, 2 or 3 of Schedule 11.

(2) Those persons are—

(a) in respect of notification under regulation 27(3)(b) the licence holder;

(b) in respect of a notification under regulation 45H(3)(b) the person registered as a broker;

(c) in respect of a notification under regulation 45R(3)(b) the person with an active substance registration;

(d) in respect of a notification under regulation 256J(4)(b) the person on the list in accordance with Part 12A; and

(e) in respect of a notification under Part 1, 2 or 3 of Schedule 11—

(i) an applicant for a UK marketing authorisation, **[**[F1005]parallel import licence,**]** certificate of registration or traditional herbal registration,

(ii) an applicant for the renewal of an authorisation, **[**[F1006]licence,**]** certificate or registration, and

(iii) the holder of an authorisation, **[**[F1006]licence,**]** certificate or registration.**]**

Textual Amendments

F1004 Sch. 5 para. 1 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(a)**

F1005 Words in Sch. 5 para. 1(2)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F1006 Words in Sch. 5 para. 1(2)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Appointment of reviewers

2.—(1) The licensing authority must—

(a) appoint a panel of at least two persons ("the reviewers") to conduct the review; and

(b) provide facilities for the applicant to have the opportunity to appear before the reviewers.

(2) A person must not be appointed under sub-paragraph (1) if within the period of one year immediately preceding that time the person has been a member of—

(a) the Commission;

(b) an expert committee appointed by the licensing authority;

(c) an expert advisory group;

(d) the British Pharmacopoeia Commission or any of its sub-committees;

(e) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Medicines Act 1968; or

(f) the Herbal Medicines Advisory Committee formerly established under section 4 of the Medicines Act 1968.

(3) A person appointed under sub-paragraph (1) must not be an officer or servant of a Minister of the Crown, the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister.

Procedure before hearing

3.—(1) The applicant must supply the reviewers with a written summary of the oral representations that the applicant wishes to make and any documents on which the applicant wishes to rely in support of them before the end of the period of three months beginning with the date of the notification mentioned in paragraph 1.

(2) The reviewers may, at the request of the applicant and after consulting the licensing authority, extend the period mentioned in sub-paragraph (1) up to a maximum of six months beginning with the date of that notification.

(3) The applicant may submit additional written representations or documents after the end of the periods for doing so only with the permission of the reviewers.

(4) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the representations and documents referred to in paragraphs (1) and (3)—

(a) must not be based on any evidence or data that was not available to the licensing authority at the time that the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority; unless

(b) the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(5) The reviewers must notify the applicant and the licensing authority of the date of the hearing at least 28 days before that date, unless the applicant and the licensing authority agree to a shorter period of notice.

(6) The reviewers may establish at any stage of the procedures described in this Schedule a date by which all of those procedures, except for the hearing, must be completed, and notify this date to the applicant and to the licensing authority.

(7) The date established under sub-paragraph (6) must not be earlier than whichever is the earlier of—

(a) the first day after the end of the period of three months beginning with the date of the notification mentioned in paragraph 1; or

(b) the first day after the end of the period of 28 days beginning with the date on which the reviewers receive the written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1) and (3) of this paragraph,

and in any case not earlier than the first day after the period of seven days beginning on the day after the notification under sub-paragraph (6).

(8) A date established under sub-paragraph (6) may be varied or withdrawn on the application of the applicant or of the licensing authority.

(9) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the reviewers must not take into account any documents or other evidence, or any representations based on such documents or evidence, in the conduct of the hearing if it thinks that the data or evidence on which the documents or representations are based, or the evidence that is presented, were not available to the licensing authority at the time when the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority, unless the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(10) The reviewers may give such other directions as they think fit for the conduct of the hearing, including—

(a) the postponing or adjournment of the hearing for such period as it may decide; and

(b) establishing a list of documents that will be taken into account in the conduct of the hearing.

(11) If the applicant fails to comply with a time limit under sub-paragraph (1), (2) or (6)—

(a) the applicant may not appear before the reviewers; and

(b) the licensing authority must decide whether—

(i) to proceed with its proposal to revoke, vary or suspend the licence,

(ii) to confirm or alter its decision,

F1007(iii) . . . . . .

(iv) to grant or renew the UK marketing authorisation, **[**F1008parallel import licence,**]** certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application, F1009...

(v) to revoke, vary or suspend the authorisation, **[**F1010licence,**]** certificate or registration,

[F1011(vi) to proceed to suspend, vary or remove the person's broker registration,

(vii) ro proceed to suspend, vary or remove the person's active substance registration, or

(viii) to proceed to suspend, vary or remove the person's entry on the list,**]**

as the case may be.

(12) The licensing authority must notify the applicant of its decision.

Textual Amendments

F1007 Sch. 5 para. 3(11)(b)(iii) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F1008 Words in Sch. 5 para. 3(11)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F1009 Word in Sch. 5 para. 3(11)(b)(iv) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(i)**

F1010 Words in Sch. 5 para. 3(11)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F1011 Sch. 5 para. 3(11)(b)(vi)-(viii) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(ii)**

Procedure at hearing

4.—(1) Both the applicant and the licensing authority may make representations at the hearing.

(2) The hearing must be in public if the applicant so requests.

(3) If the applicant fails to appear at the hearing, the reviewers may conduct the review on the basis of the applicant's written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1), (2) and (3) of paragraph 3.

Procedure following hearing

5.—(1) After the hearing the reviewers must provide a report to the licensing authority and to the applicant either—

(a) by the end of the period of 60 days beginning with the day after the conclusion of the hearing; or

(b) within such further period as the reviewers may notify to the licensing authority and to the applicant within that 60 day period.

(2) The licensing authority must take the report into account and decide whether—

(a) to proceed with its proposal to revoke, vary or suspend the licence;

(b) to confirm or alter its decision;

F1012(c) . . . . . .

(d) to grant or renew the UK marketing authorisation, **[**F1013parallel import licence,**]** certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application; F1014...

[F1015(e) to revoke, vary or suspend the authorisation, certificate or registration;

(f) to proceed to suspend, vary or remove a person's broker registration;

(g) to proceed to suspend, vary or remove a person's active substance registration; or

(h) to proceed to suspend, vary or remove a person's entry on the list,**]**

as the case may be.

(3) The licensing authority must notify the applicant of its decision.

Textual Amendments

F1012 Sch. 5 para. 5(2)(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F1013 Words in Sch. 5 para. 5(2)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F1014 Word in Sch. 5 para. 5(2)(d) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(i)**

F1015 Sch. 5 para. 5(2)(e)-(h) substituted for Sch. 5 para. 5(2)(e) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(ii)**

SCHEDULE 6

Regulations 36(3) and 42(3)

Manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products

PART 1

Manufacturer's licences

1. The requirements in paragraphs 2 to 12 apply to a manufacturer's licence insofar as it relates to the manufacture and assembly of exempt advanced therapy medicinal products.

2. The licence holder must inform the licensing authority of any adverse reaction or suspected adverse reaction of which the holder is aware within the period of 15 days beginning on the day following the first day on which the holder knew about the reaction.

3. The licence holder must ensure, if using human cells or tissues in an exempt advanced therapy medicinal product, that the donation, procurement and testing of those cells or tissues is in accordance with **[**F1016requirements imposed pursuant to—

(a) paragraphs 6 to 9 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and

(b) paragraphs 9 to 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.**]**

Textual Amendments

F1016 Sch. 6 para. 3(a)(b) and words substituted for words (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **26(2)**; 2020 c. 1, Sch. 5 para. 1(1)

4. The licence holder must ensure that any human tissue or cell component imported into the United Kingdom and used by the holder as a starting material or raw material in the manufacture of an exempt advanced therapy medicinal product shall meet equivalent standards of quality and safety to those **[**F1017imposed pursuant to—

(a) Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and

(b) Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.**]**

Textual Amendments

F1017 Sch. 6 para. 4(a)(b) and words substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **26(3)**; 2020 c. 1, Sch. 5 para. 1(1)

5. The licence holder must ensure that any blood or blood component imported into the United Kingdom and used by the manufacturer's licence holder as a starting material or raw material in the manufacture of an exempt advanced therapy medicinal product meets equivalent standards of quality and safety to those laid down in **[**[F1018]the Blood Quality and Safety Regulations 2005**]**.

Textual Amendments

F1018 Words in Sch. 6 para. 5 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **26(4)**; 2020 c. 1, Sch. 5 para. 1(1)

6. Where the holder of a manufacturer's licence distributes by way of wholesale dealing any exempt advanced therapy medicinal product manufactured or assembled pursuant to the licence that person must comply with—

(a) the requirements of paragraphs 15, 16, 18 and 19; and

(b) the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive;

as if that person were the holder of a wholesale dealer's licence.

7. The licence holder must, at the written request of the licensing authority, set up a risk management system designed to identify, characterise, prevent or minimise risks related to the exempt advanced therapy medicinal product.

8. The licence holder must establish and maintain a system ensuring that the exempt advanced therapy medicinal product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the establishment where the product is used.

9. The licence holder must, subject to paragraph 27 of Schedule 4, keep the data referred to in paragraph 8 for a minimum of 30 years after the expiry date of the exempt advanced therapy medicinal product.

10. The licence holder must secure that the data referred to in paragraph 8 will, in the event that—

(a) the licence is suspended, revoked or withdrawn; or

(b) the licence holder becomes bankrupt or insolvent,

be held available to the licensing authority by the holder of a manufacturer's licence for the period described in paragraph 9 or such longer period as may be required pursuant to paragraph 27 of Schedule 4.

11. The licence holder must, where an exempt advanced therapy medicinal product contains human cells or tissues, ensure that the traceability system established in accordance with paragraph 8 is complementary to and compatible with the requirements **[**[F1019]imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990;

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005; and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007**]**.

Textual Amendments

F1019 Sch. 6 paras. 11(a)-(c) and words substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **26(5)**; 2020 c. 1, Sch. 5 para. 1(1)

12. The licence holder must not import or export any exempt advanced therapy medicinal product.

PART 2

Wholesale dealer's licences

13. The requirements in paragraphs 14 to 20 apply to a wholesale dealer's licence insofar as it relates to exempt advanced therapy medicinal products.

14. The licence holder must obtain supplies of exempt advanced therapy medicinal products only from—

(a) the holder of a manufacturer's licence in respect of those products; or

(b) the holder of a wholesale dealer's licence in respect of those products.

15. The licence holder must distribute an exempt advanced therapy medicinal product by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence in respect of those products; or

(b) a person who—

(i) may lawfully administer those products, and

(ii) solicited the product for an individual patient.

16. The licence holder must establish and maintain a system ensuring that the exempt advanced therapy medicinal product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the establishment where the product is used.

17. The licence holder must inform the licensing authority of any adverse reaction to any exempt advanced therapy medicinal product supplied by the holder of the wholesale dealer's licence of which the holder is aware.

18. The licence holder must, subject to paragraph 44 of Schedule 4, keep the data referred to in paragraph 16 for a minimum of 30 years after the expiry date of the exempt advanced therapy medicinal product.

19. The licence holder must secure that the data referred to in paragraph 16 will, in the event that—

(a) the licence is suspended, revoked or withdrawn; or

(b) the licence holder becomes bankrupt or insolvent,

be held available to the licensing authority by the holder of a wholesale dealer's licence for the period described in paragraph 18 or such longer period as may be required pursuant to paragraph 44 of Schedule 4.

20. The licence holder must not import or export any exempt advanced therapy medicinal product.

SCHEDULE 7 Regulation 41

Qualified persons

PART 1

Qualification requirements for qualified person

1. A person must satisfy the requirements in paragraphs 2 and 8 or, alternatively, the requirements in paragraphs 7 and 8, of this Schedule before acting as a qualified person (but this is subject to Part 2).

2. The person must have a degree, diploma or other formal qualification which satisfies the requirements of this Part, in one of the following subjects—

(a) pharmacy;

(b) medicine;

(c) veterinary medicine;

(d) chemistry;

(e) pharmaceutical chemistry and technology; or

(f) biology,

but this paragraph is subject to paragraph 7.

3. A qualification satisfies the requirements of this Part if it is awarded on completion of a university course of study, or a course recognised as equivalent by **[**F1020the licensing authority**]**, which—

(a) satisfies the minimum requirements specified in paragraph 4; and

(b) extends over a period of at least four years of theoretical and practical study of a subject specified in paragraph 2 (but this is subject to paragraphs 5 and 6).

Textual Amendments

F1020 Words in Sch. 7 para. 3 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

4.—(1) A course should include at least the following core subjects—

(a) experimental physics;

(b) general and inorganic chemistry;

(c) organic chemistry;

(d) analytical chemistry;

(e) pharmaceutical chemistry, including analysis of medicinal products;

(f) general and applied medical biochemistry;

(g) physiology;

(h) microbiology;

(i) pharmacology;

(j) pharmaceutical technology;

(k) toxicology; and

(l) pharmacognosy.

(2) The subjects mentioned in sub-paragraph (1) should be balanced in such a way as to enable the person to fulfil the obligations specified in Part 3 of this Schedule.

5. If the course referred to in paragraph 3 is followed by a period of theoretical and practical training of at least one year, including a training period of at least six months in a pharmacy open to the public and a final examination at university level, the minimum duration of the course is three and a half years.

6. If two university courses, or courses recognised as of university equivalent standard, co-exist, one of which extends over four years and the other over three years, the three-year course is to be treated as fulfilling the condition as to the duration of the course in paragraph 3, provided that **[**[F1021]the licensing authority**]** recognises the formal qualifications gained from each course as being equivalent.

Textual Amendments

F1021 Words in Sch. 7 para. 6 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

7. If the person's formal qualifications do not satisfy the requirements of this Part, the person may act as a qualified person if the licensing authority is satisfied, on the production of evidence, that the person has adequate knowledge of the subjects specified in paragraph 4(1).

8.—(1) The person must (subject to sub-paragraph (2)) have at least two years' practical experience in an undertaking authorised to manufacture medicinal products of—

(a) qualitative analysis of medicinal products;

(b) quantitative analysis of active substances; and

(c) the testing and checking necessary to ensure the quality of medicinal products.

(2) But—

(a) if the person has completed a university course lasting at least five years, the minimum period of practical experience under this paragraph is one year; and

(b) if the person has completed a university course lasting at least six years, the minimum period of practical experience under this paragraph is six months.

PART 2

Qualified persons with long experience

9.—(1) This paragraph applies to a person who has acted as a qualified person since the coming into force of Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [M87].

(2) A person to whom this paragraph applies may continue to act as a qualified person.

Marginal Citations

M87 OJ No L 147, 9.6.1975, p.13, no longer in force.

10.—(1) This paragraph applies to a person who—

(a) holds a degree, diploma or other formal qualification in a scientific discipline awarded on completion of a university course or course recognised as equivalent; and

(b) began the course before 21 May 1975.

(2) A person to whom this paragraph applies may act as a qualified person provided that sub-paragraph (3) (and, where applicable, paragraph 11) is satisfied.

(3) This sub-paragraph is satisfied if, for at least two years before 21 May 1985, the person has carried out one of the following activities in an undertaking authorised to manufacture medicinal products—

(a) production supervision;

(b) qualitative and quantitative analysis of active substances; or

(c) testing and checking, under the direct supervision of the qualified person in respect of the undertaking, to ensure the quality of the medicinal products.

11. If a person to whom paragraph 10 applies acquired the practical experience mentioned in paragraph 10(3) before 21 May 1965, the person must complete a further one year's practical experience of the kind specified in that paragraph immediately before the person may act as a qualified person.

PART 3

Obligations of qualified person

12.—**[**F1022(1)**]** **[**F1023In Great Britain, the qualified person**]** is responsible for securing—

(a) that each batch of medicinal products manufactured in **[**F1024Great Britain**]** has been manufactured and checked in accordance with these Regulations and the requirements of the **[**F1025UK marketing authorisation**]**, certificate of registration or traditional herbal registration **[**F1026, or an equivalent authorisation,**]** relating to those products; F1027... **[**F1028and**]**

(b) in the case of **[**F1029medicinal products imported from a country other than approved country for import, irrespective of whether the products have been manufactured in the United Kingdom or an approved country for import**]**, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the **[**F1030UK marketing authorisation**]**, certificate of registration or traditional herbal registration **[**F1031, or an equivalent authorisation,**]** relating to those products; **[**F1032and**]**

F1033(c) . . . . . .

[F1034(2) In this paragraph "equivalent authorisation" means, in respect of a medicinal product that does not have a UK marketing authorisation, certificate of registration or traditional herbal registration, such equivalent authorisation or registration granted by an appropriate authority for the licensing of medicinal products in an approved country for import.**]**

Textual Amendments

F1022 Sch. 7 para. 12 renumbered as Sch. 7 para. 12(1) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F1023 Words in Sch. 7 para. 12(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(a)(ia)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(a)**)

F1024 Words in Sch. 7 para. 12(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(a)(ii)(zaa)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(b)**)

F1025 Words in Sch. 7 para. 12(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F1026 Words in Sch. 7 para. 12(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F1027 Word in Sch. 7 para. 12(a) omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(a)** and word in Sch. 7 para. 12(a) omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(a)**

F1028 Word in Sch. 7 para. 12(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F1029 Words in Sch. 7 para. 12(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F1030 Words in Sch. 7 para. 12(1)(b)(iii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F1031 Words in Sch. 7 para. 12(1)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F1032 Sch. 7 para. 12(c) and preceding word inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(b)** and Sch. 7 para. 12(c) and preceding word inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(b)**

F1033 Sch. 7 para. 12(1)(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F1034 Sch. 7 para. 12(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

[F1035**12A.**—(1) In Northern Ireland, the qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in Northern Ireland has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(b) in the case of medicinal products imported from a country other than an EEA State, irrespective of whether the products have been manufactured in Northern Ireland or an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a country other than an EEA State, that the features specified in paragraph 18A of Schedule 24 have been affixed on the packaging.**]**

[F1036(2) This paragraph does not apply in relation to listed NIMAR products in Northern Ireland.**]**

Textual Amendments

F1035 Sch. 7 para. 12A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **32(3)(aa)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1036 Sch. 7 para. 12A(2) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **26**

13.—(1) This paragraph applies **[**F1037in Northern Ireland**]** where—

(a) a medicinal product which has undergone the controls referred to in **[**F1038paragraph 12A in a member State is imported to Northern Ireland**]**; and

(b) each batch of the product is accompanied by control reports signed by another qualified person in respect of the medicinal product.

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph **[**F1039**12A]**.

Textual Amendments

F1037 Words in Sch. 7 para. 13(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

F1038 Words in Sch. 7 para. 13(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

F1039 Word in Sch. 7 para. 13(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(iii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

14.—(1) This paragraph applies where—

(a) medicinal products are imported **[**F1040into Great Britain from a country other than an approved country for import or into Northern Ireland**]** from a country other than an EEA State; and

[F1041(b) appropriate arrangements have been made, in the case of import into Great Britain by the licensing authority with the country from which those products are imported and, in the case of a product for import into Northern Ireland by the European Union with that country, to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down—

(aa) in the case of a product for sale or supply in Great Britain, in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17, and

(bb) in the case of a product for sale or supply in Northern Ireland, by the European Union;

(ii) the controls referred to in paragraph 12(b) or 12A(b) (as appropriate) have been carried out in that country.**]**

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph 12 **[**F1042or 12A**]**.

[F1043(3) The licensing authority must publish a list of the countries with whom it has made appropriate arrangements under sub-paragraph (1)(b) ("approved country for batch testing list").

(4) A country may be included in the approved country for batch testing list subject to any condition or restriction that the licensing authority considers appropriate, including as to categories of medicinal product, and any such condition or restriction must be included in the list.

(5) In order to satisfy itself of the matters specified in sub-paragraph (1)(b)(i) and (ii), the licensing authority may, in particular, take into account—

(a) the country's rules for good manufacturing practice;

(b) the regularity of inspections to verify compliance with good manufacturing practice;

(c) the effectiveness of enforcement of good manufacturing practice;

(d) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers;

(e) any on-site review of that country's regulatory system undertaken by the licensing authority;

(f) any on-site inspection of a manufacturing site in that country observed by the licensing authority;

(g) any other relevant documentation available to the licensing authority.

(6) The licensing authority must—

(a) review any appropriate arrangements it has made under sub-paragraph (1)(b) to determine if that country still satisfies the requirements of sub-paragraph (1)(b)(i) and (ii), and whether any condition or restriction in those arrangements remains appropriate;

(b) if it is not so satisfied, remove that country from the approved country for batch testing list or, as the case may be, amend or remove that condition or restriction; and

(c) undertake such a review at least every three years beginning with the date on which the country is included in that list.**]**

Textual Amendments

F1040 Words in Sch. 7 para. 14(1)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(i)**)

F1041 Sch. 7 para. 14(1)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(ii)**)

F1042 Words in Sch. 7 para. 14(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(iia)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(iii)**)

F1043 Sch. 7 para. 14(3)-(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

15.—(1) The qualified person is responsible for ensuring, in relation to a medicinal product, that documentary evidence is produced that each batch of the product satisfies the requirements of paragraph 12.

(2) The documentary evidence referred to in sub-paragraph (1) must be kept up to date and must be available for inspection by the licensing authority for a period of at least five years.

[F1044 SCHEDULE 7A

Regulation 45N(5)(b)

Information to be provided for registration as an importer, manufacturer or distributor of active substances

Textual Amendments

F1044 Sch. 7A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **33**

1. The name and address of the applicant.

2. The name and address of the person (if any) making the application on the applicant's behalf.

3. The address of each of the premises where any operations to which the registration relates are to be carried out.

4. The address of any premises not mentioned by virtue of the above requirement, where—

(a) the applicant proposes to keep any living animals, from which substance(s) used in the production of the active substance(s) to which the application relates are to be derived;

(b) materials of animal origin from which an active substance is to be derived, as mentioned in the above sub-paragraph, are to be kept.

5. The address of each of the premises where active substances are to be stored, or from which active substances are to be distributed.

6. The address of each of the premises where any testing associated with the manufacture or assembly of active substances to which the registration relates.

7. The name, address, qualifications and experience of the person whose duty it will be to supervise any manufacturing operations, and the name and job title of the person to whom they report.

8. The name, address, qualifications and experience of the person who will have responsibility for the quality control of active substances, and the name and job title of the person to whom they report.

9. The name, address, qualifications and experience of the person whose duty it will be to supervise any importation, storage or distribution operations, and the name and job title of the person to whom they report.

10. The name, address and qualifications of the person to be responsible for any animals kept as mentioned in paragraph 4(a).

11. The name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of an active substance.

12. For each active substance to be manufactured, imported, or distributed—

(a) the CAS registration number assigned to that active substance by the Chemical Abstracts Service, a division of the American Chemical Society;

(b) where applicable, the Anatomical Therapeutic Category code assigned to that active substance under the Anatomical Therapeutic Chemical Classification System used for the classification of drugs by the World Health Organisation's Collaborating Centre for Drug Statistics Methodology;

(c) either—

(i) the International Union of Pure and Applied Chemistry nomenclature, or

(ii) the common name; and

(d) the intended quantities of each active substance to be manufactured, imported or distributed.

13. Details of the operations to which the registration relates, including a statement of whether they include—

(a) the manufacture of active substances;

(b) the importation of active substances [F1045]...;

(c) the storage of active substances; or

(d) the distribution of active substances.

Textual Amendments

F1045 Words in Sch. 7A para. 13(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **43(2)**; 2020 c. 1, Sch. 5 para. 1(1)

14. A statement of the facilities and equipment available at each of the premises where active substances are to be manufactured, stored or distributed.

15. A statement as to whether the particular active substances are intended for—

(a) use in a medicinal product with an EU marketing authorisation;

(b) use in a special medicinal product; or

(c) export [F1046]....

Textual Amendments

F1046 Words in Sch. 7A para. 15(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **43(3)**; 2020 c. 1, Sch. 5 para. 1(1)

16. A separate statement in respect of each of the premises mentioned in the application of—

(a) the manufacturing, storage or distribution operations carried out at those sites, and the specific active substances to which those activities relate; and

(b) the equipment available at those premises for carrying out those activities.

17. A statement of the authority conferred on the person responsible for quality control to reject unsatisfactory active substances.

18. A description of the arrangements for the identification and storage of materials before and during the manufacture of active substances.

19. A description of the arrangements for the identification and storage of active substances.

20. A description of the arrangements at each of the premises where the applicant proposes to store active substances for ensuring, as far as practicable, the turn-over of stocks of active substances.

21. A description of the arrangements for maintaining—

(a) production records, including records of manufacture and assembly;

(b) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials use in manufacture, or of active substances, with the specification for such materials or active substances;

(c) records of importation;

(d) records of storage and distribution.

22. A description of the arrangements for keeping reference samples of—

(a) materials used in the manufacture of active substances; and

(b) active substances.

23. Where the application relates to active substances intended for use in an advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow traceability containing sufficient detail to enable the linking of an active substance to the advanced therapy medicinal product it was used in the manufacture of and vice versa.

24. Details of—

(a) any manufacturing, importation, storage or distribution operations, other than those to which the application for registration relates, carried on by the applicant on or near each of the premises, and

(b) the substances or articles to which those operations relate.**]**

SCHEDULE 8

Regulation 50(1)

Material to accompany an application for a UK marketing authorisation

PART 1

General requirements

1. The name or corporate name and permanent address of the applicant and (where applicable) of the manufacturer of the medicinal product.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the marketing authorisation holder.

3. Qualitative and quantitative particulars of the constituents of the medicinal product, including—

(a) where there is an international non-proprietary name recommended by the World Health Organisation for a constituent, a reference to that name; or

(b) otherwise, a reference to the relevant chemical name.

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

5. A description of the methods of manufacturing the medicinal product.

6. The therapeutic indications and contra-indications for the medicinal product and the adverse reactions associated with it.

7. The posology and pharmaceutical form of the medicinal product, its method and route of administration and its expected shelf life.

8. The reasons for any precautionary and safety measures to be taken for—

(a) the storage of the medicinal product;

(b) the administration of the medicinal product to patients; and

(c) the disposal of the medicinal product and any waste products,

with an indication of the potential risks presented by the medicinal product for the environment.

9. A description of the control methods employed by the manufacturer.

[F1047 9A. A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with the principles and guidelines of good manufacturing practice by conducting audits, in accordance with regulation 37(5)(a) and containing—

(a) information about the date of the audit; and

(b) a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.**]**

Textual Amendments

F1047 Sch. 8 para. 9A inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **34**

10. The results of the following in relation to the medicinal product and its constituent active substances—

(a) pharmaceutical (physico-chemical, biological or microbiological) tests;

(b) pre-clinical (toxicological and pharmacological) tests; and

(c) clinical trials.

11. A detailed summary of those results prepared and signed by an expert with appropriate technical or professional qualifications, which must be set out in a brief curriculum vitae.

12. A summary of the applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance **[**F1048who is ordinarily resident, and operates, in the United Kingdom or a member State**]**;

[F1049(b) the country (which must be either the United Kingdom or a member State) in which the appropriately qualified person resides and carries out his or her tasks;**]**

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

[F1050(e) a reference to the physical location where the pharmacovigilance system master file for the medicinal product can be accessed electronically, which must be in the United Kingdom.**]**

Textual Amendments

F1048 Words in Sch. 8 para. 12(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **50(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 38(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1049 Sch. 8 para. 12(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **50(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(a)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1050 Sch. 8 para. 12(e) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **50(2)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(a)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

13. The risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

14. Where any clinical trials have been carried out outside the European Union, a statement to the effect that the trials met the ethical requirements of the Clinical Trials Directive.

15. A summary of the product characteristics for the medicinal product in accordance with Part 2 of this Schedule.

16. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

17. A document showing that the manufacturer of the medicinal product is authorised to produce medicinal products in the manufacturer's own country.

[F1051**18.** Where—

(a) in the case of a UKMA(NI) or a UKMA(UK), an application for authorisation for the medicinal product to be placed on the market is under consideration in one or more member States—

(i) a list of the member State or States concerned, and

(ii) in relation to each such application, a copy of the summary of the product characteristics, and the package leaflet, proposed by the applicant;

(b) in the case of a medicinal product for sale or supply in Great Britain, an application for authorisation for the medicinal product to be placed on the market is under consideration in a country other than the United Kingdom, or by the EMA, notification of that fact.**]**

Textual Amendments

F1051 Sch. 8 para. 18 substituted (31.12.2020) by S.I. 2019/775, regs. 1, **50(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(b)**)

19. Where an authorisation for the medicinal product to be placed on the market has been granted by **[**F1052, in the case of a medicinal product for sale or supply in Northern Ireland, a member State or by a country other than an EEA State, or in the case of a medicinal product for sale or supply in Great Britain, by a country other than the United Kingdom or by the European Commission**]**—

(a) a copy of that authorisation;

(b) a summary of the safety data, including the data contained in the periodic safety update reports, where available; and

(c) any suspected adverse reaction reports.

Textual Amendments

F1052 Words in Sch. 8 para. 19 substituted (31.12.2020) by S.I. 2019/775, **reg. 50(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(c)**)

20. Where **[**F1053, in the case of a medicinal product for sale or supply in Northern Ireland,**]** an authorisation for the medicinal product to be placed on the market has been granted by a member State in accordance with the 2001 Directive, a copy of—

(a) the summary of the product characteristics approved by the competent authority of the member State; and

(b) the package leaflet approved by that competent authority.

Textual Amendments

F1053 Words in Sch. 8 para. 20 inserted (31.12.2020) by S.I. 2019/775, **reg. 50(5)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(d)**)

[F1054**21.** Where an authorisation for the medicinal product to be placed on the market has been refused—

(a) in the case of a medicinal product for sale or supply in Northern Ireland, by a member State or by a country other than an EEA State, or

(b) in the case of a medicinal product for sale or supply in Great Britain, by a country other than the United Kingdom,

details of that decision and of the reasons for it.**]**

Textual Amendments

F1054 Sch. 8 para. 21 substituted (31.12.2020) by S.I. 2019/775, **reg. 50(6)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(e)**)

22. **[**[F1055] In the case of a medicinal product for sale or supply in Northern Ireland, a copy of any**]** designation of the medicinal product as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [M88] together with a copy of the relevant Agency opinion.

Textual Amendments

F1055 Words in Sch. 8 para. 22 substituted (31.12.2020) by S.I. 2019/775, **reg. 50(7)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(f)**)

Marginal Citations

M88 OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.

PART 2

Summary of the product characteristics

The summary of the product characteristics must contain the following information in the following order—

[[F1056]**23.** For medicinal products included on the list referred to—

(a) in the case of a medicinal product for sale or supply in Northern Ireland, in Article 23 of Regulation (EC) No 726/2004, the symbol and statement "▼ This medicinal product is subject to additional monitoring", or

(b) in the case of a medicinal product for sale or supply in Great Britain, in regulation 202A, the symbol and statement "▼ This medicinal product is subject to additional monitoring".**]**

Textual Amendments

F1056 Sch. 8 para. 23 substituted (31.12.2020) by S.I. 2019/775, **reg. 50(8)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(g)**)

24. The name of the medicinal product followed by its strength and pharmaceutical form.

25. The qualitative and quantitative composition, using the usual common name or chemical description, of the medicinal product in terms of—

(a) the active substances; and

(b) those excipients of which knowledge is essential for proper administration of the medicinal product.

[[F1057]**25A.** In the case of an advanced therapy medicinal product for sale or supply in Great Britain which contains cells or tissues, a detailed description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.**]**

Textual Amendments

F1057 Sch. 8 para. 25A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **50(9)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 38(h)**); 2020 c. 1, **Sch. 5 para. 1(1)**

26. The pharmaceutical form of the medicinal product.

27. Clinical particulars in relation to the medicinal product, covering—

(a) therapeutic indications;

(b) posology and method of administration for adults and, where necessary, for children; therapeutic indications;

(c) contra-indications;

(d) special warnings and precautions for use and, in the case of immunological medicinal products any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient;

(e) interaction with other medicinal products and other forms of interactions;

(f) use during pregnancy and lactation;

(g) effects on ability to drive and to use machines;

(h) other undesirable effects; and

(i) information on overdose (including symptoms, emergency procedures and antidotes).

28. The pharmacological properties of the medicinal product, covering—

(a) pharmacodynamic properties;

(b) pharmacokinetic properties; and

(c) pre-clinical safety data.

29. Pharmaceutical particulars in relation to the medicinal product, covering—

(a) a list of excipients;

(b) major incompatibilities;

(c) shelf life after reconstitution of the medicinal product or when the immediate packaging is opened for the first time (as appropriate);

(d) special precautions for storage;

(e) nature and contents of container; and

(f) special precautions for disposal of the used medicinal product or waste materials derived from the medicinal product (as appropriate).

30. The holder of the UK marketing authorisation.

31. The number of the UK marketing authorisation.

32. The date of the first UK marketing authorisation or, where the UK marketing authorisation has been renewed, the date of the last renewal.

33. The date of any revisions of the text of the summary of the product characteristics.

34. For radiopharmaceuticals, full details of internal radiation dosimetry.

35. For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.

[F1058 36. In the case of an advanced therapy medicinal product for sale or supply in Great Britain—

(a) references in this Part of this Schedule to administration of a product include references to the advanced therapy medicinal product's use, application or implantation; and

(b) descriptions, instructions and warnings must include explanatory drawings and pictures where necessary.**]**

Textual Amendments

F1058 Sch. 8 para. 36 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **50(10)** (as amended by (S.I. 2020/1488, reg. 1, **Sch. 2 para. 38(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F1059SCHEDULE 8A

Regulation 50(1A)

Material to accompany an application for a parallel import licence

Textual Amendments

F1059 Sch. 8A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **26** and Sch. 8A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **26**

1. The name or corporate name and permanent address of the applicant.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the parallel import licence holder.

3. Details of the product to be imported if requested by the licensing authority.

4. Details of the UK reference product.

5. If requested by the licensing authority, an evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

6. If requested by the licensing authority, a summary of the applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance **[**F1060who resides and operates in the United Kingdom**]**;

F1061(b) . . . . . .

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept **[**F1062or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom**]**.

Textual Amendments

F1060 Words in Sch. 8A para. 6(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F1061 Sch. 8A para. 6(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F1062 Words in Sch. 8A para. 6(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(c)**; 2020 c. 1, Sch. 5 para. 1(1)

7. If requested by the licensing authority, the risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

8. If requested by the licensing authority, a summary of the product characteristics for the medicinal product in accordance with Part 2 of Schedule 8.

9. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.**]**

[F1063 SCHEDULE 8B

Regulation 8(1)

Modifications of Annex I to the 2001 Directive

Textual Amendments

F1063 Sch. 8B inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 2** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 189**); 2020 c. 1, **Sch. 5 para. 1(1)**

Provision of Annex I	***Modification subject to which that provision is to be read***
Paragraph (1) of the Introduction and general principles	The reference to "Articles 8 and 10(1)" is to be read as a reference to regulation 50 of the Human Medicines Regulations 2012.
Paragraphs (1) and (2) of the Introduction and general principles	If the licensing authority has published guidelines under regulation 50(5B)(a) of the Human Medicines Regulations 2012, the reference to "the rules governing medicinal products in the European Community, Volume 2B, Notice to applicants, medicinal products for human use, presentation and content of the

	dossier, Common Technical Document" is to be read as a reference to that guidance.
Paragraph (4) of the Introduction and general principles	If the licensing authority has published guidelines under regulation 50(5B)(b) of the Human Medicines Regulations 2012, the reference to "the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and the European Medicines Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different volumes of the rules governing medicinal products in the European Community" is to be read as a reference to those guidelines.
Paragraph (6) of the Introduction and general principles	The reference to "the requirements of Commission Directive 91/356/EEC laying down the principles of and guidelines of Good Manufacturing Practice for medicinal products for human use" is to be read as a reference to the Good Manufacturing Practice Directive, as defined in regulation 8(1) of the Human Medicines Regulations 2012.
Paragraph (6) of the Introduction and general principles	If the licensing authority has published principles and guidelines under regulation C17(1) of the Human Medicines Regulations 2012, the reference to "the principles and guidelines on GMP published by the Commission in the rules governing medicinal products in the European Community, Volume 4" is to be read as a reference to those principles and guidelines.
Paragraph (8) of the Introduction and general principles	References to "the European Community" are to be read as references to the United Kingdom.
Paragraph (8) of the Introduction and general principles	The references to "Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" are to be read as references to the Medicinal Products for Human Use (Clinical Trials) Regulations 2004.
Paragraph (9) of the Introduction and general principles	The reference to "Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances and 88/320/

	EEC on the inspection and verification of good laboratory practice" is to be read as a reference to the Good Laboratory Practice Regulations 1999.
Paragraph (10) of the Introduction and general principles	The reference to "Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes" is to be read as a reference to the Animals (Scientific Procedures) Act 1986.
Paragraph (11) of the Introduction and general principles	The paragraph is to be read as follows: "In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmacovigilance information shall be submitted to the licensing authority. After a marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the licensing authority in accordance with the requirements of Schedule 10A to the Human Medicines Regulations 2012, as well as the requirements of Schedule 12A to those Regulations."
Part I, paragraph 1.2, fourth paragraph	This paragraph is to be read as follows: "Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in regulation 17 of the Human Medicines Regulations 2012."
Part I, paragraph 1.3.1	The reference to "Article 11" is to be read as a reference to Part 2 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 1.3.2	The reference to "Title V" is to be read as a reference to Part I3 of the Human Medicines Regulations 2012, and the references to Articles 63 and 59 are to be read as references to regulations 260 and 266 of the Human Medicines Regulations 2012.
Part I, paragraph 1.3.4	This paragraph is to be read as omitted.
Part I, paragraph 1.4	The reference to "Article 12.2" is to be read as a reference to paragraph 11 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 2, first paragraph	The reference to "Article 12" is to be read as a reference to paragraph 11 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 3.2(5), first paragraph	The reference to a "Member State" is to be read as including the United Kingdom.
Part I, paragraph 3.2(5), second paragraph	The references to "the national pharmacopoeia of a Member State" are to be read as including references to the British Pharmacopoeia.

Part I, paragraph 3.2(6)	The reference to "the pharmacopoeia of a Member State" is to be read as including a reference to the British Pharmacopoeia.
Part I, paragraph 3.2(12)	The words "which is required by Community legislation" are to be read as omitted.
Part I, paragraph 3.2.1.2	If the licensing authority has published guidelines under regulation 50(5B)(c) of the Human Medicines Regulations 2012, the reference to "guidelines published by the Agency" is to be read as a reference to those guidelines.
Part I, paragraph 3.2.2.1, second paragraph	The reference to "Article 8(3)(c)" is to be read as a reference to paragraph 3 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 3.2.2.1, second paragraph, first indent	The reference to "the national pharmacopoeia of one of the Member States" is to be read as including the British Pharmacopoeia.
Part I, paragraph 3.2.2.1, fifth paragraph	The reference to "any Member State" is to be read as a reference to the United Kingdom and the reference to "the Member States" is to be read as a reference to the United Kingdom.
Part I, paragraph 3.2.2.3(a)	The reference to "Article 8(3)(d)" is to be read as a reference to paragraph 5 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 4.2.2, fifth paragraph	The reference to "this Directive" is to be read as a reference to the Human Medicines Regulations 2012.
Part I, paragraph 5.2(a)	The reference to "the clinical particulars provided pursuant to Articles 8(3)(i) and 10(1)" is to be read as a reference to those particulars provided pursuant to paragraph 10 of Schedule 8 to, and regulations 51A, 52A, 53A and 54 to 56 of, the Human Medicines Regulations 2012.
Part I, paragraph 5.2(c)	The references to "the European Community" are to be read as references to the United Kingdom.
Part I, paragraph 5.2(c), fifth paragraph	The reference to "Directive 2001/20/EC and implementing detail guidelines" is to be read as a reference to the Medicinal Products for Human Use (Clinical Trials) Regulations 2004.
Part I, paragraph 5.2.1, second paragraph	The reference to "Article 10(1)(a)" is to be read as a reference to regulation 51A of the Human Medicines Regulations 2012.
Part II, paragraph 1, first paragraph	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 54 of the Human Medicines Regulations 2012.

Part II, paragraph 2(a)	The reference to "Article 10(1)(a)(i)" is to be read as a reference to regulation 56 of the Human Medicines Regulations 2012.
Part II, paragraph 2(b)	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 51A of the Human Medicines Regulations 2012.
Part II, paragraph 4, first paragraph	The first sentence is to be read as omitted and the words "in accordance with regulation 53A of the Human Medicines Regulations 2012" are to be read as added at the end of the second sentence.
Part II, paragraph 5, first paragraph	The reference to "Article 10(1)(b)" is to be read as a reference to regulation 55 of the Human Medicines Regulations 2012.
Part II, paragraph 6, first paragraph	The reference to "Article 22" is to be read as a reference to regulation 60 of the Human Medicines Regulations 2012.
Part III, paragraph 1.1(a), first indent	The reference to "Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices incorporating stable derivatives of human blood or blood plasma" is to be read as a reference to the Medical Devices Regulations 2002.
Part III, paragraph 1.1(a), third indent	The reference to "the Agency or the competent authority" is to be read as a reference to the licensing authority.
Part III, paragraph 1.1(a), fourth indent	This indent is to be read as omitted.
Part III, paragraph 1.1(b)	The reference to "Article 109, as amended by Directive 2002/98/EC" is to be read as a reference to the Blood Safety and Quality Regulations 2005.
Part III, paragraph 1.1(b)(3), second paragraph	The reference to "medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" is to be read as a reference to investigational medicinal products.
Part III, paragraph 1.1.(c), second indent	This indent is to be read as follows: "The Plasma Master File is subject to a scientific and technical evaluation by the licensing authority."
Part III, paragraph 1.1(c), fourth indent	This indent is to be read as follows: "Changes subsequently introduced to the terms of a Plasma Master File must follow the variation procedure in Schedule 10A to the Human Medicines Regulations 2012."

Part III, paragraph 1.1(c), final indent	This indent is to be read as omitted.
Part III, paragraph 1.2(c), first indent	The references to "a competent authority" and to "the Agency" are to be read as references to the licensing authority and the final two sentences are to be read as omitted.
Part III, paragraph 1.2(c), second indent	The reference to "the Community" is to be read as a reference to the United Kingdom.
Part III, paragraph 1.2(c), third indent	This indent is to be read as follows: "Changes in the content of a Vaccine Antigen Master File must follow the variation procedure in Schedule 10A to the Human Medicines Regulations 2012."
Part III, paragraph 1.2(c), fourth indent	This indent is to be read as omitted.
Part III, paragraph 1.2(c), fifth indent	This indent is to be read as omitted.
Part III, paragraph 2.1	The reference to "applications based on Articles 6(2) and 9" is to be read as a reference to applications in relation to radionuclide generators, radionuclide kits, radionuclide precursors and radiopharmaceuticals.
Part III, paragraph 2.2, fourth paragraph	The reference to "Council Directives 87/18/EEC and 88/320/EEC" is to be read as a reference to the Good Laboratory Practice Regulations 1999.
Part III, paragraph 3, second paragraph	The reference to "Article 15" is to be read as a reference to regulation 103 of the Human Medicines Regulations 2012, the reference to "Article 14(1)" is to be read as a reference to regulation 102 of the Human Medicines Regulations 2012 and the words "referred to in Article 16(1)" are to be read as "which are not registerable homoeopathic medicinal products".
Part III, paragraph 3(a)	The reference to "an official pharmacopoeia of a Member State" is to be read as including the British Pharmacopoeia and any pharmacopoeia used officially in a country that is included in a list published by the licensing authority for that purpose, and the reference to "the traditional names used in each Member State" is to be read as including the traditional name used in the United Kingdom.
Part III, paragraph 3(b), final paragraph	The reference to "an official pharmacopoeia of a Member State" is to be read as including the British Pharmacopoeia.
Part III, paragraph 3, penultimate paragraph	The reference to "Article 14(1)" is to be read as a reference to regulation 102 of the Human Medicines Regulations 2012.
Part III, paragraph 5, first indent	The reference to "an orphan medicinal product in the meaning of Regulation (EC) No 141/2000"

	is to be read as a reference to a medicinal product to which the orphan criteria are claimed to apply.
Part III, paragraph 5, second indent	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 54 of the Human Medicines Regulations 2012 and the reference to "Article 5" is to be read as a reference to regulation 167 of the Human Medicines Regulations 2012.
Part IV, paragraph 1, first paragraph	The reference to "point (a) of Article 2(1) of Regulation (EC) No 1394/2007" is to be read as a reference to regulation 2A of the Human Medicines Regulations 2012.
Part IV, paragraph 2	This paragraph is to be read as omitted.
Part IV, paragraph 3.1, second paragraph	The reference to "Directive 2004/23/EC" is to be read as a reference to the Human Fertilisation and Embryology Act 1990and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the reference to "Directive 2002/98/EC" is to be read as a reference to the Blood Safety and Quality Regulations 2005.
Part IV, paragraph 3.3.2.1(a)	The reference to "Directive 2004/23/EC" is to be read as a reference to the Human Fertilisation and Embryology Act 1990 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007.
Part IV, paragraph 3.4.1, heading	The reference to "devices as referred to in Article 7 of Regulation (EC) No 1394/2007" is to be read as a reference to medical devices, bio-materials, scaffolds or matrices.
Part IV, paragraph 3.4.2, heading	The reference to "Article 2(1)(d) of Regulation (EC) No 1394/2007" is to be read as a reference to regulation 2A(10) of the Human Medicines Regulations 2012.
Part IV, paragraph 3.4.2(c)	The reference to "Commission Directive 2003/32/EC" is to be read as a reference to the Medical Devices Regulations 2002.
Part IV, paragraph 3.4.2(d)	The reference to "Directive 93/42/EEC or Directive 90/385/EEC" is to be read as a reference to the Medical Devices Regulations 2002.
Part IV, paragraph 3.4.2, final paragraph	The first sentence is to be read as follows: "The applicant shall make available on request of the licensing authority any information related to the assessment by the notified body which has carried out the assessment referred to in point (d) of this section."**]**

[F1064SCHEDULE 8C

Regulation 50(1)

Material to accompany an application for a UK marketing authorisation under the unfettered access route

Textual Amendments

F1064 Sch. 8C inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 2A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 190**)

1. A copy of the application submitted in connection with the granting of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

2. A copy of all material submitted in support of the application for the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.

3. A copy of the EU marketing authorisation or UKMA(NI) which authorises the sale or supply of the medicinal product in Northern Ireland.**]**

SCHEDULE 9

Regulation 50(4)

Undertakings by non- **[**F1065United Kingdom**]** manufacturers

Textual Amendments

F1065 Words in Sch. 9 heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(2)**; 2020 c. 1, Sch. 5 para. 1(1)

1. The manufacturer must provide and maintain such staff, premises and plant as are necessary for the carrying out in accordance with the **[**F1066UK**]** marketing authorisation of such stages of the manufacture and assembly of the medicinal products to which the authorisation relates as are undertaken by the manufacturer.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

2. The manufacturer must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates and which the manufacturer handles, stores or distributes as are necessary to avoid deterioration of the medicinal products.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

3. The manufacturer must provide and maintain a designated quality control department having authority in relation to quality control and being independent of all other departments.

4. The manufacturer must conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates conform with the standards of strength, quality and purity applicable to them under the **[**[F1066]UK**]** marketing authorisation.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

5. The manufacturer must maintain an effective pharmaceutical quality assurance system involving the active participation of the management and personnel of the different services involved.

6. Where animals are used in the production of any medicinal product and the **[**[F1066]UK**]** marketing authorisation contains provisions relating to them the manufacturer must arrange for the animals to be housed in premises of such a nature and to be managed in such a way as will facilitate compliance with such provisions.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

7. The manufacturer must make such adequate and suitable arrangements as are necessary for carrying out in accordance with the **[**[F1066]UK**]** marketing authorisation any tests of the strength, quality or purity of the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

8. The manufacturer must inform the holder of the **[**[F1066]UK**]** marketing authorisation of any material alteration in the premises or plant used in connection with the manufacture or assembly of the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates or in the operations for which such premises or plant are so used, and of any change since the granting of the relevant **[**[F1066]UK**]** marketing authorisation in respect of any person—

(a) responsible for supervising the production operations;

(b) responsible for quality control of the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates;

(c) in charge of the animals from which are derived any substance used in the production of the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates; or

(d) responsible for the culture of any living tissues used in the manufacture of the medicinal products to which the **[**[F1066]UK**]** marketing authorisation relates.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

9.—(1) The manufacturer shall keep readily available for inspection by a person authorised by the licensing authority durable records of—

(a) the details of manufacture and assembly of each batch of the medicinal product to which the **[**[F1066]UK**]** marketing authorisation relates; and

(b) the tests carried out on the product,

in such a form that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is exported from the country where it has been manufactured or assembled.

(2) The manufacturer shall permit the person authorised to take copies of or make extracts from such records.

(3) Such records shall not be destroyed for a period of five years from the date of release of the batch concerned, or one year after the expiry date of the batch, whichever is the later.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

10. The manufacturer must keep readily available for examination by a person authorised by the licensing authority samples of—

(a) each batch of finished products for at least a period of one year after their expiry date; and

(b) starting materials (other than solvents, gases or water) for at least a period of two years after release of the medicinal product of which those materials formed part,

except where the manufacturer is authorised by the licensing authority to destroy such samples earlier.

11.—(1) The manufacturer must implement a system for recording and reviewing complaints in relation to medicinal products to which a **[**[F1066]UK**]** marketing authorisation relates, together with an effective system for recalling promptly and at any time the medicinal products in the distribution network.

(2) The manufacturer must record and investigate all complaints described in sub-paragraph (1) and must immediately inform the licensing authority of any defect which could result in a recall from sale, supply or export or in an abnormal restriction on such sale, supply or export.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

12. The manufacturer must inform the holder of the **[**F1066UK**]** marketing authorisation of any material change since the day upon which the authorisation was granted in respect of—

(a) the facilities and equipment available at each of the premises of the manufacturer for carrying out any stage of the manufacture or assembly of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates;

(b) the facilities and equipment available at each of the premises of the manufacturer for the storage of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates on, and the distribution of the products from or between, such premises;

(c) any manufacturing operations, not being operations in relation to the medicinal products to which the **[**F1066UK**]** marketing authorisation relates, which are carried on by the manufacturer on or near any of the premises on which medicinal products to which the **[**F1066UK**]** marketing authorisation relates are manufactured or assembled, and the substances or articles in respect of which such operations are carried on;

(d) the arrangements for the identification and storage of materials and ingredients before and during manufacture or assembly of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates and the arrangements for the storage of the products after they have been manufactured or assembled;

(e) the arrangements for ensuring a satisfactory turnover of stocks of medicinal products to which the **[**F1066UK**]** marketing authorisation relates;

(f) the arrangements for maintaining production records and records of analytical and other testing procedures applied in the course of manufacture or assembly of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates; or

(g) the arrangements for keeping reference samples of materials used in the manufacture of the medicinal products to which the **[**F1066UK**]** marketing authorisation relates and reference samples of the medicinal products themselves.

Textual Amendments

F1066 Word in Sch. 9 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **52(3)**; 2020 c. 1, Sch. 5 para. 1(1)

[F1067SCHEDULE 9A

Regulation 50G(4)

Meaning of terms used in the orphan criteria and in regulation 58D

Textual Amendments

F1067 Sch. 9A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 4** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 191**); 2020 c. 1, **Sch. 5 para. 1(1)**

Prevalence of a condition in Great Britain

1.—(1) The following provisions apply for the purposes of establishing, pursuant to regulation 50G(2)(a) and (b)(i), that a medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in Great Britain.

(2) The material provided pursuant to regulation 50G(3) must include—

(a) material which demonstrates that the disease or condition for which the medicinal product would be authorised affects not more than five in 10,000 persons in Great Britain at the time at which the application for an orphan marketing authorisation is submitted, where this is available;

(b) details of the condition intended to be treated and a justification of the life-threatening or chronically debilitating nature of the condition, supported by scientific or medical references; and

(c) copies of, or references to, relevant scientific literature, as well as copies of information from relevant databases in Great Britain, where available.

(3) If there are no databases as referred to in paragraph (2)(c), information from relevant databases in other countries may be supplied, provided appropriate extrapolations are made.

Potential for return on investment

2.—(1) The following provisions apply for the purposes of establishing, pursuant to regulation 50G(2)(a) and (b)(ii), that a medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition in Great Britain and that the medicinal product is unlikely, when marketed, to generate sufficient financial return to justify the necessary investment.

(2) The material provided pursuant to regulation 50G(3) must include—

(a) details of the condition intended to be treated and a justification of the life-threatening or chronically debilitating nature of the condition, supported by scientific or medical references;

(b) details of the costs incurred in connection with the development of the medicinal product;

(c) details of any grants, tax incentives or other cost recovery provisions received in Great Britain or any other country in relation to the development of the medicinal product;

(d) where the medicinal product is already authorised in Great Britain for any indication, or where the product is under investigation for one or more other indications, an explanation of, and justification for, the method that is used to apportion the development costs among the various indications;

(e) a statement of and justification for all development costs that the applicant expects to incur after the submission of the application for a UK marketing authorisation;

(f) a statement of and justification for all production and marketing costs that the applicant has incurred in the past and expects to incur in the first ten years that the medicinal product is authorised;

(g) an estimate of and justification for the expected revenues from sales of the medicinal product in Great Britain and elsewhere during the first ten years that the medicinal product is authorised; and

(h) information on the prevalence and incidence in Great Britain of the condition for which the medicinal product would be authorised at the time at which the application for an orphan marketing authorisation application is submitted.

(3) The information concerning costs and revenue referred to in sub-paragraph (2) must be determined in accordance with generally accepted accounting principles and must be certified by a person who is a member of a body of accountants which is established in the United Kingdom and which is approved by the licensing authority for the purposes of this paragraph.

Existence of other methods of diagnosis, prevention or treatment

3.—(1) The following provisions apply for the purposes of establishing, pursuant to regulation 50G(2)(c), that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in Great Britain, or if such method exists, that the medicinal product will be of significant benefit to those affected by the condition.

(2) The material provided pursuant to regulation 50G(3) must include—

(a) details of any existing methods of diagnosis, prevention or treatment of the condition in question that have been authorised in Great Britain, making reference to scientific or medical literature or other relevant information, including information relating to authorised medicinal products, medical devices or other methods of diagnosis, prevention or treatment which are used in Great Britain; and

(b) a justification as to why either—

(i) the methods referred to in paragraph (a) are not considered satisfactory; or

(ii) the medicinal product for which an orphan marketing authorisation is sought will be of significant benefit to those affected by the condition.

(3) In this paragraph, "significant benefit" means a clinically relevant advantage or a major contribution to patient care.

Increased safety or effectiveness and clinical superiority

4.—(1) The following provisions apply for the purposes of establishing, pursuant to regulation 58D(6)(c), that a second medicinal product is similar to a medicinal product to which an orphan marketing authorisation relates or is safer or more effective than, or clinically superior to, that product.

(2) The following definitions apply for the purposes of this paragraph—

"clinically superior", in relation to a medicinal product, means that it is shown to provide a significant therapeutic or diagnostic advantage over and above that provided by an authorised orphan medicinal product in one or more of the following ways—

(a) greater efficacy;

(b) greater safety in a substantial portion of the target population, as evidenced where appropriate through comparative clinical trials; or

(c) in exceptional cases, where neither greater safety nor greater efficacy has been shown, a demonstration that the medicinal product otherwise makes a major contribution to diagnosis or to patient care;

"similar active substance" means an identical active substance, or an active substance with the same principal molecular structural features, but not necessarily all of the same molecular structural features, and which acts via the same mechanism, however, in the case of advanced therapy medicinal products, for which the principal molecular structural features cannot be fully defined, the similarity between two active substances is to be assessed on the basis of the biological and functional characteristics;

"similar medicinal product" means a medicinal product containing a similar active substance or substances as contained in a currently authorised orphan medicinal product, and which is intended for the same therapeutic indication.

(3) For the purposes of the definition of "clinically superior" in relation to a medicinal product which shows that superiority by means of greater efficacy, this is to be assessed by the effect on a clinically meaningful endpoint in adequate and well controlled clinical trials, representing the same kind of evidence needed to support a comparative efficacy claim for two different medicinal products.

(4) The clinical trials referred to in paragraph (3) should be direct comparative clinical trials, unless comparisons based on other endpoints, including surrogate endpoints, can be justified.

(5) Paragraphs 5 to 8 make further provision about the definition of "similar active substance" in relation to certain types of product.

5.—(1) This paragraph applies for the purposes of the definition of "similar active substance" in relation to chemical medicinal products.

(2) The principal molecular structural features are the relevant structural components of an active substance, which may be the whole or part of the molecule.

(3) Whether the principal molecular structural features are the same between two or more molecules will be identified by comparison of their structures.

(4) Isomers, mixtures of isomers, complexes, esters, ethers, salts and derivatives of the original active substance, or an active substance that differs from the original active substance only with respect to minor changes in the molecular structure, such as a structural analogue, are to be considered similar.

(5) Synthetic polynucleotide substances, single or double stranded, consisting of two or more distinct nucleotides where—

(a) the difference in the nucleotide sequence of the purine and pyrimidine bases or their derivatives is not major, are to be considered similar, therefore for antisense or interfering nucleotide substances, addition, substitution or deletion of a nucleotide not significantly affecting the kinetics of hybridisation to the target are usually to be considered similar; and

(b) the difference in structure related to modifications of the ribose or deoxyribose backbone sugars or to the replacement of the backbone sugars by synthetic analogues usually result in substances being considered similar, and for antisense or interfering nucleotide substances, changes in the ribose or deoxyribose backbone sugars not significantly affecting the kinetics of hybridisation to the target are usually to be considered similar.

6.—(1) This paragraph applies for the purposes of the definition of "similar active substance" in relation to biological medicinal products other than advanced therapy medicinal products.

(2) The principal molecular structural features are the structural components of an active substance that are relevant for the functional characteristics of that substance.

(3) The principal molecular structural features may be composed of a therapeutic moiety or a therapeutic moiety in combination with an additional structural element significantly contributing to the functional characteristics of the active substance.

(4) An additional structural element as described in paragraph (3) may be conjugated, fused or linked by other means to the therapeutic moiety or may be an extension of the therapeutic moiety protein backbone by additional amino acids.

(5) Substances with structural elements for which similar methods of modification or conjugation technology are used usually result in similar substances.

(6) Biological active substances which differ from the original biological substance only with respect to minor changes in the molecular structure are to be considered similar.

(7) In relation to proteinaceous substances—

(a) if the difference in structure between them is due to post-translational events, such as different glycosylation patterns, substances are usually to be considered similar; however, exceptionally some post-translational modifications may result in a non-similar substance if there is significant effect on the functional characteristics of the substance;

(b) if the difference in the amino acid sequence is not major, substances are usually to be considered similar; therefore two pharmacologically related protein substances of the same group, for example, having differences related to N-terminal methionine, naturally extracted as opposed to recombinant nucleic acid-derived proteins or other minor variants, are usually to be considered similar; however, the addition of a structural element may result in substances not being considered similar if this significantly affects the functional characteristics of the substance;

(c) monoclonal antibodies binding to the same target epitope are usually to be considered similar; however, two monocloncal antibody conjugates or fusion proteins may be considered not to be similar if either the Complementary Determining Region sequences of the antibody or the additional structural element of the conjugated monoclonal antibody is different.

(8) In relation to polysaccharide substances—

(a) if the substances have identical saccharide repeating units, even if the number of units varies, the substances are usually to be considered similar; and

(b) a conjugated polysaccharide vaccine compared to a non-conjugated polysaccharide vaccine containing the same antigen is considered not to be similar.

7.—(1) This paragraph applies for the purposes of the definition of "similar active substance" in relation to advanced therapy medicinal products.

(2) In relation to cell-based advanced therapy medicinal products, these are not to be considered similar if—

(a) there are differences in starting materials or the final composition of the product which have a significant impact on the biological characteristics or biological activity relevant for the intended therapeutic effect or safety attributes of the product, and the different source of the starting materials, such as in the case of autologous advanced therapy medicinal products, is not sufficient to support a claim that two products are not similar; or

(b) there are differences in the manufacturing technology having a significant impact on the biological characteristics or the biological activity relevant for the intended therapeutic effect or safety attributes of the product.

(3) In relation to gene therapy medicinal products—

(a) two gene therapy medicinal products are not to be considered similar when there are differences in the therapeutic sequence, viral vector, transfer system, regulatory sequences or manufacturing technology which significantly affect the biological characteristics or biological activity relevant for the intended therapeutic effect or safety attributes of the product; and

(b) differences in the therapeutic sequence with a significant impact on the intended therapeutic effect are not sufficient to support a claim that two gene therapy medicinal products are not similar.

(4) The considerations in paragraphs (2) and (3) also apply in relation to genetically modified cells.

8.—(1) This paragraph applies for the purposes of the definition of "similar active substance" in relation to radiopharmaceuticals.

(2) The same radiopharmaceutical active substance, or one differing from the original in radionuclide, ligand, site of labelling or molecule-radionuclide coupling mechanism linking the molecule and radionuclide which acts via the same mechanism, are to be considered similar substances.**]**

SCHEDULE 10

Regulations 50(6)(g) and 64(5)(b)

National homoeopathic products

Meaning of "national homoeopathic product"

1.—(1) In this Schedule "national homoeopathic product" means a homoeopathic medicinal product that—

(a) is not a registrable homoeopathic medicinal product; and

(b) is indicated for the relief or treatment of minor symptoms or minor conditions in human beings.

(2) For this purpose symptoms or conditions are minor if they can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.

General requirements for application

2.—(1) An application for the grant of a UK marketing authorisation for a national homoeopathic product does not need be made in accordance with, and an applicant for such an authorisation does not need to comply with—

(a) paragraphs (b) and (c) of paragraph 10 of Schedule 8 (requirement to submit results of pre-clinical tests and clinical trials);

(b) the guidance referred to in paragraph (1) in the "Introduction and general principles" of Annex 1 to the 2001 Directive in so far as it relates to the requirement to submit the results of pre-clinical tests and clinical trials; or

(c) the following provisions of Part 1 of that Annex—

(i) sections 2.4 to 2.7 (non-clinical and clinical overview and non-clinical and clinical summaries),

(ii) section 4 (Module 4: non-clinical reports), or

(iii) section 5 (Module 5: clinical study reports).

(2) The applicant must submit with the application—

(a) particulars and documents relating to the safety of the product in accordance with paragraph 3 (subject to paragraph 4); and

(b) particulars and documents relating to the efficacy of the product in accordance with paragraph 5.

(3) References in Annex 1 to the 2001 Directive to non-clinical reports, non-clinical documentation and non-clinical data apply in relation to the application as if they were references to the particulars and documents referred to in paragraph 3.

(4) References in that Annex to clinical study reports, clinical documentation and clinical data apply in relation to the application as if they were references to the particulars and documents referred to in paragraph 5.

Requirement to submit safety data

3.—(1) The applicant must submit data as to the safety of the product unless paragraph 4 applies.

(2) The data must include information about the following aspects of the safety of the product—

(a) pharmacology;

(b) pharmacokinetics; and

(c) toxicology, including its toxicity, genotoxicity, reproductive and developmental toxicity and local tolerance.

(3) The data must be scientific data unless sub-paragraph (5) applies.

(4) For this purpose "scientific data" means—

(a) study reports in relation to the product;

(b) published scientific data; or

(c) a combination of data within paragraph (a) and data within paragraph (b).

(5) The applicant may submit other data in relation to an aspect of the safety of the product if having made reasonable attempts to obtain scientific data in relation to that aspect—

(a) the applicant is satisfied that no such scientific data is available; or

(b) the applicant thinks that such scientific data as is available may be inadequate to demonstrate an acceptable level of safety in relation to that aspect.

(6) The applicant must include with the data—

(a) a table of contents; and

(b) an evaluation of the scientific data, including an explanation of how it demonstrates an acceptable level of safety.

(7) If the applicant submits data other than scientific data, the applicant must include—

(a) a statement that sub-paragraph (5) applies; and

(b) an explanation of why an acceptable level of safety can be demonstrated despite the lack of scientific data.

Exceptions to requirement to submit safety data

4.—(1) The applicant does not need to submit data as to the safety of the product if—

(a) condition A, B or C is met; and

(b) the application is accompanied by a written statement that the condition is met.

(2) Condition A is that the product—

(a) is derived from a homoeopathic stock that is commonly present in food; and

(b) is intended to be administered orally.

(3) For this purpose "food" has the meaning given by Council Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [M89].

(4) Condition B is that—

(a) the product is derived from a homoeopathic stock from which is derived a medicinal product that has a **[**[F1068]UK**]** marketing authorisation, certificate of registration or traditional herbal registration ("the source product");

(b) the source product is subject to general sale within the meaning of regulation 5(1); and

(c) the product has the same route of administration and the same degree of dilution as the source product.

(5) Condition C is that the product is derived from a homoeopathic stock that—

(a) is diluted to at least 1 in 10^{24} of the stock; and

(b) is not a material derived from a human or animal source.

Textual Amendments

F1068 Word in Sch. 10 para. 4(4)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **55**; 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M89 OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p. 14).

Requirement to submit efficacy data

5.—(1) The applicant must submit data as to the efficacy of the product.

(2) The data must consist of at least one the following—

(a) study reports in relation to the product;

(b) published scientific literature; or

(c) the results of investigations (commonly known as homoeopathic provings) consisting of the administration of a substance to a human subject to ascertain the symptoms it produces.

(3) The applicant must include with the data—

(a) a table of contents; and

(b) an evaluation of the data, including an explanation of how the data establishes that the product has a recognised level of efficacy in the therapeutic indication for which authorisation is sought.

[F1069 SCHEDULE 10A

Regulation 65C(2)

Variations to a UK marketing authorisation

Textual Amendments

F1069 Sch. 10A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 5**; 2020 c. 1, Sch. 5 para. 1(1)

Interpretation

1. In this Schedule—

"change of, or addition of a new, route of administration", in relation to parenteral administration, includes any change or addition as between intra-arterial, intra-venous, intramuscular, subcutaneous and any other route;

"extension of a UK marketing authorisation" or "extension" means a variation which consists of—

(a) a change to one or more active substances that involves—

(i) replacement of a chemical active substance by a different salt, ester, complex or derivative, with the same therapeutic moiety, where the efficacy and safety characteristics are not significantly different,

(ii) replacement by a different isomer, a different mixture of isomers, of a mixture by an isolated isomer (for example, racemate by a single enantiomer), where the efficacy and safety characteristics are not significantly different,

(iii) replacement of a biological active substance with one of a slightly different molecular structure where the efficacy and safety characteristics are not significantly different, with the exception of changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza,

(iv) modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the efficacy and safety characteristics are not significantly different,

(v) a new ligand or coupling mechanism for a radiopharmaceutical, where the efficacy and safety characteristics are not significantly different, or

(vi) change to the extraction solvent or the ratio of herbal drug to herbal drug preparation where the efficacy and safety characteristics are not significantly different; or

(b) a change to strength, pharmaceutical form and route of administration that involves—

(i) change of bioavailability,

(ii) change of pharmacokinetics, for example change in rate of release,

(iii) change or addition of a new strength or potency,

(iv) change or addition of a new pharmaceutical form, or

(v) change or addition of a new route of administration;

"holder" means UK marketing authorisation holder;

"major variation of type II" means a variation which is not an extension and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned namely—

(a) variations related to the addition of a new therapeutic indication or to the modification of an existing one;

(b) variations related to significant modifications of the summary of product characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance findings;

(c) variations related to changes outside the range of approved specifications, limits or acceptance criteria;

(d) variations related to substantial changes to the manufacturing process, formulation, specifications or impurity profile of the active substance or finished medicinal product which may have a significant impact on the quality, safety or efficacy of the medicinal product;

(e) variations related to modifications in the manufacturing process or sites of the active substance for a biological medicinal product;

(f) variations related to the introduction of a new design space or the extension of an approved one, where the design space has been developed in accordance with international scientific guidelines; or

(g) variations related to changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;

"minor variation of type IA" means a variation which has only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product concerned namely—

(a) variations of purely administrative nature that are related to the identity and contact details of—

(i) the holder,

(ii) the manufacturer or supplier of any starting material, reagent, intermediate, active substance used in the manufacturing process or finished product;

(b) variations related to the identity, location and contact details of the qualified person for pharmacovigilance, or the location of the pharmacovigilance system master file;

(c) variations related to the deletion of any manufacturing site, including for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place;

(d) variations related to minor changes to an approved physico-chemical test procedure, where the updated procedure is demonstrated to be at least equivalent to the former test procedure, appropriate validation studies have been performed and the results show that the updated test procedure is at least equivalent to the former;

(e) variations related to changes made to the specifications of the active substance or of an excipient in order to comply with an update of the relevant monograph of the European Pharmacopoeia or of the British Pharmacopoeia, where the change is made exclusively to comply with the pharmacopoeia and the specifications for product specific properties are unchanged;

(f) variations related to changes in the packaging material not in contact with the finished product, which do not affect the delivery, use, safety or stability of the medicinal product;

(g) variations related to the tightening of specification limits, where the change is not a consequence of any commitment from previous assessment to review specification limits and does not result from unexpected events arising during manufacture;

"minor variation of type IB" means a variation which is not a minor variation of type IA, a major variation of type II nor an extension; and

"urgent safety restriction" means an interim change in the terms of the UK marketing authorisation due to new information having a bearing on the safe use of the medicinal product.

Classification of variations

2.—(1) Except where sub-paragraph (2) applies, a variation which is not an extension, and whose classification is undetermined after—

(a) application of the provisions in this Schedule; and

(b) taking into account—

(i) the guidance referred to in regulation 65C(4) or (6) as the case may be), and

(ii) where relevant, any recommendations delivered pursuant to paragraph 3,

is to be treated by the licensing authority as a minor variation of type IB.

(2) The licensing authority must treat a variation that would otherwise fall within sub-paragraph (1) as a major variation of type II in the following cases—

(a) upon request from the holder when submitting the variation; or

(b) where the licensing authority concludes, following the assessment of validity of a notification in accordance with paragraph 7(1), and taking into account the recommendations given under paragraph 3, that the variation may have a significant impact on the quality, safety or efficacy of the medicinal product concerned.

Licensing authority recommendation on unclassified variations

3.—(1) Prior to the submission of a variation whose classification is not provided for in this Schedule—

(a) the holder may request a recommendation on the classification of the variation from the licensing authority; and

(b) the licensing authority must notify the holder of its recommendation within 45 days of that request, beginning with the date on which the request is received by the licensing authority.

(2) The 45-day period referred to in sub-paragraph (1)(b) may be extended by 25 days where the licensing authority deems it necessary.

Variations leading to the revision of product information

4. Where a variation leads to the revision of the summary of product characteristics, labelling or the package leaflet, the revision must be considered by the licensing authority as part of that variation.

Grouping of variations

5.—(1) Except where sub-paragraph (2) applies, where several variations are notified or applied for, a separate notification or application in accordance with paragraph 6, 7, 8 or 11 of this Schedule is to be submitted in respect of each variation sought.

(2) This sub-paragraph applies—

(a) where one or more of the same minor variations of type IA to the terms of one or more UK marketing authorisations owned by the same holder are notified at the same time to the licensing authority, in which case a single notification as referred to in paragraph 6 may cover all such variations;

(b) where several variations to the terms of the same UK marketing authorisation are submitted at the same time, a single submission may cover all such variations provided that the variations concerned fall within one of the relevant circumstances specified in sub-paragraph (3);

(c) where one or more of the same variation to the terms of one or more UK marketing authorisations held by the same holder are submitted at the same time and the variations do not fall within paragraph (a) or (b), a single submission may cover all such variations provided that the licensing authority agrees to such single submission.

(3) The relevant circumstances are—

(a) one of the variations in the group is an extension of the UK marketing authorisation;

(b) one of the variations in the group is a major variation of type II, but all other variations in the group are variations which are consequential to this major variation of type II;

(c) one of the variations in the group is a minor variation of type IB, but all other variations in the group are minor variations which are consequential to this minor variation of type IB;

(d) all variations in the group relate solely to changes of an administrative nature to the summary of product characteristics, labelling and package leaflet or insert;

(e) all variations in the group are changes to an Active Substance Master File, Vaccine Antigen Master File or Plasma Master File;

(f) all variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or one or more of its active substances;

(g) all variations in the group are changes affecting the quality of a human pandemic influenza vaccine;

(h) all variations in the group are changes to the pharmacovigilance system referred to in paragraph 12 of Schedule 8;

(i) all variations in the group are consequential to a given urgent safety restriction and submitted in accordance with paragraph 14;

(j) all variations in the group relate to the implementation of a given class labelling;

(k) all variations in the group are consequential to the assessment of a given periodic safety update report;

(l) all variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder;

(m) all variations in the group are consequential to a condition imposed under regulation 59(4C) or (4D).

(4) The submission referred to in sub-paragraph (2)(b) and (c) must be made by means of the following—

(a) a single notification in accordance with paragraph 7 where at least one of the variations is a minor variation of type IB and the remaining variations are minor variations;

(b) a single application in accordance with paragraph 8 where at least one of the variations is a major variation of type II and none of the variations is an extension; or

(c) a single application in accordance with paragraph 11 where at least one of the variations is an extension.

Notification procedure for minor variations of type IA

6.—(1) Subject to sub-paragraph (2), where a minor variation of type IA is made, the holder must submit to the licensing authority a notification containing the elements listed in paragraph 9 within 12 months, beginning with the date on which the variation is implemented by the holder.

(2) The notification referred to in sub-paragraph (1) must be submitted immediately after the implementation of the variation in the case of minor variations requiring immediate notification for the continuous supervision of the medicinal product concerned.

(3) Within 30 days beginning with the date on which the licensing authority receives a notification under this paragraph, the measures provided for in paragraph 10 are to be taken.

Notification procedure for minor variations of type IB

7.—(1) The holder must for minor variations of type IB submit to the licensing authority a notification containing the elements listed in paragraph 9, and if the notification contains those elements, the licensing authority must acknowledge receipt of a valid notification.

(2) If within 30 days beginning with the date on which the licensing authority acknowledges receipt of a valid notification, the licensing authority has not sent the holder an unfavourable opinion, the notification is deemed to be accepted by the licensing authority.

(3) Where the notification is accepted by the licensing authority, the measures provided for in paragraph 10 are to be taken.

(4) Where the licensing authority is of the opinion that the notification cannot be accepted, it must inform the holder, stating the grounds on which its unfavourable opinion is based.

(5) Within 30 days beginning with the date on which the holder receives the unfavourable opinion, the holder may submit to the licensing authority an amended notification in order to take due account of the grounds laid down in that opinion.

(6) If the holder does not amend the notification in accordance with sub-paragraph (5), the notification is deemed to be rejected.

(7) Where an amended notification has been submitted, the licensing authority must assess it within 30 days beginning with the date on which it receives the amended notification, and the measures provided for in paragraph 10 are to be taken.

(8) This paragraph does not apply where—

(a) a type IB variation request is submitted in a grouping that includes a variation type II and does not contain an extension: in such a case, the prior approval procedure in paragraph 8 applies; or

(b) a type IB variation request is submitted in a grouping that includes an extension: in such a case, the procedure in paragraph 11 applies.

Prior approval procedure for major variations of type II

8.—(1) The holder must submit to the licensing authority an application containing the elements listed in paragraph 9, and if the application contains those elements, the licensing authority must acknowledge receipt of a valid application.

(2) Subject to sub-paragraph (3), within 60 days beginning with the date on which the licensing authority acknowledges receipt of a valid application under sub-paragraph (1), the licensing authority must conclude the assessment.

(3) The licensing authority may—

(a) reduce the period referred to in sub-paragraph (2), having regard to the urgency of the matter; or

(b) extend it to 90 days for—

(i) variations concerning a change to, or addition of, therapeutic indications, or

(ii) grouping of variations in accordance with paragraph 5(2)(c).

(4) Within the periods referred to in sub-paragraph (2) or (3), the licensing authority may request the holder to provide supplementary information within a time limit that it specifies, in which case—

(a) the procedure is suspended from the date on which such a request is made until the date on which that supplementary information has been provided; and

(b) the licensing authority may extend the period referred to in sub-paragraph (2) by the period for which the procedure is so suspended.

(5) Within 30 days beginning with the date on which the licensing authority concludes its assessment of the application, the measures provided for in paragraph 10 are to be taken.

(6) This paragraph does not apply where a type II variation request is submitted in a grouping that includes an extension: in such case, the procedure in paragraph 11 applies.

Elements to be submitted

9. An application or notification under this Schedule must include—

(a) a list of all the UK marketing authorisations affected by the notification or application;

(b) a description of all the variations submitted, including—

(i) in the case of minor variations of type IA, the date of implementation for each variation described,

(ii) in the case of minor variations of type IA which do not require immediate notification, a description of all minor variations of type IA made in the last 12 months to the terms of any affected UK marketing authorisation, such period beginning with the day on which the application or notification is submitted, and which have not been already notified,

(iii) any documents specified in guidance published under regulation 65C(4) or (6) (as the case may be), insofar as relevant to the type of variation notified or applied for,

(iv) where a variation leads to or is the consequence of other variations to the terms of the same UK marketing authorisation, a description of the relationship between those variations, and

(v) the relevant fee provided for in the Fees Regulations.

Measures to close the procedures specified in paragraphs 6 to 8

10. Where reference is made to this paragraph, the licensing authority must take the following measures—

(a) inform the holder as to whether the variation is accepted or rejected;

(b) where the variation is rejected, inform the holder of the grounds for the rejection; and

(c) where necessary, amend the decision granting the UK marketing authorisation in accordance with the accepted variation within the time limit laid down in paragraph 15.

Extensions of marketing authorisations

11.—(1) An application for an extension of a UK marketing authorisation must be assessed by the licensing authority in accordance with the same or equivalent procedure that applied under Part 5 to the initial UK marketing authorisation to which it relates.

(2) An extension must either be granted a UK marketing authorisation in accordance with the same or equivalent procedure as for the granting of the initial UK marketing authorisation to which it relates, or be included in that initial UK marketing authorisation.

Human influenza vaccines

12.—(1) By way of exception from paragraph 8, the procedure laid down in sub-paragraphs (2) to (4) applies to the examination of variations concerning changes to the active substance for the purposes of the annual update of a human influenza vaccine.

(2) The holder must submit to the licensing authority an application containing the elements listed in paragraph 9, and if it does so, the licensing authority must acknowledge receipt of a valid application.

(3) The licensing authority must assess the application submitted, and where it deems it necessary, the licensing authority may request additional data from the holder in order to complete its assessment.

(4) The licensing authority must—

(a) adopt a decision within 45 days, beginning with the date on which it receives a valid application; and

(b) take the measures provided for in paragraph 10.

(5) The 45-day period referred to in sub-paragraph (4) is to be suspended from the date on which the additional data referred to in sub-paragraph (3) is requested until the date on which that data is received by the licensing authority.

Pandemic situation with respect to human influenza

13.—(1) By way of exception to the provisions of this Schedule, where a pandemic situation with respect to human influenza is duly recognised by the World Health Organisation, or the licensing authority, the licensing authority may exceptionally and temporarily accept a variation to the terms of a UK marketing authorisation for a human influenza vaccine, where certain non-clinical or clinical data are missing.

(2) Where a variation is accepted pursuant to sub-paragraph (1), the holder must submit the missing non-clinical and clinical data within a time limit set by the licensing authority.

Urgent safety restrictions

14.—(1) Where, in the event of a risk to public health, the holder takes urgent safety restrictions on its own initiative, it must forthwith notify the licensing authority.

(2) If the licensing authority has not raised objections within 24 hours following receipt of that information, the urgent safety restrictions are deemed to be accepted.

(3) In the event of a risk to public health in relation to a medicinal product, the licensing authority may impose urgent safety restrictions on the holder of the UK marketing authorisation in respect of that product.

(4) Where an urgent safety restriction is taken by the holder, or imposed by the licensing authority, the holder must submit the corresponding application for variation within 15 days beginning with the date on which that restriction is initiated.

Amendments to the decision granting the marketing authorisation

15.—(1) Amendments to the decision granting the UK marketing authorisation resulting from the procedures laid down in this Schedule must be made by the licensing authority—

(a) in the case of major variations of type II, within two months, beginning with the date on which the information referred to in paragraph 10(a) is sent to the holder; or

(b) in the other cases, within six months, beginning with the date on which the information referred to in paragraph 10(a) is sent to the holder,

and the licensing authority must notify the holder of the amended decision without delay.

(2) The statement indicating compliance with the agreed completed paediatric investigation plan provided for under regulation 58A(2)(a) must be included within the technical dossier of the UK marketing authorisation, and the licensing authority must confirm to the holder that it is so included when it notifies the holder under paragraph 10(a).

Implementation of variations

16.—(1) Minor variations of type IA may be implemented any time before completion of the procedures laid down in paragraph 6.

(2) Where a notification concerning one or several minor variations of type IA is rejected, the holder must cease to apply the rejected variation immediately after receipt of the information referred to in paragraph 10(a).

(3) Minor variations of type IB may only be implemented after the licensing authority has informed the holder that it has accepted the notification pursuant to paragraph 7, or after the notification is deemed accepted pursuant to paragraph 7(2).

(4) Major variations of type II may only be implemented after the licensing authority has informed the holder that it has accepted the variation pursuant to paragraph 10.

(5) An extension may only be implemented after the licensing authority has amended the decision granting the marketing authorisation and notified the holder accordingly.

(6) Urgent safety restrictions, and variations which are related to safety issues, must be implemented within a time frame agreed by the holder and the licensing authority.

Continuous monitoring

17. Where requested to do so by the licensing authority, the holder must supply to the licensing authority without delay any information related to the implementation of a given variation.**]**

SCHEDULE 11

Regulations 58(5);59(7); 60(11);66(8); 68(12); 104(4);105(9); 108(8); 110(9);130(11); 133(8); and 137

Advice and representations

PART 1

General procedures

Application of this Part

1.—(1) This Part of this Schedule applies to—

(a) an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration;

(b) an application to renew a UK marketing authorisation, certificate of registration or traditional herbal registration; **F1070**...

(c) a proposal to revoke, vary or suspend a UK marketing authorisation, certificate of registration or traditional herbal registration (including variation by the variation or removal of a condition to which a UK marketing authorisation or a certificate of registration is subject) other than a proposal to vary the authorisation, certificate or registration on the application of or by agreement with its holder **[F1071**; and

(d) a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.**]**

[F1072(1A) Paragraphs 12 and 13 of this Part also apply to—

(a) an application for the grant of a parallel import licence;

(b) an application to renew a parallel import licence;

(c) a proposal to revoke, vary or suspend a parallel import licence (including variation by the variation or removal of a condition to which a parallel import licence is subject) other than a proposal to vary the licence on the application of or by agreement with its holder; and

(d) a refusal to vary a parallel import licence following an application for a variation by the holder.**]**

[F1073(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.**]**

Textual Amendments

F1070 Word in Sch. 11 para. 1(1)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F1071 Sch. 11 para. 1(1)(d) and word inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2)(a)(ii)** (as substituted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(2)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1072 Sch. 11 para. 1(1A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F1073 Sch. 11 para. 1(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 63(2)(c)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(a)**)

Requirement to consult the appropriate committee

2.—(1) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety, quality or efficacy—

(a) to refuse to grant or renew a UK marketing authorisation or traditional herbal registration in response to the application; or

(b) to revoke, vary or suspend a UK marketing authorisation or traditional herbal registration.

(2) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety or quality—

(a) to refuse to grant or renew a certificate of registration in response to the application; or

(b) to revoke, vary or suspend a certificate of registration.

[F1074(2A) The licensing authority must consult the appropriate committee if the authority proposes to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.**]**

(3) This paragraph is subject to paragraphs 3 and 4 (exceptions to requirement to consult).

(4) In this Schedule "the appropriate committee" in relation to any function means whichever of the bodies listed in paragraph (5) the licensing authority considers to be the appropriate body to perform that function.

(5) Those bodies are—

(a) the Commission; and

(b) any expert committee appointed by the licensing authority.

Textual Amendments

F1074 Sch. 11 para. 2(2A) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2A)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

Exceptions to requirement to consult

3.—(1) Paragraph 2 does not apply to a proposal to refuse to grant or renew a UK marketing authorisation, certificate of registration or traditional herbal registration **[**F1075, or to a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation,**]** if—

(a) the licensing authority has asked the applicant to supply information that the licensing authority thinks is relevant to enable the application to be determined **[**F1076or the decision to be made**]**; and

(b) the information has not been supplied to the authority within the relevant period.

(2) The relevant period is—

(a) where the licensing authority has completed its initial full assessment of the application, the period of six months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1); or

(b) where the licensing authority has completed its assessment of any supplemental information, the period of three months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1).

(3) The licensing authority may extend the relevant period if—

(a) the applicant asks it to do so;

(b) the applicant provides the grounds for that request; and

(c) the licensing authority thinks that the grounds are exceptional.

Textual Amendments

F1075 Words in Sch. 11 para. 3(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2B)(a)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1076 Words in Sch. 11 para. 3(1)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2B)(b)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

4.—(1) Paragraph 2 does not apply to a proposal to suspend a UK marketing authorisation, certificate of registration or traditional herbal registration if the licensing authority thinks that, in the interests of safety, it is necessary to suspend the authorisation, certificate or registration with immediate effect for not more than three months.

(2) In that event the licensing authority must report the suspension to the appropriate committee forthwith.

(3) Sub-paragraph (4) applies if, following a suspension to which this paragraph applies—

(a) the licensing authority thinks that the authorisation, certificate or registration should be further suspended, or varied or revoked; or

(b) the appropriate committee advises that the authorisation, certificate or registration should be further suspended, or varied or revoked.

(4) The provisions of this Part of this Schedule (including this paragraph) apply accordingly to the suspension, variation or revocation.

Provisional opinion against authorisation

5.—(1) If the appropriate committee is consulted under paragraph 2(1) it may give a provisional opinion that on grounds relating to safety, quality or efficacy—

(a) it may be unable to advise the licensing authority to grant or renew the UK marketing authorisation or traditional herbal registration;

(b) it may be unable to advise the licensing authority to grant the authorisation or registration unless—

(i) it contains terms other than those in the application, or

(ii) it is granted subject to conditions; or

(c) it may have to advise the licensing authority to revoke, vary or suspend the authorisation or registration.

(2) If the Commission is consulted under paragraph 2(2), it may give a provisional opinion that, on grounds relating to safety or quality—

(a) it may be unable to advise the licensing authority to grant or renew the certificate of registration;

(b) it may be unable to advise the licensing authority to grant the certificate unless—

(i) it contains terms other than those in the application, or

(ii) it is granted subject to conditions; or

(c) it may have to advise the licensing authority to revoke, vary or suspend the certificate.

[F1077(2A) If the appropriate committee is consulted under paragraph 2(2A), it may give a provisional opinion that it may be unable to advise the licensing authority to decide that the orphan criteria are met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.**]**

(3) The appropriate committee must notify the applicant for the grant or renewal **[**F1078 , the applicant intending to demonstrate that the orphan criteria are met in relation to a medicinal product,**]** or (as the case may be) the holder of the authorisation, certificate or registration in writing of its provisional opinion.

Textual Amendments

F1077 Sch. 11 para. 5(2A) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2C)(a)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1078 Words in Sch. 11 para. 5(3) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2C)(b)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

Opportunity to make representations

6.—(1) An applicant or holder notified under paragraph 5 may, by notice in writing to the appropriate committee, request the opportunity to make written or oral representations to the appropriate committee.

(2) The applicant or holder must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

Written representations

7.—(1) If the applicant or holder requests the opportunity to make written representations, the applicant or holder must provide the appropriate committee with those representations and any documents on which the applicant or holder wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.

(2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.

(3) The applicant or holder may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

8.—(1) If the applicant or holder requests the opportunity to make oral representations, the applicant or holder must provide the appropriate committee with a written summary of those representations and any documents on which the applicant or holder wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.

(2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.

(3) The applicant or holder may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant or holder to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

9.—(1) This paragraph applies if the applicant or holder—

(a) does not request the opportunity to make written or oral representations to the appropriate committee within the period mentioned in paragraph 6;

(b) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(c) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

10.—(1) After receiving the appropriate committee's report under paragraph 7 or 8 or notification under paragraph 9 the licensing authority must—

(a) decide whether to grant or renew the UK marketing authorisation, certificate of registration or traditional herbal registration;

(b) decide whether to grant or renew the authorisation, certificate or registration in accordance with the application; [F1079]...

(c) decide whether to proceed with its proposal to revoke, vary or suspend the authorisation, certificate or registration **[**[F1080]; or

(d) decide whether to proceed with its proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation,**]**

as the case may be.

(2) If the appropriate committee has given a report under paragraph 7 or 8, the licensing authority must take the report into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Textual Amendments

F1079 Word in Sch. 11 para. 10(1)(b) omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(2D)(a)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1080 Sch. 11 para. 10(1)(d) and word inserted (31.12.2020) by S.I. 2019/775, **reg. 63(2D)(b)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(3)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

Right to review after paragraph 10 notification

11.—(1) A person to whom a notification is given under paragraph 10 may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(2) The person must give the notification within the period of 28 days beginning with the day on which the notification under paragraph 10 is given or such longer period as the licensing authority may allow.

(3) The review must be conducted in accordance with Schedule 5.

(4) This paragraph does not apply if—

(a) the person has not made any representations in accordance with paragraph 7 or 8; and

(b) the decision of the licensing authority is in accordance with the advice of the appropriate committee.

Licensing authority decisions in other cases

12.—(1) This paragraph applies if the appropriate committee has not been consulted under paragraph 2(1) because the licensing authority proposes on grounds not relating to safety, quality or efficacy—

(a) to refuse to grant or renew a UK marketing authorisation **[**F1081, parallel import licence**]** or traditional herbal registration in response to the application;

(b) to grant or renew a UK marketing authorisation **[**F1081, parallel import licence**]** or traditional herbal registration otherwise than in accordance with the application; or

(c) to revoke, vary or suspend a UK marketing authorisation **[**F1081, parallel import licence**]** or traditional herbal registration.

(2) This paragraph also applies if, having been consulted under paragraph 2(1), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(1), and the licensing authority proposes—

(a) to determine the application for the UK marketing authorisation or traditional herbal registration in a way that differs from the appropriate committee's advice;

(b) to revoke, vary or suspend the authorisation or registration against such advice; or

(c) on grounds not relating to safety, quality or efficacy—

(i) to refuse to grant or renew the authorisation or registration,

(ii) to grant or renew the authorisation or registration otherwise than in accordance with the application, or

(iii) to revoke, vary or suspend the authorisation or registration.

(3) This paragraph also applies if the appropriate committee has not been consulted under paragraph 2(2) because the licensing authority proposes on grounds not relating to safety or quality—

(a) to refuse to grant or renew a certificate of registration in response to the application;

(b) to grant or renew a certificate of registration otherwise than in accordance with the application; or

(c) to revoke, vary or suspend a certificate of registration.

(4) This paragraph also applies if, having been consulted under paragraph 2(2), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2), and the licensing authority proposes—

(a) to determine the application for the certificate of registration in a way that differs from the appropriate committee's advice;

(b) to revoke, vary or suspend the authorisation against such advice; or

(c) on grounds not relating to safety or quality—

(i) to refuse to grant or renew the certificate,

(ii) to grant or renew the certificate otherwise than in accordance with the application, or

(iii) to revoke, vary or suspend the certificate.

[F1082(4A) This paragraph also applies if, having been consulted under paragraph 2(2A), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2A) and the licensing authority proposes to decide, against that committee's advice, that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.**]**

(5) The licensing authority must notify the applicant for the grant or renewal or (as the case may be) the holder of the authorisation **[**[F1083], licence**]**, certificate or registration in writing of its proposal.

(6) The notification must state—

(a) the reasons for the proposal; and

(b) any advice of the appropriate committee and any reasons it has given for that advice.

Textual Amendments

F1081 Words in Sch. 11 para. 12(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(3)(a)** (as substituted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(4)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1082 Sch. 11 para. 12(4A) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(3)(c)** (as substituted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(4)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

F1083 Word in Sch. 11 para. 12(5) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(3)(b)** (as substituted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(4)**; 2020 c. 1, **Sch. 5 para. 1(1)**)

Right to review or representations after paragraph 12 notification

13.—(1) A person to whom a notification is given under paragraph 12 may—

(a) notify the licensing authority in writing that the person wishes the licensing authority to submit the proposal to review upon oral representations, or

(b) make representations in writing to the licensing authority with respect to the proposal.

(2) The person must give the notification or make the representations within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(3) A review in accordance with sub-paragraph (1)(a) must be conducted in accordance with Schedule 5.

(4) If the person makes written representations in accordance with sub-paragraph (1)(b) the licensing authority must take them into account before determining the matter.

[[F1084]**PART 1A**

Paediatric Decisions

Textual Amendments

F1084 Sch. 11 Pt. 1A inserted by S.I. 2019/775, **reg. 63(3A)** (as inserted by The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385), reg. 1, **Sch. 1 para. 7(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application of this Part

13A. This Part applies to a proposed decision by the licensing authority—

(a) to refuse to agree a paediatric investigation plan (including a waiver or deferral proposed to be included in that plan), or to agree such a plan otherwise than in accordance with the request for agreement;

(b) to refuse to agree a modification to a paediatric investigation plan (including a waiver or deferral which is, or is proposed to be, included in that plan), or to agree such a modification otherwise than in accordance with the request for the modification;

(c) to impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) to provide to the licensing authority the results of all studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan; or

(d) to revoke a waiver which was agreed as part of an agreed paediatric investigation plan.

Opportunity to make representations

13B.—(1) If the licensing authority proposes to make a decision to which this Part applies, the licensing authority must notify the person to whom the proposed decision would be addressed ("the applicant").

(2) The applicant may, by notice in writing to the licensing authority, request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request before the end of the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant's request.

Written representations

13C.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may at the request of the applicant extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

13D.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

13E.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

13F.—(1) The licensing authority must decide whether to proceed with its proposed decision—

(a) if the applicant requested the opportunity to make written or oral representations, after receiving the appropriate committee's report under paragraph 13C or 13D or notification under paragraph 13E; or

(b) if the applicant did not request the opportunity to make written or oral representations, after the expiry of the period of time for notifying a request for that opportunity.

(2) If the appropriate committee gives a report under paragraph 13C or 13D, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 13F notification

13G.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 13F.

(2) The applicant may notify the licensing authority in writing that the applicant wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification before the end of the period of 28 days beginning with the day on which the notification is given to the applicant under paragraph 13F or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the applicant has not made any representations in accordance with paragraph 13C or 13D.**]**

PART 2

Type II variation applications, complex variation applications and new excipient variation applications

Application of this Part

14. This Part applies—

(a) to an application (a "Type II variation application") to vary a UK marketing authorisation if the variation is a major variation of Type II within the meaning of Article 2(3) of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [M90]**[**[F1085]or paragraph 1 of Schedule 10A**]**; and

(b) to an application to vary a traditional herbal registration that is—

(i) a complex variation application, or

(ii) a new excipient variation application.

Textual Amendments

F1085 Words in Sch. 11 para. 14(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 63(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(b)**)

Marginal Citations

M90 OJ No L 334, 12.12.2008, p.7.

15.—(1) In paragraph 14(b)(i) "complex variation application" means an application by the holder of the registration to vary it so that one or more of the following changes can be made to the product to which it relates—

(a) a change in the product's active ingredients by the addition of an active ingredient from a new source;

(b) a change in the product's excipients by the addition of a TSE risk excipient from a new source; or

(c) a change by the addition of a vitamin or mineral from a new source, where no European Pharmacopoeia certificate of suitability for the vitamin or mineral is submitted with the application.

(2) For the purpose of sub-paragraph (1), an ingredient, vitamin or mineral is "from a new source" if its manufacturer as named in the application has not been named as its manufacturer in a **[**[F1086]UK**]** marketing authorisation or traditional herbal registration granted for a medicinal product including the ingredient, vitamin or mineral.

(3) For the purpose of sub-paragraph (1), an excipient is a "TSE risk excipient from a new source" if—

(a) it has been manufactured from raw materials of ruminant origin or such raw materials have been used in its manufacture; and

(b) its manufacturer as named in the application has not been named as its manufacturer in a **[**[F1087]UK**]** marketing authorisation or traditional herbal registration granted for a medicinal product that includes the excipient.

Textual Amendments

F1086 Word in Sch. 11 para. 15(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(5)**; 2020 c. 1, Sch. 5 para. 1(1)

F1087 Word in Sch. 11 para. 15(3)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(5)**; 2020 c. 1, Sch. 5 para. 1(1)

16.—(1) In paragraph 14(b)(ii) "new excipient variation application" means an application (other than a complex variation application) by the holder of the registration to vary it so that the formulation of the medicinal product to which it relates can be changed by the addition of a new excipient.

(2) For the purpose of sub-paragraph (1) "new excipient" means, subject to paragraphs (3) and (4), an ingredient of a medicinal product that is not an active ingredient and that has not been included in a medicinal product—

(a) intended to be administered by the same route as the product to which the application relates; and

(b) for which a **[**[F1088]UK**]** marketing authorisation (other than a product licence of right) or traditional herbal registration has been granted.

(3) In the application of sub-paragraph (1) to a medicinal product intended to be administered orally, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in food or in a food product.

(4) In the application of sub-paragraph (1) to a medicinal product intended for external use only, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in a cosmetic product.

(5) In this paragraph "enactment" includes an enactment comprised in subordinate legislation [F1089]....

Textual Amendments

F1088 Word in Sch. 11 para. 16(2)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F1089 Words in Sch. 11 para. 16(5) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F1090]**17.** In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.**]**

Textual Amendments

F1090 Sch. 11 para. 17 substituted (31.12.2020) by S.I. 2019/775, **reg. 63(7)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(c)**)

Opportunity to make representations

18.—(1) This paragraph applies if the licensing authority notifies the applicant for a variation to which this Part applies that it has decided, on grounds relating to safety, quality or efficacy—

(a) to refuse to grant the application, or

(b) to grant it otherwise than in accordance with the application.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

19.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

20.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.

(3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

21.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

22.—(1) After receiving the appropriate committee's report under paragraph 19 or 20 or notification under paragraph 21 the licensing authority must confirm or alter its decision.

(2) If the appropriate committee gives a report under paragraph 19 or 20, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 22 notification

23.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 22—

(a) to refuse the application; or

(b) to grant it otherwise than in accordance with the application.

(2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 19 or 20.

PART 3

Referral to the [F1091appropriate committee for traditional herbal registrations]

Textual Amendments

F1091 Words in Sch. 11 Pt. 3 heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

Application of this Part

24.—(1) This Part applies if the licensing authority proposes to refer an application for a traditional herbal registration to the [F1092appropriate committee in accordance with regulation 130A(1)].

[F1093(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.]

Textual Amendments

F1092 Words in Sch. 11 para. 24(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(8)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F1093 Sch. 11 para. 24(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 63(8)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(d)**)

Opportunity to make representations

25.—(1) The licensing authority must notify the applicant of the authority's proposal.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

26.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 25.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

27.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 24.

(3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the appropriate committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

28.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

29.—(1) After receiving the appropriate committee's report under paragraph 26 or 27 or notification under paragraph 28 the licensing authority must decide whether to **[**[F1094]grant or refuse the application**]**.

(2) If the appropriate committee gives a report under paragraph 26 or 27, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Textual Amendments

F1094 Words in Sch. 11 para. 29(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(8)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Right to review after paragraph 29 notification

30.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 29 to refer the applicant to the Committee on Herbal Medicinal Products as proposed.

(2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the licensing authority's notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 26 or 27.

PART 4

Exceptions to Schedule

F1095 31. . . . . . .

Textual Amendments

F1095 Sch. 11 para. 31 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**)

32. This Schedule does not apply to an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration if the application has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive.

33. This Schedule ceases to apply if at any time the matter in question is referred to the Committee for Medicinal Products for Human Use or the Committee for Herbal Medicinal Products under Article 30 or 31 of the 2001 Directive for the application of the procedure laid down in Articles 32 to 34 of that Directive.

F1096 34. . . . . . .

Textual Amendments

F1096 Sch. 11 para. 34 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**)

F1097**35.** . . . . . .

Textual Amendments

F1097 Sch. 11 para. 35 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**)

36. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a UK marketing authorisation that—

(a) was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure);

(b) was granted before 1st January 1995 by member States in accordance with Article 4 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology [M91]; or

(c) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorisation.

Marginal Citations

M91 OJ No L 15, 17.1.1987. p.38.

F1098**37.** . . . . . .

Textual Amendments

F1098 Sch. 11 para. 37 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**)

F1099**38.** . . . . . .

Textual Amendments

F1099 Sch. 11 para. 38 omitted (31.12.2020) by virtue of S.I. 2019/775, **reg. 63(9)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**)

39. This Schedule does not apply if—

(a) the licensing authority refuse to grant an application for a traditional herbal registration;

(b) the application was referred to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive; and

(c) the Committee for Herbal Medicinal Products did not support the grant of the application.

SCHEDULE 12 Regulation 128(1)

Material to accompany an application for a traditional herbal registration

PART 1

General requirements

1. The name or corporate name and permanent address of the applicant and (where applicable) of the manufacturer of the medicinal product.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the holder of the traditional herbal registration.

3. Qualitative and quantitative particulars of the constituents of the medicinal product, including—

(a) where there is an international non-proprietary name recommended by the World Health Organisation for a constituent, a reference to that name; or

(b) otherwise, a reference to the relevant chemical or botanical name.

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

5. A description of the methods of manufacturing the medicinal product.

6. The therapeutic indications and contra-indications for the medicinal product and the adverse reactions associated with it.

7. The posology and pharmaceutical form of the medicinal product, its method and route of administration and its expected shelf life.

8. The reasons for any precautionary and safety measures to be taken for—

(a) the storage of the medicinal product;

(b) the administration of the medicinal product to patients; and

(c) the disposal of the medicinal product and any waste products,

with an indication of the potential risks presented by the medicinal product for the environment.

9. A description of the control methods employed by the manufacturer.

10. Results of pre-clinical (toxicological and pharmacological) tests in relation to the medicinal product and its constituent active substances.

11. A detailed summary of those results prepared and signed by an expert with appropriate technical or professional qualifications, which must be set out in a brief curriculum vitae.

12. A summary of the product characteristics for the medicinal product in accordance with Part 2 of this Schedule.

13. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

14. A document showing that the manufacturer of the medicinal product is authorised to produce medicinal products in the manufacturer's own country.

15. Where the medicinal product consists of a combination of one or more herbal substances and one or more herbal preparations, or the medicinal product contains one or more vitamins or minerals—

(a) data on the traditional use of the medicinal product as a whole; and

(b) if any of the medicinal product's individual active ingredients are not sufficiently known, data on the traditional use of those active ingredients.

This covers (in particular)—

(c) evidence that the product is not harmful in the specified conditions of use; and

(d) evidence as to the pharmacological effects or efficacy of the product on the basis of long-standing use and experience.

16. Details of any authorisation or registration obtained by the applicant in **[**F1100a country other than the United Kingdom**]** allowing the medicinal product to be placed on the market.

Textual Amendments

F1100 Words in Sch. 12 para. 16 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **115(2)**; 2020 c. 1, Sch. 5 para. 1(1)

17. Details of any decision in **[**F1101a country other than the United Kingdom**]** to refuse to grant an authorisation or registration allowing the medicinal product to be placed on the market, with the reasons for any such decision.

Textual Amendments

F1101 Words in Sch. 12 para. 17 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **115(2)**; 2020 c. 1, Sch. 5 para. 1(1)

18. Bibliographical or expert evidence of the traditional use of the medicinal product or a product corresponding to the medicinal product.

For this purpose a product ("A") corresponds to a medicinal product ("B") if—

(a) product A has the same active ingredients as product B (regardless of the excipients used in either product);

(b) product A's intended purpose is the same as or similar to product B's intended purpose;

(c) product A has a strength and dosage equivalent to that of product B; and

(d) product A's route of administration is the same as or similar to product B's route of administration.

19. A bibliographic review of safety data.

20. An expert report on safety.

PART 2

Summary of the product characteristics

The summary of the product characteristics must contain the following information in the following order—

21. For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004**[**F1102or regulation 202A, as the case may be**]**, the **[**F1103symbol and**]** statement "**[**F1104▼**]** This medicinal product is subject to additional monitoring".

Textual Amendments

F1102 Words in Sch. 12 para. 21 inserted (31.12.2020) by S.I. 2019/775, **reg. 115(3)(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 86**)

F1103 Words in Sch. 12 para. 21 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **115(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F1104 Symbol in Sch. 12 para. 21 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **115(3)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

22. The name of the medicinal product followed by its strength and pharmaceutical form.

23. The qualitative and quantitative composition, using the usual common name or chemical description, of the medicinal product in terms of—

(a) the active substances; and

(b) those excipients of which knowledge is essential for proper administration of the medicinal product.

24. The pharmaceutical form of the medicinal product.

25. The pharmacological properties of the medicinal product, covering—

(a) pharmacodynamic properties;

(b) pharmacokinetic properties; and

(c) pre-clinical safety data.

26. Pharmaceutical particulars of the medicinal product, covering—

(a) a list of excipients;

(b) major incompatibilities;

(c) shelf life after reconstitution of the medicinal product or when the immediate packaging is opened for the first time (as appropriate);

(d) special precautions for storage;

(e) nature and contents of the container; and

(f) special precautions for disposal of the used medicinal product or waste materials derived from the medicinal product (as appropriate).

27. The holder of the traditional herbal registration.

28. The number of the traditional herbal registration.

29. The date of the first traditional herbal registration or, where the traditional herbal registration has been renewed, the date of the last renewal.

30. The date of any revisions of the text of the summary of the product characteristics.

[F1105SCHEDULE 12A

Regulation 205A

Further provision as to the performance of pharmacovigilance activities

Textual Amendments

F1105 Sch. 12A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 6** (as amended by S.I. 2019/1385, reg. 1, **Sch. 1 para. 9** and S.I. 2020/1488, reg. 1, **Sch. 2 para. 192**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 1

Pharmacovigilance system master file

Structure of the pharmacovigilance system master file

1.—(1) The information in the pharmacovigilance system master file must be accurate and reflect the pharmacovigilance system in place.

(2) The holder may, where appropriate, use separate pharmacovigilance systems for different categories of medicinal products and if it does so, each such system must be described in a separate pharmacovigilance system master file.

(3) All medicinal products for which the holder obtained a UKMA(GB) in accordance with these Regulations must be covered by a pharmacovigilance system master file.

Content of the pharmacovigilance system master file

2. The pharmacovigilance system master file must, as a minimum, contain—

(a) the following information relating to the qualified person responsible for pharmacovigilance—

(i) a description of the responsibilities demonstrating that the qualified person for pharmacovigilance has sufficient authority over the pharmacovigilance system in order to promote, maintain and improve compliance with pharmacovigilance tasks and responsibilities,

(ii) a summary curriculum vitae of the qualified person responsible for pharmacovigilance,

(iii) contact details of the qualified person for pharmacovigilance,

(iv) details of back-up arrangements to apply in the absence of the qualified person responsible for pharmacovigilance, and

(v) responsibilities and contact details of the nominated person (where a person is nominated under regulation 182(2A));

(b) a description of the organisational structure of the holder, including the list of each site where one or more of the following pharmacovigilance activities are undertaken—

(i) individual case safety report collection and evaluation,

(ii) safety database case entry,

(iii) periodic safety update report production,

(iv) signal detection and analysis,

(v) risk management plan management,

(vi) pre and post-authorisation study management, and

(vii) management of safety variations to the terms of a UK marketing authorisation;

(c) a description of the location of, functionality of and operational responsibility for computerised systems and databases used to receive, collate, record and report safety information, and an assessment of their fitness for purpose;

(d) a description of data handling and recording and of the process used for each of the following pharmacovigilance activities—

(i) the continuous monitoring of the risk-benefit balance of each medicinal product, the result of that monitoring and the decision-making process for taking appropriate measures,

(ii) operation of each risk management system and of the monitoring of the outcome of risk minimisation measures,

(iii) collection, assessment and reporting of individual case safety reports,

(iv) drafting and submission of periodic safety update reports, and

(v) procedures for communicating safety concerns and safety variations to the summary of product characteristics and package leaflet to healthcare professionals and the general public;

(e) a description of the quality system for the performance of pharmacovigilance activities, including—

(i) a description of—

(aa) the organisational structure for the performance of pharmacovigilance activities,

(bb) a summary description of the training concept, including a reference to the location of training files and qualifications records, and

(cc) instructions on critical processes,

(ii) a description of the record management system referred to in paragraph 12, including the location of the documents used for pharmacovigilance activities,

(iii) a description of the system for monitoring the performance of the pharmacovigilance system; and

(f) where applicable, a description of the activities or services subcontracted by the holder.

Content of the Annex to the pharmacovigilance system master file

3. The pharmacovigilance system master file must have an Annex containing the following documents—

(a) a list of medicinal products covered by the pharmacovigilance system master file, including the name of each medicinal product, the international non-proprietary name (INN) of each active substance and the countries other than the United Kingdom in which the products covered are authorised to be marketed;

(b) a list of written policies and procedures for the purpose of complying with Part 11 of these Regulations;

(c) the list of any sub-contracts falling within paragraph 6(1);

(d) a list of the tasks that have been delegated by the qualified person for pharmacovigilance;

(e) a list of all scheduled and completed audits;

(f) where applicable, a list of the performance indicators that support the quality system for pharmacovigilance specified in paragraph 2(e);

(g) where applicable, a list of other pharmacovigilance system master files held by the same holder; and

(h) a logbook containing a record of any alteration of the content of the pharmacovigilance system master file made within the preceding 5 year period, except any alteration of the content that is specified in of paragraph 2(a)(ii) to (iv) or this paragraph.

Maintenance of the pharmacovigilance system master file

4.—(1) The holder must keep the pharmacovigilance system master file up to date and, where necessary, revise it to take account of experience gained, and of technical and scientific progress.

(2) The pharmacovigilance system master file and its Annex must be subject to version control and, in particular, must indicate the date when it was last updated by the holder.

(3) Any deviations from the pharmacovigilance procedures, their impact and their management must be documented in the pharmacovigilance system master file until resolved.

Form of the documents contained in the pharmacovigilance system master file

5.—(1) The pharmacovigilance system master file documents must be complete and legible.

(2) Subject to sub-paragraph (1), in the pharmacovigilance system master file—

(a) where appropriate, information may be provided in the form of charts or flow diagrams;

(b) all documents must be indexed and archived so as to ensure their accurate and ready retrieval throughout the period for record-keeping; and

(c) the particulars and documents may be presented in modules in accordance with the system delineated in detail in the guidance on good pharmacovigilance practices which applies by virtue of regulation 205B.

(3) The pharmacovigilance system master file may be stored in electronic form provided that the media used for storage remain readable over time, and a clearly arranged printed copy can be made available for audits and inspections.

Subcontracting

6.—(1) The holder may subcontract certain activities of the pharmacovigilance system to third parties, but if it does so it must nevertheless retain full responsibility for the completeness and accuracy of the pharmacovigilance system master file.

(2) The holder must draw up a list of the existing subcontracts between it and the third parties referred to in sub-paragraph (1), specifying each product and each country concerned.

Availability and location of the pharmacovigilance system master file

7.—(2) The holder must ensure that the qualified person and nominated person (where a person is nominated under regulation 182(2A)) for pharmacovigilance have permanent access to the pharmacovigilance system master file.

(3) For the purposes of regulation 182(2)(b), the licensing authority may limit its request to specific parts or modules of the pharmacovigilance system master file and the holder is to bear the costs of submitting the copy of the pharmacovigilance system master file.

(4) The licensing authority may request the holder to submit a copy of the logbook referred to in paragraph 3(h) at regular intervals.

PART 2

Minimum requirements for the quality systems for the performance of pharmacovigilance activities by the licensing authority and holders

Quality system

8.—(1) Any holder, and the licensing authority, must establish and use a quality system that is adequate and effective for the performance of their pharmacovigilance activities.

(2) The quality system must cover organisational structure, responsibilities, procedures, processes and resources, appropriate resource management, compliance management and record management.

(3) The quality system must be based on all of the following activities—

(a) quality planning: establishing structures and planning integrated and consistent processes;

(b) quality adherence, namely carrying out tasks and responsibilities in accordance with quality requirements;

(c) quality control and assurance, namely monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are being carried out; and

(d) quality improvements, namely correcting and improving the structures and processes where necessary.

(4) All elements, requirements and provisions adopted for the quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality plans, quality manuals and quality records.

(5) All persons involved in the procedures and processes of the quality systems established by the licensing authority for the performance of pharmacovigilance activities shall be responsible for the good functioning of those quality systems, and must ensure a systematic approach towards quality and towards the implementation and maintenance of the quality system.

Performance indicators

9.—(1) The holder and the licensing authority may use performance indicators to continuously monitor the good performance of pharmacovigilance activities.

(2) The licensing authority may publish a list of performance indicators.

PART 3

Minimum requirements for the quality systems for the performance of pharmacovigilance activities by holders

Management of human resources

10.—(1) The holder must have sufficient competent and appropriately qualified and trained personnel available for the performance of pharmacovigilance activities.

(2) For the purposes of sub-paragraph (1), the holder must—

(a) ensure that the qualified person responsible for pharmacovigilance has acquired adequate theoretical and practical knowledge for the performance of pharmacovigilance activities; and

(b) where the qualified person has not completed basic medical training in accordance with Article 24 of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, ensure that the qualified person responsible for pharmacovigilance is assisted by a medically trained person, with such assistance being duly documented.

(3) The duties of the managerial and supervisory staff, including the qualified person responsible for pharmacovigilance, must be defined in job descriptions and their hierarchical relationships must be defined in an organisational chart.

(4) The holder must ensure that the qualified person responsible for pharmacovigilance has sufficient authority to influence the performance of the quality system and the pharmacovigilance activities of the holder.

(5) All personnel involved in the performance of pharmacovigilance activities must receive initial and continued training in relation to their role and responsibilities, and the holder must keep training plans and records for documenting, maintaining and developing the competences of personnel and make them available for audit or inspection.

(6) The holder must provide appropriate instructions on the processes to be used in case of urgency, including business continuity.

Compliance management

11.—(1) Specific quality system procedures and processes must be in place in order to ensure the following—

(a) the continuous monitoring of pharmacovigilance data, the examination of options for risk minimisation and prevention and that appropriate measures are taken by the holder;

(b) the scientific evaluation by the holder of all information on the risks of medicinal products, as referred to in regulation 182(4)(a);

(c) the submission of accurate and verifiable data on serious and non-serious adverse reactions to the licensing authority within the time limits provided for in regulation 188(1)(a) or (b);

(d) the quality, integrity and completeness of the information submitted on the risks of medicinal products, including processes to avoid duplicate submissions;

(e) effective communication by the holder with the licensing authority, including communication on—

(i) new risks or changed risks,

(ii) the pharmacovigilance system master file,

(iii) risk management systems,

(iv) risk minimisation measures,

(v) periodic safety update reports,

(vi) corrective and preventive actions, and

(vii) post-authorisation studies;

(f) the update of product information by the holder in the light of scientific knowledge, including the assessments and recommendations made public via the UK web-portal, and on the basis of a continuous monitoring by the holder of information published on that web-portal; and

(g) appropriate communication by the holder of relevant safety information to healthcare professionals and patients.

(2) Where a holder has subcontracted some of its pharmacovigilance tasks, it must retain responsibility for ensuring that an effective quality system is applied in relation to those tasks.

Record management and data retention

12.—(1) A holder must record all pharmacovigilance information and ensure that it is handled and stored so as to allow for accurate reporting, interpretation and verification of that information.

(2) A holder must put in place a record management system for all documents used for pharmacovigilance activities that ensures—

(a) the retrievability of those documents; and

(b) the traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process.

(3) A holder must establish mechanisms enabling the traceability and follow-up of adverse reaction reports.

(4) A holder must arrange for the elements referred to in sub-paragraph (2) to be kept for at least five years, beginning with the day after the system as described in the pharmacovigilance system master file has been formally terminated by the holder.

(5) Pharmacovigilance data and documents relating to individual authorised medicinal products must be retained as long as the product is authorised and for at least 10 years, beginning with the date on which the UKMA(GB) ceased to exist.

Audit

13.—(1) Risk-based audits of the quality system must be performed at regular intervals to ensure that the quality system complies with the quality system requirements set out in paragraphs 8, 10, 11 and 12, and to determine its effectiveness.

(2) The audits referred to in sub-paragraph (1) must be conducted by individuals who have no direct involvement in or responsibility for the matters or processes being audited.

(3) Following a risk-based audit—

(a) any corrective action, including a follow-up audit of deficiencies, must be taken where necessary;

(b) a report on the results of the audit must be drawn up for each audit and follow-up audit;

(c) the audit report must be sent to the management responsible for the matters audited; and

(d) the dates and results of audits and follow-up audits must be documented in accordance with regulation 184(1)(b).

PART 4

Minimum requirements for the quality systems for the performance of pharmacovigilance activities by the licensing authority

Management of human resources

14.—(1) The licensing authority must have sufficient competent and appropriately qualified and trained personnel available for the performance of pharmacovigilance activities: the organisational structures and the distribution of tasks and responsibilities must be clear and, to the extent necessary, accessible.

(2) Named contact points in the licensing authority for pharmacovigilance activities must be established.

(3) The licensing authority must ensure that—

(a) all of its personnel involved in the performance of pharmacovigilance activities receive initial and continued training;

(b) it keeps training plans and records for documenting, maintaining and developing the competences of personnel; and

(c) such plans and records are available for audit.

(4) The licensing authority must ensure that it provides to its personnel performing pharmacovigilance activities appropriate instructions on the processes to be used in case of urgency, including business continuity.

Compliance management

15. The licensing authority must establish specific procedures and processes in order to achieve the following objectives—

(a) ensuring the evaluation of the quality, including completeness, of pharmacovigilance data submitted;

(b) ensuring the assessment of pharmacovigilance data and its processing within the timelines provided for in Part 11 of these Regulations;

(c) ensuring independence in the performance of pharmacovigilance activities;

(d) ensuring effective communication among regulatory bodies in countries other than the United Kingdom who have the same or similar functions as the licensing authority, as well as with patients, healthcare professionals, marketing authorisation holders and the general public; and

(e) conducting inspections, including pre-authorisation inspections.

Record management and data retention

16.—(1) The licensing authority must—

(a) record all pharmacovigilance information, and ensure that it is handled and stored so as to allow for accurate reporting, interpretation and verification of that information; and

(b) put in place a record management system for all documents used for pharmacovigilance activities that ensures—

(i) the retrievability of those documents, and

(ii) the traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process.

(2) The licensing authority must arrange for the essential documents describing their pharmacovigilance system to be kept for at least five years, such period beginning with the day after the system has been formally terminated.

(3) Pharmacovigilance data and documents relating to individual authorised medicinal products must be retained by the licensing authority for as long as the product is authorised and for at least 10 years, such period beginning with the day after the UKMA(GB) has expired.

Audit

17.—(1) Risk-based audits of the quality system must be performed by the licensing authority at regular intervals to ensure that the quality system complies with the requirements set out in paragraphs 8, 14, 15 and 16, and to ensure its effectiveness.

(2) Following a risk-based audit—

(a) any corrective action, including a follow-up audit of deficiencies, must be taken where necessary;

(b) a report on the results of the audit must be drawn up for each audit and follow-up audit;

(c) the audit report must be sent to the management responsible for the matters audited; and

(d) the dates and results of audits and follow-up audits must be documented.

PART 5

Use of terminology, formats and standards

Use of internationally agreed terminology, formats and standards

18. The licensing authority may publish a list of which of the internationally agreed—

(a) terminology; and

(b) formats and standards,

are to be used for the description, classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information.

PART 6

Transmission of reports of suspected adverse reactions

Individual case safety reports

19. Individual case safety reports must be used for reporting to the licensing authority suspected adverse reactions to a medicinal product that occur in a single patient at a specific point in time.

Content of the individual case safety report

20.—(1) Holders must—

(a) ensure that individual case safety reports are as complete as possible; and

(b) communicate the updates of those reports to the licensing authority in an accurate and reliable manner.

(2) In the case of expedited reporting, the individual case safety report must include at least an identifiable reporter, an identifiable patient, one suspected adverse reaction and any medicinal product concerned.

(3) Holders and the licensing authority must record the details necessary for obtaining follow-up information on individual case safety reports and such reports must be adequately documented.

(4) When reporting suspected adverse reactions, holders must provide all available information on each individual case, including—

(a) administrative information, namely—

(i) report type, date and a worldwide unique case identification number as well as unique sender identification and sender type,

(ii) the date on which the report was first received from the source and the date of receipt of the most recent information, using a precise date, and

(iii) other case identifiers and their sources, as well as references to additional available documents held by the sender of the individual case safety report, where applicable;

(b) literature reference in accordance with the 'Vancouver style' as developed by the International Committee of Medical Journal Editors for adverse reactions reported in the worldwide literature, including a comprehensive English summary of the article;

(c) study type, study name and the sponsor's study number or study registration number for reports from studies not covered by the Clinical Trials Regulations;

(d) information on any primary source, namely information identifying the reporter, including country of residence and professional qualifications;

(e) information identifying the patient (and parent in the case of a parent-child report), including age at the time of the onset of the first reaction, age group, gestation period when reaction or event was observed in the foetus, weight, height or gender, last menstrual date and, where relevant, gestation period at time of exposure;

(f) relevant medical history and concurrent conditions;

(g) the name of any medicinal product suspected to be related to the occurrence of the adverse reaction, including interacting medicinal products or, where the name is not known, any active substance and any other characteristics that allow for the identification of a medicinal product, including—

(i) the name of the holder, UK marketing authorisation number, pharmaceutical form and each (parent) route of administration,

(ii) any indication for use in the case, dose administered, start date and end date of administration,

(iii) actions taken with any medicinal product, and

(iv) effect of the dechallenge and rechallenge for suspect medicinal products;

(h) for a biological medicinal product, the batch number;

(i) concomitant medicinal products, identified in accordance with paragraph (g), which are not suspected to be related to the occurrence of the adverse reaction and past-medical drug therapy for the patient (and for the parent), where applicable;

(j) information on any suspected adverse reaction, including—

(i) start date and end date of any suspected adverse reaction or duration,

(ii) seriousness,

(iii) outcome of any suspected adverse reaction at the time of last observation,

(iv) time intervals between suspect medicinal product administration and start of any adverse reaction,

(v) the original reporter's words or short phrases used to describe any reaction, and

(vi) country of occurrence of the suspected adverse reaction;

(k) results of tests and procedures relevant to the investigation of the patient;

(l) in the event of death of the patient, date and reported cause of death, including autopsy-determined causes;

(m) a case narrative, where possible, providing all relevant information for individual cases with the exception of non-serious adverse reactions; and

(n) reasons for nullifying or amending an individual case safety report.

(5) For the purposes of—

(a) sub-paragraph (4)(b), upon request of the licensing authority, the holder that transmitted the initial report must provide a copy of the relevant article taking into account copyright restrictions, and a full translation of that article into English;

(b) sub-paragraph (4)(h), a follow-up procedure must be in place to obtain the batch number where it is not indicated in the initial report;

(c) sub-paragraph (4)(m), the information must be presented in a logical time sequence, in the chronology of the patient's experience including clinical course, therapeutic measures, outcome and follow-up information obtained: any relevant autopsy or post-mortem findings must also be summarised in the narrative.

(6) Suspected adverse reactions must be reported in English.

Format of electronic transmission of suspected adverse reactions

21. Holders must use the formats and terminology specified in the list published under paragraph 18 for the electronic transmission of suspected adverse reactions, if the licensing authority has published a list under that paragraph.

PART 7

Risk management plans

Content of the risk management plan

22.—(1) The risk management plan established by the holder must contain the following elements—

(a) an identification or characterisation of the safety profile of the medicinal product concerned;

(b) an indication of how to characterise further the safety profile of the medicinal product(s) concerned;

(c) a documentation of measures to prevent or minimise the risks associated with the medicinal product, including an assessment of the effectiveness of those measures; and

(d) a documentation of post-authorisation obligations that have been imposed as a condition of the UKMA(GB).

(2) Medicinal products may, where appropriate be subject to the same risk management plan if they—

(a) contain the same active substance; and

(b) belong to the same holder.

(3) Where a risk management plan refers to post-authorisation studies—

(a) it must indicate whether those studies are initiated, managed or financed by the holder voluntarily, or pursuant to obligations imposed by the licensing authority or an equivalent authority to the licensing authority in another country; and

(b) all post-authorisation obligations must be listed in the summary of the risk management plan referred to in paragraph 23, together with a timeframe for meeting those obligations.

Summary of the risk management plan

23.—(1) The summary of the risk management plan to be made publicly available in accordance with regulation 203(2)(d) (obligations on licensing authority in relation to national medicines

web-portal) must include key elements of the risk management plan with a specific focus on risk minimisation activities and, with regard to the safety specification of the medicinal product concerned, important information on potential and identified risks as well as missing information.

(2) Where a risk management plan concerns more than one medicinal product, a separate summary of the risk management plan must be provided by holders for each medicinal product.

Updates of the risk management plan

24.—(1) Subject to sub-paragraph (2), where the holder updates a risk management plan, it must submit the updated risk management plan to the licensing authority.

(2) If the licensing authority agrees, the holder may submit only the modules concerned by the update.

(3) If necessary, the holder must provide the licensing authority with an updated summary of the risk management plan.

(4) Each submission of the risk management plan must—

(a) have a distinct version number; and

(b) be dated.

Format of the risk management plan

25. The risk management plan must be in the following format—

(a) Part I: product overview;

(b) Part II: safety specification consisting of—

(i) Module SI: epidemiology of each indication and each target population,

(ii) Module SII: non-clinical part of the safety specification,

(iii) Module SIII: clinical trial exposure,

(iv) Module SIV: populations not studied in clinical trials,

(v) Module SV: post-authorisation experience,

(vi) Module SVI: additional EU requirements for the safety specification,

(vii) Module SVII: identified and potential risks, and

(viii) Module SVIII: summary of the safety concerns;

(c) Part III: pharmacovigilance plan, including post-authorisation safety studies;

(d) Part IV: plans for post-authorisation efficacy studies;

(e) Part V: risk minimisation measures, including evaluation of the effectiveness of risk minimisation activities;

(f) Part VI: summary of the risk management plan; and

(g) Part VII: annexes.

PART 8

Periodic safety update reports

Content of periodic safety update reports

26.—(1) The periodic safety update report (“PSUR”) must—

(a) be based on all available data; and

(b) focus on new information which has emerged since the data lock point of the last PSUR.

(2) The PSUR must provide an accurate estimate of the population exposed to the medicinal product, including all data relating to the volume of sales and volume of prescriptions.

(3) The estimate of exposure referred to in sub-paragraph (2) must be accompanied by a qualitative and quantitative analysis of actual use, which must indicate, where appropriate, how actual use differs from the indicated use based on all data available to the holder, including the results of observational or drug utilisation studies.

(4) The PSUR must contain the results of assessments of the effectiveness of risk minimisation activities relevant to the risk–benefit assessment.

(5) Where any conditions are imposed under regulation 59(4A) (conditions in relation to UK marketing authorisations to which paediatric specific provisions apply) or 59(4D) (conditions in relation to UK marketing authorisations for advanced therapy medicinal products), the PSUR must also include an assessment of the effectiveness of any risk management system, and the results of any studies performed, in order to comply with those conditions.

(6) Subject to sub-paragraph (7), holders are not required to include systematically detailed listings of individual cases, including case narratives, in the PSUR.

(7) Holders must provide case narratives in the relevant risk evaluation section of the PSUR where integral to the scientific analysis of a signal or safety concern in the relevant risk evaluation section.

(8) Based on the evaluation of the cumulative safety data and the risk-benefit analysis, the holder must draw conclusions in the PSUR as to the need for changes or actions, including implications for the approved summary of product characteristics for each product for which the PSUR is submitted.

(9) Unless otherwise agreed with the licensing authority, a single PSUR must be prepared for all medicinal products which—

(a) contain the same active substance; and

(b) are authorised for the same holder,

and sub-paragraph (10) applies to that single PSUR.

(10) Where this sub-paragraph applies—

(a) the PSUR must cover all indications, routes of administration, dosage forms and dosing regimens, irrespective of whether authorised under different names and through separate procedures; and

(b) where relevant, data relating to a particular indication, dosage form, route of administration or dosing regimen must be presented in a separate section of the PSUR, with any safety concerns addressed accordingly.

(11) Unless otherwise agreed with the licensing authority, if the substance that is the subject of the PSUR is also authorised as a component of a fixed combination medicinal product, the holder must either—

(a) submit a separate PSUR for the combination of active substances authorised for the same holder, with cross-references to each relevant single-substance PSUR; or

(b) provide the combination data within one of the single-substance PSURs.

Format of periodic safety update reports

27.—(1) Electronic PSURs must be submitted in the following format—

(a) Part I: title page including signature;

(b) Part II: executive summary; and

(c) Part III: table of contents which contains—

(i) introduction,

(ii) worldwide marketing authorisation status,

(iii) actions taken in the reporting interval for safety reasons,

(iv) changes to reference safety information,

(v) estimated exposure and use patterns—

(aa) cumulative subject exposure in clinical trials,

(bb) cumulative and interval patient exposure from marketing experience,

(vi) data in summary tabulations—

(aa) reference information,

(bb) cumulative summary tabulations of serious adverse events in clinical trials,

(cc) cumulative and interval summary tabulations from post-marketing data sources,

(vii) summaries of significant findings from clinical trials during the reporting interval—

(aa) completed clinical trials,

(bb) ongoing clinical trials,

(cc) long-term follow-up,

(dd) other therapeutic use of medicinal product,

(ee) new safety data related to fixed combination therapies,

(viii) findings from non-interventional studies,

(ix) information from other clinical trials and sources,

(x) non-clinical data,

(xi) literature,

(xii) other periodic reports,

(xiii) lack of efficacy in controlled clinical trials,

(xiv) late-breaking information,

(xv) overview on signals: new, ongoing or closed,

(xvi) signal and risk evaluation—

(aa) summaries of safety concerns,

(bb) signal evaluation,

(cc) evaluation of risks and new information,

(dd) characterisation of risks, and

(ee) effectiveness of risk minimisation (if applicable),

(xvii) benefit evaluation—

(aa) important baseline efficacy and effectiveness information,

(bb) newly identified information on efficacy and effectiveness, and

(cc) characterisation of benefits,

(xviii) integrated benefit-risk analysis for authorised indications—

(aa) benefit-risk context: medical need and important alternatives, and

(bb) benefit-risk analysis evaluation,

(xix) conclusions and actions, and

(xx) appendices to the PSUR.

(2) In this paragraph, "signal evaluation" means the process of further evaluating a validated signal taking into account all available evidence, to determine whether there are new risks causally associated with the active substance or medicinal product, or whether known risks have changed, and that process—

(a) may include non-clinical and clinical data; and

(b) must be as comprehensive as possible regarding the sources of information used for that process.

PART 9

Post-authorisation safety studies

Scope and interpretation

28.—(1) This Part applies to non-interventional post-authorisation safety studies initiated, managed or financed by a holder under obligations imposed under regulation 59 or 61 (conditions of UK marketing authorisation).

(2) In this Part—

"start of data collection" means the date on which information on the first study subject is first recorded in the study dataset or, in the case of the secondary use of data, the date on which the data extraction starts; and

"end of data collection" means the date on which the analytical dataset is completely available.

Obligations as to post-authorisation safety studies

29.—(1) The holder must submit in English—

(a) the study protocol; and

(b) the abstract of the final study report and the final study report.

(2) The holder must ensure that—

(a) all study information is handled and stored so as to allow for accurate reporting, interpretation and verification of that information;

(b) the confidentiality of the records of the study subjects remains protected; and

(c) the analytical dataset and statistical programmes used for generating the data included in the final study report are kept in electronic format and are available for auditing and inspection.

(3) The licensing authority may publish appropriate templates for the protocol, abstract and final study report.

Format of the study protocol

30. The study protocol for a non-interventional post-authorisation safety studies must be submitted in the following format—

(a) title: informative title including a commonly used term indicating the study design and the medicinal product, substance or drug class concerned, and a sub-title with a version identifier and the date of the last version;

(b) name of holder;

(c) responsible parties including a list of all collaborating institutions and other relevant study sites.

(d) abstract, which must consist of a stand-alone summary of the study protocol, including the following subsections—

(i) title with subtitles including version and date of the protocol and name and affiliation of the main author,

(ii) rationale and background,

(iii) research question and objectives,

(iv) study design,

(v) population,

(vi) variables,

(vii) data sources,

(viii) study size,

(ix) data analysis, and

(x) milestones;

(e) amendments and updates, namely any substantial amendment and update to the study protocol after the start of data collection, including a justification for the amendment or update, the date of the change, and a reference to the section of the protocol where the change has been made.

(f) milestones, namely a table with planned dates for the following milestones—

(i) start of data collection,

(ii) end of data collection,

(iii) any study progress report as referred to in regulation 198(2),

(iv) any interim report of study results, if applicable, and

(v) final report of study results;

(g) rationale and background, namely a description of any safety hazard, the safety profile or the risk management measures that led to the study being imposed as an obligation for a UKMA(GB);

(h) research question and objectives in accordance with the decision of the licensing authority in imposing the study as an obligation;

(i) research methods, namely a description of the research methods, including—

(i) study design,

(ii) setting, namely the study population defined in terms of persons, place, time period, and selection criteria, including the rationale for any inclusion and exclusion criteria: where any sampling from a source population is undertaken, a description of the source population and details of sampling methods must be provided and where the study design is a systematic review or a meta-analysis, the criteria for the selection and eligibility of studies must be explained,

(iii) variables,

(iv) data sources, namely strategies and data sources for determining exposures, outcomes and all other variables relevant to the study objectives: where the study will use an existing data source, such as electronic health records, any information on the validity of the recording and coding of the data must be reported and in the

case of a systematic review or meta-analysis, the search strategy and processes and any methods for confirming data from investigators must be described,

(v) study size, namely any projected study size, precision sought for study estimates and any calculation of the study size that can minimally detect a pre-specified risk with a pre-specified interpretative power,

(vi) data management,

(vii) data analysis,

(viii) quality control, and

(ix) limitations of the research methods;

(j) protection of human subjects, namely safeguards in order to comply with national requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies;

(k) management and reporting of adverse events or adverse reactions and other medically important events while the study is being conducted;

(l) plans for disseminating and communicating study results; and

(m) references.

Format of the abstract of the final study report

31. The abstract of the final study report for a non-interventional post-authorisation safety studies must be submitted in the following format—

(a) title, with subtitles including date of the abstract and name and affiliation of main author;

(b) keywords (not more than five keywords indicating the main study characteristics);

(c) rationale and background;

(d) research question and objectives;

(e) study design;

(f) setting;

(g) subjects and study size, including dropouts;

(h) variables and data sources;

(i) results;

(j) discussion (including, where relevant, an evaluation of the impact of study results on the risk–benefit balance of the product);

(k) name of holder; and

(l) names and affiliations of principal investigators.

Format of the final study report

32. The final study report for a non-interventional post-authorisation safety studies must be submitted in the following format—

(a) title, including a commonly used term indicating the study design; sub-titles with date of final report and name and affiliation of the main author;

(b) abstract, namely a stand-alone summary referred to in paragraph 31;

(c) name and address of the holder;

(d) investigators, namely the names, titles, degrees, addresses and affiliations of the principal investigator and all co-investigators, and list of all collaborating primary institutions and other relevant study sites;

(e) milestones, namely the dates for the following milestones—

(i) start of data collection (planned and actual dates),

(ii) end of data collection (planned and actual dates),

(iii) study progress reports,

(iv) interim reports of study results, where applicable,

(v) final report of study results (planned and actual date), and

(vi) any other important milestone applicable to the study, including date of study registration in the electronic study register

(f) rationale and background, namely a description of the safety concerns that led to the study being initiated, and critical review of relevant published and unpublished data evaluating pertinent information and gaps in knowledge that the study is intended to fill;

(g) research question and objectives;

(h) amendments and updates to the protocol, namely a list of any substantial amendments and updates to the initial study protocol after the start of data collection, including a justification for each amendment or update;

(i) research methods, namely—

(i) study design: key elements of the study design and rationale for this choice,

(ii) setting: setting, locations, and relevant dates for the study, including periods of recruitment, follow-up, and data collection: in the case of a systematic review or meta-analysis, study characteristics used as criteria for eligibility, with rationale,

(iii) subjects: any source population and eligibility criteria for study subjects. Sources and methods for selection of participants shall be provided, including, where relevant, methods for case ascertainment, as well as number of and reasons for dropouts,

(iv) variables: all outcomes, exposures, predictors, potential confounders, and effect modifiers, including operational definitions: diagnostic criteria shall be provided, where applicable,

(v) data sources and measurement: for each variable of interest, sources of data and details of methods of assessment and measurement; if the study has used an existing data source, such as electronic health records, any information on the validity of the recording and coding of the data must be reported and in the case of a systematic review or meta-analysis, description of all information sources, search strategy, methods for selecting studies, methods of data extraction and any processes for obtaining or confirming data from investigators,

(vi) bias,

(vii) study size: study size, rationale for any study size calculation and any method for attaining projected study size,

(viii) data transformation: transformations, calculations or operations on the data, including how quantitative data were handled in the analyses and which groupings were chosen and why,

(ix) statistical methods: description of the following items—

(aa) main summary measures,

(bb) all statistical methods applied to the study,

(cc) any methods used to examine subgroups and interactions,

(dd) how missing data were addressed,

(ee) any sensitivity analyses, and

(ff) any amendment to the plan of data analysis included in the study protocol, with rationale for the change, and

(x) quality control: mechanisms to ensure data quality and integrity;

(j) results: comprising the following subsections—

(i) participants, namely numbers of study subjects at each stage of study: in the case of a systematic review or meta-analysis, number of studies screened, assessed for eligibility and included in the review with reasons for exclusion at each stage,

(ii) descriptive data: characteristics of study participants, information on exposures and potential confounders and number of participants with missing data. In the case of a systematic review or meta-analysis, characteristics of each study from which data were extracted,

(iii) outcome data: numbers of study subjects across categories of main outcomes,

(iv) main result: unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision and where relevant, estimates of relative risk must be translated into absolute risk for a meaningful time period,

(v) other analyses, and

(vi) adverse events and adverse reactions;

(k) discussion which must include—

(i) key results with reference to the study objectives, prior research in support of and conflicting with the findings of the completed post-authorisation safety study, and, where relevant, the impact of the results on the risk–benefit balance of the product,

(ii) limitations of the study taking into account circumstances that may have affected the quality or integrity of the data, limitations of the study approach and methods used to address them, sources of potential bias and imprecision, and validation of the events; both the direction and magnitude of potential biases must be discussed,

(iii) interpretation of results, considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence, and

(iv) generalisability; and

(l) references.**]**

SCHEDULE 13

Regulations 214(4) and 216(1)

Prescription only medicines for which community practitioner nurse prescribers are appropriate practitioners

Co-danthramer Capsules NPF

Co-danthramer Capsules Strong NPF

Co-danthramer Oral Suspension NPF

Co-danthramer Oral Suspension Strong NPF

Co-danthrusate Capsules

Co-danthrusate Oral Suspension NPF

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

Water for injections

In this Schedule "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

SCHEDULE 14

Regulation 215

Prescription etc by supplementary prescribers: particulars of clinical management plan

A clinical management plan must contain the following particulars—

(a) the name of the patient to whom the plan relates;

(b) the illnesses or conditions which may be treated by the supplementary prescriber;

(c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;

(d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;

(e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;

(f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;

(g) the arrangements for notification of—

(i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and

(ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and

(h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.

SCHEDULE 15

Regulation 221

Requirements for specific products subject to general sale

1. A medicinal product that contains aloxiprin, aspirin or paracetamol (or, where appropriate, any combination of those substances) and that is in the form specified in column 1 of the following

table must be presented for sale in a separate and individual package containing not more than the amount of the product specified in the corresponding entry in column 2—

Column 1	*Column 2*
Effervescent tablets— (a) that do not contain aspirin, or (b) that do not contain more than 325 milligrams of aspirin per tablet.	30 tablets
Effervescent tablets— (a) that contain more than 325 milligrams of aspirin per tablet, but (b) that do not contain more than 500 milligrams per tablet.	20 tablets
Non-effervescent tablets— (a) that are enteric-coated, (b) that contain aspirin only, and (c) that do not contain more than 75 milligrams per tablet.	28 tablets
Other non-effervescent tablets	16 tablets
Powder or granules	10 sachets
Capsules	16 capsules
Liquid preparations of paracetamol intended for persons aged 12 years and over	160 millilitres
Liquid preparations of paracetamol intended for persons aged less than 12 years	Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses

2. A medicinal product that contains ibuprofen and that is in the form specified in column 1 of the following table must be presented for sale in a separate and individual package containing not more than the amount of the product specified in the corresponding entry in column 2—

Form of product	*Maximum amount*
Tablets	16 tablets
Capsules	16 capsules
Powder or granules	12 sachets
Liquid preparations of ibuprofen	Individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses

SCHEDULE 16 Regulations 229, 230, 231,232, 233 and 234

Patient group directions

PART 1

Particulars to be included in a patient group direction

1. The period during which the direction is to have effect.

2. The description or class of medicinal product to which the direction relates.

3. The clinical situations which medicinal products of that description or class may be used to treat or manage in any form.

4. Whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions.

5. The clinical criteria under which a person is to be eligible for treatment.

6. Whether any class of person is excluded from treatment under the direction and, if so, what class of person.

7. Whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances.

8. The pharmaceutical form or forms in which medicinal products of that description or class are to be administered.

9. The strength, or maximum strength, at which medicinal products of that description or class are to be administered.

10. The applicable dosage or maximum dosage.

11. The route of administration.

12. The frequency of administration.

13. Any minimum or maximum period of administration applicable to medicinal products of that description or class.

14. Whether there are any relevant warnings to note and, if so, what warnings.

15. Whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances.

16. Arrangements for referral for medical advice.

17. Details of the records to be kept of the supply, or the administration, of products under the direction.

PART 2

Persons on whose behalf a patient group Direction must be signed

Column 1: Class of person by whom product is supplied	***Column 2: Person on whose behalf direction must be signed***
Common Services Agency	The Agency

Health authority	The health authority
Special health authority	The special health authority
NHS trust or NHS foundation trust	The trust
[F1106Local authority	The Chief Executive or Director of Public Health of the local authority**]**
[F1107Public Health England	The Chief Executive of Public Health England**]**
[F1107Public Health Agency	The Public Health Agency**]**
F1108	F1108
...	...
A person who supplies medicinal products pursuant to an arrangement made with— (a) the Common Services Agency; (b) a health authority; (c) a special health authority; (d) an NHS trust; **[**F1109(da) **[**F648an integrated care board**]**; (db) **[**F649NHS England**]**; (dc) a local authority; F1110...**]** **[**F1111(dd) Public Health England; (de) Public Health Agency; or**]** (e) an NHS foundation trust; F1112... F1112(f)	The Common Services Agency (where the arrangement has been made with the Agency); otherwise the— (a) health authority, (b) special health authority, (c) NHS trust, **[**F1113(ca) **[**F648an integrated care board**]**, (cb) **[**F649NHS England**]**, (cc) a local authority, F1114...**]** **[**F1115(cd) Chief Executive of Public Health England, (ce) Public Health Agency, or**]** (d) NHS foundation trust, F1116... F1116(e) . . . . . with which the arrangement has been made.

Textual Amendments

F1106 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(a)** (with Sch. 3 para. 28)

F1107 Words in Sch. 16 Pt. 2 added (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(a)** and words in Sch. 16 Pt. 2 added (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(a)**

F1108 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(b)** (with Sch. 3 para. 28)

F1109 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(c)(i)** (with Sch. 3 para. 28)

F1110 Word in Sch. 16 Pt. 2 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(b)(i)** and word in Sch. 16 Pt. 2 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(b)(i)**

F1111 Words in Sch. 16 Pt. 2 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(b)(ii)** and words in Sch. 16 Pt. 2 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(b)(ii)**

F1112 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(c)(ii)** (with Sch. 3 para. 28)

F1113 Words in Sch. 16 Pt. 2 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(d)(i)** (with Sch. 3 para. 28)

F1114 Word in Sch. 16 Pt. 2 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(c)(i)** and word in Sch. 16 Pt. 2 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(c)(i)**

F1115 Words in Sch. 16 Pt. 2 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(2)(c)(ii)** and words in Sch. 16 Pt. 2 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(2)(c)(ii)**

F1116 Words in Sch. 16 Pt. 2 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(7)(d)(ii)** (with Sch. 3 para. 28)

PART 3

Persons by whom or on whose behalf a patient group direction used as described in regulation 234 must be signed

Column 1: Force or service by whom or on whose behalf the health care is provided	***Column 2: Person by whom or on whose behalf direction must be signed***
A police force in England and Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996 **M92**)
A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1967 **M93**)
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(a) the Surgeon General, (b) a Medical Director General, or (c) a chief executive of an executive agency of the Ministry of Defence

[F1117Contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency	Medical Director of the contractor carrying out search and rescue operations on behalf of the Maritime and Coastguard Agency**]**

Textual Amendments

F1117 Words in Sch. 16 Pt. 3 added (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **7(3)** and words in Sch. 16 Pt. 3 added (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **7(3)**

Marginal Citations

M92 1996 c.16.

M93 1967 c.77.

PART 4

Classes of individuals by whom supplies may be made

Pharmacists.

Registered chiropodists and podiatrists.

Registered dental hygienist.

Registered dental therapist.

Registered dietitians.

Registered midwives.

Registered nurses.

Registered occupational therapists.

Registered optometrists.

Registered orthoptists.

Registered orthotists and prosthetists.

Registered paramedics.

Registered physiotherapists.

Registered radiographers.

Registered speech and language therapists.

SCHEDULE 17 Regulations 223(5)(b) and (c) 235,250(5) and 253(5)(d)

Exemption for sale, supply or administration by certain persons

PART 1

Exemption from restrictions on sale and supply of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***Conditions***
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines.	1. The sale or supply shall be— (a) subject to the presentation of an order signed by the principal of an institution concerned with educational research or the appropriate head of department in charge of a specified course of research stating— (i) the name of the institution for which the prescription only medicine is required, and (ii) the purpose for which the prescription only medicine is required, and (iii) the total quantity required; and (b) for the purpose of the education or research with which the institution is concerned.
2. Persons selling or supplying prescription only medicines to any of the following— (a) a public analyst appointed under section 27 of the Food Safety Act 1990 [M94] or article 27 of the Food Safety (Northern Ireland) Order 1991 [M95]; (b) an authorised officer within the meaning of section 5(6) of the Food Safety Act 1990 [M96]; (c) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989 [M97]; (d) an inspector acting under regulations 325 to 328;	2. All prescription only medicines.	2. The sale or supply shall be subject to the presentation of an order signed by or on behalf of any person listed in column 1 stating the status of the person signing it and the amount of prescription only medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.

(e) a sampling officer within the meaning of Schedule 31.		
3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 2006 **M98** , the National Health Service (Scotland) Act 1978 **M99** , the National Health Service (Wales) Act 2006 **M100** and the Health and Personal Social Services (Northern Ireland) Order 1972 **M101** , or under any subordinate legislation made under those Acts or that Order.	3. All prescription only medicines	3. The sale or supply shall be— (a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of the prescription only medicine required; and (b) for the purposes of a scheme referred to in column 1 in this paragraph.
4. Registered midwives.	4. Prescription only medicines containing any of the following substances— (a) Diclofenac; (b) Hydrocortisone Acetate; (c) Miconazole; (d) Nystatin; (e) Phytomenadione;	4. The sale or supply shall be only in the course of their professional practice.
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	5. Water for injection.	5. The sale or supply is to a person— (a) for a purpose other than parenteral administration; or (b) who has been prescribed dry powder for parenteral administration but has not been prescribed the water for injection that is needed as a diluent.
6. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	6. Items which are— (a) prescription only medicines which are not for parenteral administration and which— (i) are eye drops and are prescription only medicines by reason only that they contain	6. The sale or supply shall be subject to the presentation of an order signed by— (a) a registered optometrist for a medicine listed under item (a) in column 2;

	not more than 0.5 per cent of Chloramphenicol, or (ii) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or (iii) are prescription only medicines by reason only that they contain any of the following substances— (aa) Cyclopentolate hydrochloride, (bb) Fusidic Acid, (cc) Tropicamide; (b) the following prescription only medicines— (i) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight, (ii) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in lacquer does not exceed 5 per cent by weight in volume, (iii) Amoxicillin, (iv) Co-Codamol, (v) Co-dydramol 10/500 tablets, (vi) Codeine Phosphate, (vii) Erythromycin, (viii) Flucloxacillin, (ix) Silver Sulfadiazine, (x) Tioconazole 28%, (xi) Topical hydrocortisone where the maximum strength of hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	(b) a registered chiropodist or podiatrist for a medicine listed under item (b) in column 2.
7. Registered optometrists.	7. Prescription only medicines listed in item (a) of paragraph 6 column 2.	7. The sale or supply shall be only— (a) in the course of their professional practice, and (b) in an emergency.
8. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.	8. Medicinal products not for parenteral administration which are prescription only medicines by reason only that they contain any of the following substances—	8. The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist.

	(a) Acetylcysteine, (b) Atropine sulphate, (c) Azelastine hydrochloride, (d) Diclofenac sodium, (e) Emedastine, (f) Homotropine hydrobromide, (g) Ketotifen, (h) Levocabastine, (i) Lodoxamide, (j) Nedocromil sodium, (k) Olopatadine, (l) Pilocarpine hydrochloride, (m) Pilocarpine nitrate, (n) Polymyxin B/bacitracin, (o) Polymyxin B/trimethoprim, (p) Sodium cromoglycate.	
9. Additional supply optometrists.	9. Prescription only medicines specified in paragraph 8 column 2.	9. The sale or supply shall be only— (a) in the course of their professional practice, and (b) in an emergency.
10. Holders of **[**F1118UK marketing authorisations, EU marketing authorisations**]**, product licences or manufacturer's licences.	10. Prescription only medicines referred to in those authorisations or licences.	10. The sale or supply shall be only— (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
11. Registered chiropodists or podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicine specified in column 2.	11. The following prescription only medicines— (a) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight, (b) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in lacquer does not exceed 5 per cent by weight in volume, (c) Amoxicillin, (d) Co-Codamol, (e) Co-dydramol 10/500 tablets, (f) Codeine Phosphate, (g) Erythromycin, (h) Flucloxacillin,	11. The sale or supply shall be only in the course of their professional practice.

	(i) Silver Sulfadiazine, (j) Tioconazole 28%, (k) Topical hydrocortisone where the maximum strength of hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	
[F1119 12. Persons selling or supplying prescription only medicines to a school.	12. **[**F1120 Prescription only medicines comprising: (a) an inhaler containing salbutamol; or (b) an auto-injector containing adrenaline**]**	12. The sale or supply shall be— (a) subject to the presentation of an order signed by the principal or head teacher at the school concerned stating— (i) the name of the school for which the medicinal product is required, (ii) the purpose for which that product is required, and (iii) the total quantity required, and (b) for the purpose of supplying **[**F1121 or administering**]** the medicinal product to pupils at the school in an emergency.**]**
[F1122 13 Registered orthoptists **[**F1123 against whose names are recorded in the relevant register annotations signifying that they are qualified to sell or supply the medicine specified in column 2**]**.	13 The following prescription only medicines– (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice.**]**

Textual Amendments

F1118 Words in Sch. 17 Pt. 1 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **193(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 147(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1119 Words in Sch. 17 Pt. 1 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(2)** and words in Sch. 17 Pt. 1 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(2)**

F1120 Words in Sch. 17 Pt. 1 substituted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(a)(i)** and words in Sch. 17 Pt. 1 substituted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(a)(i)**

F1121 Words in Sch. 17 Pt. 1 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(a)(ii)** and words in Sch. 17 Pt. 1 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(a)(ii)**

F1122 Words in Sch. 17 Pt. 1 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(2)** and words in Sch. 17 Pt. 1 inserted (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(2)**

F1123 Words in Sch. 17 Pt. 1 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(2)(b)** and words in Sch. 17 Pt. 1 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(2)(b)**

Marginal Citations

M94 1990 c.16. Section 27 was amended by the Local Government etc (Scotland) Act 1994 section 180(1) and Schedule 18 paragraph 163(3), the Food Standards Act 1999 section 40(1) and Schedule 5 paragraphs 7 and 8, the Local Government (Wales) Act 1994 section 22(3) and Schedule 9 paragraph 16(2), S.I. 1994/865 regulation 24, and the Local Government and Public Involvement in Health Act 2007 sections 22 and 241, Schedule 1 Part 2 paragraph 17, and Schedule 18 Part 1.

M95 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.

M96 1990 c.16.

M97 1989 No. 846 (N.I. 6).

M98 2006 c. 41.

M99 1978 c. 29.

M100 2006 c. 42.

M101 S.I. 1972/1265 (N.I. 14).

PART 2

Exemption from the restriction on supply of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***Conditions***
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines	1. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the exercise of the functions of the Institution.
2. The owner or master of a ship which does not carry a doctor	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the

on board as part of the ship's complement.		treatment of persons on the ship.
3. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 2001 M102 or regulation 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 M103 to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons employed or engaged in the provision of lawful drug treatment services.	4. Ampoules of sterile water for injection that contain no more than 2ml of water each.	4. The supply shall be only in the course of provisions of lawful drug treatment services.
⌊F1124 4a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– (a) an NHS body; (b) a local authority; (c) Public Health England; or (d) Public Health Agency.	4a A prescription only medicine F1125 ... containing naloxone hydrochloride but no other substance that is classified as a product available on prescription only.	4a The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.⌋
5. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	5. Such prescription only medicines as may be specified in the relevant enactment.	5. The supply shall be— (a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and (b) subject to such conditions and such circumstances as may be specified in the relevant enactment.
6. Persons operating an occupational health scheme.	6. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	6. The supply of the prescription only medicine shall be— (a) in the course of operating an occupational health scheme, and (b) made by— (i) a doctor, or (ii) a registered nurse acting in accordance with the written directions of a doctor as to

		the circumstance in which such medicines are to be used in the course of an occupational health scheme.
[[F1126]6a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	6b. A prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned in entry 6a in response to an order in writing signed by a doctor or an occupational health vaccinator.	6c. The supply of the medicine is in the course of an occupational health scheme mentioned in entry 6a and is made, if not by a doctor, by an occupational health vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.**]**
7. The operator or commander of an aircraft.	7. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to an operator or commander of an aircraft in response to an order in writing signed by a doctor.	7. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
8. Persons employed as qualified first-aid personnel on off-shore installations.	8. All prescription only medicines.	8. The supply shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.	9. Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.	9. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.
10. Persons ("P") who are members of Her Majesty's armed forces.	10. All prescription only medicines.	10. The supply shall be— (a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and (b) where P is satisfied that it is not practicable for another person who is legally entitled to supply a prescription only medicine to do so; and (c) only in so far as is necessary—

		(i) for the treatment of a sick or injured person in a medical emergency, or (ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not supplied.
[F1127 11. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	11. A prescription only medicinal product comprising an inhaler containing salbutamol.	11. The supply shall be— (a) in the course of P carrying on the business of a school; (b) where supply is to a pupil at that school who is known to suffer from asthma; and (c) where the pupil requires the medicinal product in an emergency.**]**
[F1128 12 Registered midwives.	12 Prescription only medicines for parenteral administration that contain– (a) Diamorphine, (b) Morphine, (c) Pethidine hydrochloride.	12 The supply shall be only in the course of their professional practice.**]**

Textual Amendments

F1124 Words in Sch. 17 Pt. 2 added (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **10(2)** and words in Sch. 17 Pt. 2 added (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **10(2)**

F1125 Words in Sch. 17 Pt. 2 omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **18(a)** and words in Sch. 17 Pt. 2 omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **18(a)**

F1126 Words in Sch. 17 Pt. 2 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(2)** and words in Sch. 17 Pt. 2 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(2)**

F1127 Words in Sch. 17 Pt. 2 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(3)** and words in Sch. 17 Pt. 2 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(3)**

F1128 Words in Sch. 17 Pt. 2 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(3)** and words in Sch. 17 Pt. 2 inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(3)**

Marginal Citations

M102 S.I. 2001/3998, to which there are amendments that are not relevant.

M103 S.R. 2002 No. 1, to which there are amendments that are not relevant.

PART 3

Exemptions from the restriction on administration of prescription only medicines

Column 1 ***Persons exempted***	Column 2 ***Prescription only medicines to which the exemption applies***	Column 3 ***Conditions***
1. Registered chiropodists or podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.	1. Prescription only medicines for parenteral administration that contain— (a) Adrenaline, (b) Bupivacaine hydrochloride, (c) Bupivacaine hydrochloride with adrenaline where the maximum strength of adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride, (d) Levobupivacaine hydrochloride, (e) Lidocaine hydrochloride, (f) Lidocaine hydrochloride with adrenaline where the maximum strength of adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride, (g) Mepivacaine hydrochloride, (h) Methylprednisolone, (i) Prilocaine hydrochloride, (j) Ropivacaine hydrochloride.	1. The administration shall only be in the course of their professional practice and where the medicine includes a combination of substances in column 2, those substances shall not have been combined by the chiropodist or podiatrist.
2. Registered midwives and student midwives.	2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance that is classified as a product available on prescription only— (a) Adrenaline, (b) Anti-D immunoglobulin, (c) Carboprost, (d) Cyclizine lactate, (e) Diamorphine, (f) Ergometrine maleate, (g) Gelofusine, (h) Hartmann's solution, (i) Hepatitis B vaccine,	2. The medicine shall— (a) in the case of Lidocaine and Lidocaine hydrochloride, be administered only while attending on a woman in childbirth, and (b) where administration is— (i) by a registered midwife, be administered in the course of their professional practice; (ii) by a student midwife— (aa) be administered under the direct supervision of a registered midwife; and

	(j) Hepatitis immunoglobulin, (k) Lidocaine hydrochloride, (l) Morphine, (m) Naloxone hydrochloride, (n) Oxytocins, natural and synthetic, (o) Pethidine hydrochloride, (p) Phytomenadione, (q) Prochloperazine, (r) Sodium chloride 0.9%.	(bb) not include Diamorphine, Morphine or Pethidine hydrochloride.
3. Persons who are authorised as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations 2001 **M104** or, regulations 8(3) or 9(3) of the Misuse of Drugs Regulations (Northern Ireland) 2002 **M105** , to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of the ship's complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.
5. Persons operating an occupational health scheme.	5. Prescription only medicines that are for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	5. The prescription only is administered in the course of an occupational health scheme, and the individual administering the medicine is— (a) a doctor, or (b) a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used.
[F1129 5a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	5b. A prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned in entry 5a in response to an order in writing	5c. The administration of the medicine is in the course of an occupational health scheme mentioned in entry 5a, and the individual administering the medicine is, if not a doctor, an occupational health vaccinator acting in accordance with the written directions of a doctor as

	signed by a doctor or an occupational health vaccinator.	to the circumstances in which such medicines are to be used.**]**
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of the doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons employed as qualified first-aid personnel on off-shore installations.	7. All prescription only medicines that are for parenteral administration.	7. The administration shall be only so far as is necessary for the treatment of persons on the installation.
8. Persons who are registered paramedics.	8. The following prescription only medicines for parenteral administration— (a) Diazepam 5 mg per ml emulsion for injection, (b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion, (c) medicines containing the substance Ergometrine Maleate 500 mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient, (d) prescription only medicines containing one or more of the following substances, but no other active ingredient— (i) Adrenaline Acid Tartrate, (ii) Adrenaline hydrochloride, (iii) Amiodarone, (iv) Anhydrous glucose, (v) Benzlypenicillin, (vi) Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution), (vii) Ergometrine Maleate, (viii) Furosemide, (ix) Glucose, (x) Heparin Sodium, (xi) Lidocaine Hydrochloride, (xii) Metoclopramide, (xiii) Morphine Sulphate, (xiv) Nalbuphine Hydrochloride,	8. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

	(xv) Naloxone Hydrochloride, (xvi) Ondansetron (xvii) Paracetamol, (xviii) Reteplase, (xix) Sodium Chloride, (xx) Streptokinase, (xxi) Tenecteplase.	
9. Persons who hold the advanced life support provider certificate issued by the Resuscitation Council (UK).	9. The following prescription only medicines for parenteral administration — (a) Adrenaline 1:10,000 up to I mg; and (b) Amiodarone.	9. The administration shall be only in an emergency involving cardiac arrest, and in the case of adrenaline the administration shall be intravenous only.
[F1130 10. Persons ("P") who are members of Her Majesty's armed forces.	10. All prescription only medicines.	10. The administration shall be— (a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and (b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine to do so; and (c) only in so far as is necessary— (i) for the treatment of a sick or injured person in an emergency, or (ii) to prevent ill-health where there is a risk that a person would suffer ill-health if the prescription only medicine is not administered.**]**
[F1131 11 A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	11 A prescription only medicine comprising an auto-injector containing adrenaline.	11 The administration shall be— (a) in the course of P carrying on the business of a school; (b) where administration is to a pupil at that school who is known to be at risk of anaphylaxis; and

		(c) where the pupil requires the medicinal product in an emergency.]

Textual Amendments

F1129 Words in Sch. 17 Pt. 3 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(3)** and words in Sch. 17 Pt. 3 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(3)**

F1130 Words in Sch. 17 Pt. 3 added (E.W.S.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.I. 2014/490), regs. 1(2), **11** and words in Sch. 17 Pt. 3 added (N.I.) (31.3.2014) by The Human Medicines (Amendment) Regulations 2014 (S.R. 2014/323), regs. 1(2), **11**

F1131 Words in Sch. 17 Pt. 3 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(3)** and words in Sch. 17 Pt. 3 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(3)**

Marginal Citations

M104 S.I. 2001/3998 as amended by S.I. 2007/2154. There are other amendments that are not relevant.

M105 S.R. 2002 No. 1, as amended by S.R. 2007 No. 348. There are other amendments that are not relevant.

PART 4

Exemptions from the restrictions in regulations 220 and 221 for certain persons who sell, supply, or offer for sale or supply certain medicinal products

Column 1 ***Persons exempted***	Column 2 ***Medicinal products to which exemption applies***	Column 3 ***Conditions***
1. Registered chiropodists and podiatrists.	1. Medicinal products on a general sale list which are for external use and are not veterinary drugs and the following pharmacy medicines for external use— (a) Potassium permanganate crystals or solution; (b) ointment of heparinoid and hyaluronidase; and (c) products containing, as their only active ingredients, any of the following substances, at a strength, in the case of each substance, not exceeding that specified in relation to that substance— (i) 9.0 per cent Borotannic complex (ii) 10.0 per cent Buclosamide	

	(iii) 3.0 per cent Chlorquinaldol (iv) 1.0 per cent Clotrimazole (v) 10.0 per cent Crotamiton (vi) 5.0 per cent Diamthazole hydrochloride (vii) 1.0 per cent Econazole nitrate (viii) 1.0 per cent Fenticlor (ix) 10.0 per cent Glutaraldehyde (x) 1.0 per cent Griseofulvin (xi) 0.4 per cent Hydrargaphen (xii) 2.0 per cent Mepyramine maleate (xiii) 2.0 per cent Miconazole nitrate (xiv) 2.0 per cent Phenoxypropan-2-ol (xv) 20.0 per cent Podophyllum resin (xvi) 10.0 per cent Polynoxylin (xvii) 70.0 per cent Pyrogallol (xviii) 70.0 per cent Salicylic acid (xix) 1.0 per cent Terbinafine (xx) 0.1 per cent Thiomersal.	
2. Registered chiropodists and podiatrists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines in column 2.	2. (a) The following prescription only medicines— (i) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight, (ii) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in the lacquer does not exceed 5 per cent by weight in volume, (iii) Amoxicillin, (iv) Co-Codamol, (v) Co-dydramol 10/500 tablets, (vi) Codeine Phosphate, (vii) Erythromycin, (viii) Flucloxacillin, (ix) Silver Sulfadiazine, (x) Tioconazole 28%, (xi) Topical hydrocortisone where the maximum strength	2. The sale or supply shall be only in the course of their professional practice, and the medicinal product must have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied.

	of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight; and (b) Ibuprofen, other than preparations of ibuprofen which are prescription only medicines.	
3. Registered optometrists.	3. All medical products on a general sale list, all pharmacy medicines and prescription only medicines which are not for parenteral administration and which— (a) are eye drops and are prescription only medicines by reason only that they contain not more than— (i) 30.0 per cent Sulphacetamide Sodium, or (ii) 0.5 per cent Chloramphenicol, or (b) are eye ointments and are prescription only medicines by reason only that they contain not more than— (i) 30.0 per cent Sulphacetamide Sodium, or (ii) 1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any of the following substances— (i) Cyclopentolate hydrochloride, (ii) Fusidic acid, (iii) Tropicamide.	3. The sale or supply shall be only— (a) in the case of medicinal products on a general sale list and pharmacy medicines, in the course of their professional practice; (b) in the case of prescription only medicines, in the course of their professional practice and in an emergency.
4. Additional supply optometrists.	4. Medicinal products which are prescription only medicines by reason only that they contain any of the following substances— (a) Acetylcysteine, (b) Atropine sulphate, (c) Azelastine hydrochloride, (d) Diclofenac sodium, (e) Emedastine, (f) Homotropine hydrobromide, (g) Ketotifen,	4. The sale or supply shall be only in the course of their professional practice and only in an emergency.

	(h) Levocabastine, (i) Lodoximide, (j) Nedocromil sodium, (k) Olopatadine, (l) Pilocarpine hydrochloride, (m) Pilocarpine nitrate, (n) Polymyxin B/bacitracin, (o) Polymyxin B/ trimethoprim, (p) Sodium Cromoglycate.	
5. Holders of manufacturer's licences where the licence in question contains a provision that the licence holder shall manufacture the medicinal product to which the licence relates only for a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.	5. Medicinal products on a general sale list which are for external use and are not veterinary drugs and pharmacy medicines which are for external use in the treatment of hair and scalp conditions and which contain any of the following— (a) not more than 5.0 per cent of Boric acid, (b) Isopropyl myristate or Lauryl sulphate, (c) not more than 0.004 per cent Oestrogens, (d) not more than 1.0 per cent of Resorcinol, (e) not more than 3.0 per cent of Salicylic acid, (f) not more than 0.2 per cent of Sodium pyrithione.	5. The licence holder shall sell or supply the medicinal product in question only to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required.
6. Persons selling or supplying medicinal products to universities, other institutions concerned with higher education or institutions concerned with research.	6. All medicinal products.	6. The sale or supply shall be— (a) Subject to the presentation of an order signed by the principal of the institution concerned with education or research or the appropriate head of department in charge of the specified course of research stating— (i) the name of the institution for which the medicinal product is required, (ii) the purpose for which the medicinal product is required, and (iii) the total quantity required, and (b) for the purposes of the education or research with which the institution is concerned.

7. Persons selling or supplying medicinal products to organisations for research purposes.	7. All medicinal products.	7. The sale or supply is only for the purposes of research and shall be— (a) subject to the presentation of an order signed by the representative of the organisation concerned stating— (i) who requires the medicine, (ii) the purposes for which it is required, (iii) the quantity required, and (iv) the purposes of the research with which the organisation is concerned; and (b) not for administration to humans.
8. Persons selling or supplying medicinal products to any of the following— (a) a public analyst appointed under section 27 of the Food Safety Act 1990 or under article 27 of the Food Safety (Northern Ireland) Order 1991; (b) an agricultural analyst appointed under section 67 of the Agriculture Act 1970 [M106], (c) a person duly authorised by an enforcement authority under regulations 325 to 328, (d) a sampling officer within the meaning a sampling officer within the meaning of Schedule 31.	8. All medicinal products.	8. The sale or supply is in connection with the exercise of any statutory function carried out by any person listed in sub-paragraphs (a) to (d) of column 1 provided that— (a) the medicinal products are requested on an order signed by or on behalf of a person listed in sub-paragraph (a) to (d) of column 1, and (b) the order gives— (i) the status of the person signing it, (ii) the amount of medicinal product required.
9. Holders of a **[**[F1132]UK marketing authorisation, EU marketing authorisation**]**, a certificate of registration or a manufacturer's licence.	9. Medicinal product referred to in the **[**[F1132]UK marketing authorisation, EU marketing authorisation**]**, certificate of registration or manufacturer's licence.	The sale or supply shall be only— (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the medical product in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
10. Registered dispensing opticians.	10. Pharmacy medicines for external use containing chloramphenicol at a strength not exceeding—	10. The sale or supply shall only be in the course of their professional practice.

	(a) 0.5 per cent in eye drops; (b) 1 per cent in ointment.	
[F1133 11. Operator or commander of an aircraft.	11. All medicinal products on a general sale list.	11. The medicinal product must— (a) have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied; and (b) be stored in a part of the aircraft which the operator is able to close so as to exclude the public.**]**
[F1133 12. The operator of a train.	12. All medicinal products on a general sale list.	12. The medicinal product must— (a) have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied; and (b) be stored in a part of the train which the operator is able to close so as to exclude the public.**]**
[F1134 13 Registered orthoptists **[**F1135 against whose names are recorded in the relevant register annotations signifying that they are qualified to sell or supply the medicine specified in column 2**]**.	13 All medicinal products on a general sale list, all pharmacy medicines and the following prescription only medicines– (a) Atropine, (b) Cyclopentolate, (c) Tropicamide, (d) Lidocaine with fluorescein, (e) Oxybuprocaine, (f) Proxymetacaine, (g) Tetracaine, (h) Chloramphenicol, (i) Fusidic acid.	13 The sale or supply shall be only in the course of their professional practice.**]**

Textual Amendments

F1132 Words in Sch. 17 Pt. 4 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **193(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 147(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1133 Sch. 17 Pt. 4 Table Item 11, 12 inserted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **9**

F1134 Words in Sch. 17 Pt. 4 inserted (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **16(4)** and words in Sch. 17 Pt. 4 inserted (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **16(4)**

F1135 Words in Sch. 17 Pt. 4 inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **8(4)** and words in Sch. 17 Pt. 4 inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **8(4)**

Marginal Citations

M106 1970 c.40: subsection (1) was amended by section 272(1) of and Schedule 30 to the Local Government Act 1972; section 16 of and Schedule 8 paragraph 15 to the Local Government Act 1985, and section 66(6) and (8) of, and Schedule 16 paragraph 38(5) and Schedule 18 to the Local Government (Wales) Act 1994. Subsection (1A) was inserted by section 66(6) of and Schedule 16 paragraph 38(5) to that Act. Subsection 2 was substituted by section 180(1) of and Schedule 13 paragraph 85(2) to the Local Government etc (Scotland) Act 1994, and subsection (7) was repealed by sections 1(1) and 194 of, and Schedule 1 paragraph 8 and Schedule 34 Part 1 to the Local Government, Planning and Land Act 1980.

PART 5

Exemptions from the restrictions in regulations 220 and 221 for certain persons who supply certain medicinal products

Column 1 ***Persons exempted***	Column 2 ***Medicinal products to which exemption applies***	Column 3 ***Conditions***
1. Royal National Lifeboat Institution and certificated first aiders of the Institution.	1. All medicinal products.	1. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
2. British Red Cross Society and certificated first aid and certificated nursing members of the Society.	2. All pharmacy medicines and all medicinal products on a general sale list.	2. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
3. St John Ambulance Association and Brigade and certificated first aid and certificated nursing members of the Association and Brigade.	3. All pharmacy medicines and all medicinal products on a general sale list.	3. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
4. St. Andrew's Ambulance Association and certificated first aid and certificated nursing members of the Association.	4. All pharmacy medicines and all medicinal products on a general sale list.	4. The supply shall be only so far as is necessary for the treatment of sick and injured persons.

5. Order of Malta Ambulance Corps and certificated first aid and certificated nursing members of the Corps.	5. All pharmacy medicines and all medicinal products on a general sale list.	5. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
6. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 2001 or regulation 5 of the Misuse of Drugs Regulations (Northern Ireland) 2002.	6. Such prescription only medicines and such pharmacy medicines as are specified in the licence.	6. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
7. Persons employed or engaged in the provision of lawful drug treatment services.	7. Ampoules of sterile water for injection that contain no more than 5ml of water each.	7. The supply shall be only in the course of provision of lawful drug treatment services.
[F1136 7a Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– (a) an NHS body; (d) a local authority; (c) Public Health England; or (d) Public Health Agency.	7a **[**F1137 A medicinal product containing naloxone hydrochloride but no other substance that is classified as a product available only on prescription or as a product available only from a pharmacy.**]**	7a The supply shall be only in the course of provisions of lawful drug treatment services and only where required for the purpose of saving life in an emergency.**]**
8. Persons requiring medicinal products for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	8. Such prescription only medicines and such pharmacy medicines as may be specified in the relevant enactment and medicinal products on a general sale list.	8. The supply shall be— (a) for the purpose of enabling compliance with any requirement made by or in pursuance of any such enactment, and (b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.
9. The owner or master of a ship which does not carry a doctor on board as part of the ship's complement.	9. All medicinal products.	9. The supply shall be only so far as is necessary for the treatment of persons on the ship.
10. Persons operating an occupational health scheme.	10. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines as are sold or supplied to a person operating an occupational health scheme in response to an order signed	10. (a) The supply shall be in the course of an occupational health scheme. (b) The individual supplying the medicinal product, if not a doctor, shall be— (i) a registered nurse, and

	by a doctor or a registered nurse.	(ii) where the medicinal product in question is a prescription only medicine, acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of an occupational health scheme.
[[F1138]10a. An NHS body or a local authority operating an occupational health scheme and occupational health vaccinators employed or engaged by them.	10b. A prescription only medicine used for vaccination or immunisation against coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned in entry 10a in response to an order in writing signed by a doctor or an occupational health vaccinator.	10c. The supply of the medicine is in the course of an occupational health scheme mentioned in entry 10a, and the individual supplying the medicine is, if not a doctor, an occupational health vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicines are to be used.**]**
11. Persons carrying on the business of a school providing full-time education.	11. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.	11. The supply shall be— (a) in the course of a school dental scheme, and (b) if to a child under 16 only where the parent or guardian of that child has consented to such supply.
12. Health authorities or Primary Health Trusts.	12. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.	12. The supply shall be in the course of— (a) a pre-school dental scheme, and the individual supplying the medicinal product shall be a registered nurse, or (b) a school dental scheme, and if to a child under 16 only where the parent or guardian of that child has consented to such supply.
13. The operator or commander of an aircraft.	13. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of an aircraft in response to an order in writing signed by a doctor.	13. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and, in the case of a prescription only medicine, shall be in accordance with the written instructions of a doctor as to the circumstances in which the prescription only medicines of the description in question are to be used on the aircraft.

14. Persons employed as qualified first-aid personnel on offshore installations.	14. All medicinal products.	14. The supply shall be only so far as is necessary for the treatment of persons on the installation.
15. A prison officer.	15. All medicinal products on the general sale list.	15. The supply shall only be so far as is necessary for the treatment of prisoners.
16. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.	16. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines which are sold or supplied to a person specified in column 1 of this paragraph in response to an order in writing signed by a doctor.	16. The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.
17. Her Majesty's armed forces.	17. All medicinal products.	17. The supply shall be only so far as is necessary for the treatment of a sick or injured person or the prevention of ill-health.
[F1139 18. A person ("P") carrying on the business of a school who is trained to administer the relevant medicine.	18. A prescription only medicinal product comprising an inhaler containing salbutamol.	18. The supply shall be— (a) in the course of P carrying on the business of a school; (b) where supply is to a pupil at that school who is known to suffer from asthma; and (c) where the pupil requires the medicinal product in an emergency.**]**
[F1140 19. Persons supplying medicinal products under an off-site emergency plan prepared under the **[**F1141 Radiation (Emergency Preparedness and Public Information) Regulations 2019**]**.**]**	**[**F1140 19. Pharmacy medicines which contain any of the following substances but no other active ingredient— (a) Potassium Iodide; (b) Potassium Iodate.**]**	**[**F1140 19. The supply shall be— (a) in accordance with the off-site emergency plan; and (b) only in the event that a radiation emergency has occurred or an event has occurred which could reasonably be expected to lead to a radiation emergency.**]**
[F1140 20. A person or body listed in Part 1 or 2 of Schedule 1 to the Civil Contingencies Act 2004.**]**	**[**F1140 20. Pharmacy medicines which contain any of the following substances but no other active ingredient— (a) Potassium Iodide;	**[**F1140 20. The supply shall only be in response to the occurrence, or likely occurrence, of one of the following events—

(b) Potassium Iodate.**]**

(a) an emergency within the meaning of section 1 of the Civil Contingencies Act 2004;

(b) a **[**[F1142]radiation**]** emergency within the meaning of regulation 24 of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.**]**

Textual Amendments

F1136 Words in Sch. 17 Pt. 5 added (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **10(3)** and words in Sch. 17 Pt. 5 added (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **10(3)**

F1137 Words in Sch. 17 Pt. 5 substituted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **18(b)** and words in Sch. 17 Pt. 5 substituted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **18(b)**

F1138 Words in Sch. 17 Pt. 5 inserted (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(3), **32(4)** and words in Sch. 17 Pt. 5 inserted (N.I.) (17.10.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(3), **32(4)**

F1139 Words in Sch. 17 Pt. 5 added (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **27(4)** and words in Sch. 17 Pt. 5 added (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **27(4)**

F1140 Words in Sch. 17 Pt. 5 inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **12(2)** and words in Sch. 17 Pt. 5 inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **12(2)**

F1141 Words in Sch. 17 Pt. 5 substituted (E.W.S.) (22.5.2019) by The Radiation (Emergency Preparedness and Public Information) Regulations 2019 (S.I. 2019/703), reg. 1(1), **Sch. 10 para. 10(3)** (with reg. 3)

F1142 Word in Sch. 17 Pt. 5 substituted (21.4.2019) by The Carriage of Dangerous Goods (Amendment) Regulations 2019 (S.I. 2019/598), regs. 1, **10**

SCHEDULE 18

Regulation 225

Substances that may not be sold or supplied by a pharmacist without a prescription in reliance on regulation 225

Ammonium bromide

Calcium bromide

Calcium bromidolactobionate

Embutramide

Fencamfamin hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone sodium
Hydrobromic acid
Meclofenoxate hydrochloride
Methohexitone sodium
Pemoline
Piracetam
Potassium bromide
Prolintane hydrochloride
Sodium bromide
Strychnine hydrochloride
Tacrine hydrochloride
Thiopentone sodium

SCHEDULE 19

Regulation 238

Medicinal products for parenteral administration in an emergency

Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis
Atropine sulphate and obidoxime chloride injection
Atropine sulphate and pralidoxime chloride injection
Atropine sulphate injection
Atropine sulphate, pralidoxime mesilate and avizafone injection
Chlorphenamine injection
Dicobalt edetate injection
Glucagon injection
Glucose injection
Hydrocortisone injection
Naloxone hydrochloride
Pralidoxime chloride injection
Pralidoxime mesilate injection
Promethazine hydrochloride injection
Snake venom antiserum
Sodium nitrite injection
Sodium thiosulphate injection
Sterile pralidoxime

SCHEDULE 20 Regulation 241

Herbal medicinal products specified for the purposes of regulation 241

PART 1

Botanical Source	***Common Name***
Apocynum cannabinum	Canadian hemp
Areca catechu	Areca
Artemisia cina	Santonica
Brayera anthelmintica	Kousso
Catha edulis	Catha
Chenopodium ambrosioides var anthelminticum	Chenopodium
Crotalaria berberoana	Crotalaria fulva
Crotalaria spectabilis	Crotalaria spect.
Cucurbita maxima	Cucurbita
Delphinium staphisagria	Stavesacre seeds
Dryopteris filix-mas	Male fern
Duboisia leichardtii Duboisia myoporoides	Duboisia
Ecballium elaterium	Elaterium
Embelia ribes Embelia robusta	Embelia
Erysimum canescens	Erysimum
Holarrhena antidysenterica	Holarrhena
Juniperus sabina	Savin
Mallotus philippinensis	Kamala
Pausinystalia yohimbe	Yohimbe bark
Punica granatum	Pomegranate bark
Rhus radicans	Poison ivy
Scopolia carniolica Scopolia japonica	Scopolia
Strophanthus courmonti Strophanthus emini Strophanthus gratus Strophanthus hispidus Strophanthus kombe Strophanthus nicholsoni Strophanthus sarmentosus	Strophanthus

Ulmus fulva Ulmus rubra	Slippery elm bark (whole or unpowdered)
Viscum album	Misletoe berry

PART 2

Column 1 **Substance** **Botanical Source**	**Common Name**	Column 2 **Maximum dose and maximum daily dose**	Column 3 **Percentage**
Aconitum balfourni Aconitum chasmanthum Aconitum deinorrhizum Aconitum lycoctonum Aconitum napellus Aconitum spicatum Aconitum stoerkianum Aconitum uncinatum var japonicum	Aconite		1.3 per cent
Adonis vernalis	Adonis vernalis	100 mg (MD) 300mg (MDD)	
Aspidosperma quebrachoblanco	Quebracho	50 mg (MD) 150 mg (MDD)	
Atropa acuminata Atropa belladonna	Belladonna herb, belladonna root	In the form of belladonna herb: 50 mg (MD) 150 mg (MDD); In the form of belladonna root: 30 mg (MD) 90 mg (MDD)	
Chelidonium majus	Celandine	2 g (MD) 6 g (MDD)	
Cinchona calisaya Cinchona ledgerana Cinchona micrantha Cinchona officinalis Cinchona succirubra	Cinchona bark	250 mg (MD) 750 mg (MDD)	
Colchicum autumnale	Colchicum corm	100 mg (MD) 300 mg (MDD)	
Conium maculatum	Conium fruits, conium leaf		7.0 per cent
Convallaria majalis	Convallaria	150 mg (MD) 450 mg (MDD)	
Datura innoxia	Stramonium	50 mg (MD)	

Datura stramonium		150 mg (MDD)	
Ephedra distachya Ephedra equisetina Ephedra gerardiana Ephedra intermedia Ephedra sinica	Ephedra	600 mg (MD) 1800 mg (MDD)	
Gelsemium sempervirens	Gelsemium	25 mg (MD) 75 mg (MDD)	
Hyoscyamus albus Hyoscyamus muticus Hyoscyamus niger	Hyoscyamus	100mg (MD) 300 mg (MDD)	
Lobelia inflata	Lobelia	200 mg (MD) 600 mg (MDD)	
Pilocarpus jaborandi Pilocarpus microphyllus	Jaborandi		5.0 per cent
Rhus toxicodendron	Poison oak		10.0 per cent
Senecio jacobaea	Ragwort		10.0 per cent

SCHEDULE 21 Regulation 242

Medicinal products at high dilutions

PART 1

Dilutions of unit preparations diluted to at least one part in a thousand (3x)

Agaricus muscarius

Ailanthus glandulosa

Apocynum cannabinum

Aurum lodatum

Belladonna

Bismuth Subgallate

Bryonia alba dioica

Calcium Fluoride

Cantharis

Cerium oxalicum

Chelidonium majus

Chenopodium oil

Cina

Colocynthis

Convallaria majalis

Gelsemium sempervirens

Hyoscyamus niger
Lycopodium
Manganese acetate
Ranunculus bulbosus
Terebinthinae oleum

PART 2

Dilutions of unit preparations diluted to at least one part in a million (6x)

Adonis vernalis
Agaricus bulbosus
Agaricus muscarius
Agnus castus
Ailanthus glandulosa
Alum
Amethyst
Ammonium Iodide
Amygdalae amarae
Apatite
Apocynum androsaemifolium
Apocynum cannabinum
Argentite
Argentum Chloride
Argentum Iodide
Arnica
Artemisia cina
Aspidium filix-mas
Aspidium anthelmintica
Aurum Sulphide
Balsamum copivae
Balsamum peruvianum
Barium Citrate
Barium Citrate
Barium Sulphate
Bismuth Metal
Bismuth Subgallate
Bismuth Subnitrate
Boletus laricis
Bovista
Cade Oil

Calcium Fluoride
Cantharis
Carduus marianus
Cedar Wood Oil
Cerium Oxalicum
Chalcocite
Chalcopyrite
Chelidonium majus
Chenopodium Oil
Colocynthis
Convallaria majalis
Copper Silicate, Nat.
Crotalus horridus
Cucurbita
Cucumis melo
Datura Stramonium
Derris
Diamond
Ephedra vulgaris
Ferric Acetate
Ferrous Iodide
Ferrous Oxalate
Ferrous Sulphide
Formic Acid
Gall
Gelsemium sempervirens
Gneiss
Granatum (Pomegranate) Bark
Harmamelis Virginiana
Hepar Sulfuris
Hyoscyamus niger
Iris florentine
Jaborandi
Juniperus sabina
Kalinite
Lachmanthus tinctoria
Lapis Albus
Lycopodium
Magnesium
Magnesium Acetate

Magnesium Chloride
Magnetite
Manganese Acetate
Nicotiana tabacum
Nicotiana tabacum oil
Oleander
Opuntia vulgaris
Oxalic Acid
Petroleum
Phellandrium aquaticum
Pix Liquida
Platinum
Platinum Chloride
Potassium Hydroxide
Potassium Silicate
Pyrethrum
Pyrolusite
Ranunculus acris
Ranunculus bulbosus
Ranunculus flammula
Ranunculus repens
Ranunculus sceleratus
Rhodium Oxynitrate
Rhododendron chrysanthemum
Rhus toxicodendron
Salicylic Acid
Scrophularia aquatica
Sodium Aluminium Chloride
Sodium Auro-chloride
Sodium Hypochlorite
Sodium Nitrate
Squill
Stannum Metal
Staphisagria
Sulphur Iodide
Tamus communis
Tannic Acid
Terebinthinae Oleum
Theridion
Thuja occidentalis

Topaz
Uric Acid
Zinc Hypophosphite
Zinc Isovalerate

PART 3

Dilutions of unit preparations diluted to at least one part in ten (1x)

Abies excelsa
Abies nigra
Abies nobilis
Acalpha indica
Agate
Alisma plantago Aq.
Alstonia scholaris
Aluminium
Amber (Succinum)
Ambra grisea
Ammonium Phosphate
Angostura vera
Anthoxanthum
Apis mellifera
Aqua Marina
Aqua Mellis
Aralia racemosa
Aranea diadema
Arum maculatum
Arum triphyllum
Asarum
Asperula odorata
Astacus fluviatillis
Auric Chloride
Badiaga
Beech (fagus sylvestris)
Bellis perennis
Berberis aquifolium
Borago officinalis
Butyric Acid
Calcium Metal
Calcium Chloride

Calcium Oxide
Calcium Sulphate
Castoreum
Ceanothus americanus
Cedron
Cerato (Ceratostigma Willmottiana)
Cherry Plum (Prunus cerasifera)
Chestnut, Red and Sweet
Cholesterinum
Chrysolite
Cistus canadensis
Clematis erecta
Conchae vera
Conchiolinum
Corallium Rubrum
Crab Apple
Crocus sativus
Erbium
Erigeron Canadense
Fuligo
Genista tinctoria
Geum urbanum
Glycogen
Gnaphalium leontopodium
Gold
Gorse (Ulex europaeus)
Graphites
Gratiola officinalis
Gymnocladus (American Coffee Tree)
Haematoxylon Campechianum
Hecla Lava (Ash from Mount Hecla)
Hedeoma pulegioides
Hedra helix
Heliotrope
Heracleum spondylium
Herniaria
Hornbeam (Carpinus betulus)
Iberis amara
Impatiens
Iris germanica

Iris pseudacorus
Jacaranda procera
Jatropha curcas
Juncus communis
Justica adhatoda
Lamium album
Laurus nobilis oil
Laurocerasus
Ledum palustre
Lilium tigrinum
Lonicera caprifolium
Lysimachia vulgaris
Magnesium Phosphate
Magnesite
Magnolia
Marum verum
Melilotus officinalis
Menispermum canadense
Pephitis putorius
Mercurialis perennis
Mimulus (Mimullis guttatus)
Moschus
Myrica gale
Myrtus communis
Ocimum basilicum
Olive
Oxalis acetosella
Pangamic Acid
Paullinia cupana
Penthorum sedoides
Pollen (mixed)
Polygonatum multiflorum
Polygonum aviculare
Polypodium vulgare
Primula vulgaris
Prunella vulgaris
Ptellea trifoliata
Ratanhia
Robinia pseudoacacia
Rubia tinctorum

Rumex acetosella
Sal Marina
Sarcolactic Acid
Sarracenia purpurea
Scleranthus (Scleranthus annuus)
Silica
Silphium laciniathum
Sodium Benzoate
Spongia marina
Star of Bethlehem (Ornithogalum umbellatum)
Ulmus campestris
Vine
Walnut (juglerus regia)
Water Violet (Hottonia palustris)
Wild Oat
Wild Rose

PART 4

Dilutions of unit preparations diluted to at least one part in ten (1x) for external use

Adonis vernalis
Agricus bulbosus
Agricus muscarius
Agnus castus
Allanthus glandulosa
Alum
Amethyst
Ammonium Iodide
Amygdalae amarae
Apatite
Apocynum androsaemifolium
Apocynum cannabinum
Argentite
Argentum Chloride
Argentum Iodide
Artemisia cina
Aspidium filix-mas
Aspidium anthelmintica
Aurum Sulphide
Balsamum copaivae

Balsamum peruvianum
Barium Citrate
Barium Sulphate
Bismuth Metal
Bismuth Subgallate
Bismuth Subnitrate
Boletus laricis
Bovista
Cade Oil
Calcium Fluoride
Carduus marianus
Cedar Wood Oil
Cerium Oxalicum
Chalcocite
Chalcopyrite
Chelidonium majus
Chenopodium Oil
Colocynthis
Convallaria majalis
Copper Silicate, Nat
Crotalus horridus
Cucurbita
Cucumis melo
Datura stramonium
Derris
Diamond
Ephedra vulgaris
Ferric Acetate
Ferrous Iodide
Ferrous Oxalate
Ferrous Sulphide
Formic Acid
Gall
Gelsemium sempervirens
Gneiss
Hamamelis virginiana
Hepar Sulfuris
Hyoscyamus niger
Iris florentine
Jaborandi

Juniperus sabina
Kaolinite
Lachmanthus tinctoria
Lapis Albus
Lycopodium
Magnesium
Magnesium Acetate
Magnesium Chloride
Magnetite
Manganese Acetate
Nicotiana tabacum
Nicotiana tabacum oil
Oleander
Opuntia vulgaris
Oxalic Acid
Petroleum
Phellandrium aquaticum
Pix Liquida
Platinum
Platinum Chloride
Potassium Hydroxide
Potassium Silicate
Pyrethrum
Pyrolusite
Ranunculus acris
Ranunculus bulbosus
Ranunculus flammula
Ranunculus repens
Ranunculus scelerantus
Rhodium Oxynitrate
Rhododendron chrysanthemum
Rhus toxicidendron
Salicylic Acid
Scrophularia aquatica
Sodium Aluminium Chloride
Sodium Auro-chloride
Sodium Hypochlorite
Sodium Nitrate
Squill
Stannum Metal

Sulphur Iodide

Tannic Acid

Terebinthinae Oleum

Topaz

Uric Acid

Zinc Hypophosphite

Zinc Isovalerate

SCHEDULE 22

Regulation 249

Classes of person for the purposes of regulation 249

Doctors

Dentists

Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.

Authorities or persons carrying on the business of—

(a) an independent hospital, independent clinic or independent medical agency,

(b) a hospital or health centre which is not an independent hospital or independent clinic, or

(c) in Northern Ireland, a nursing home.

Holders of wholesale dealer's licences or persons to whom the restrictions imposed by regulation 18(1) do not apply by virtue of an exemption in these Regulations.

Ministers of the Crown and Government departments.

Scottish Ministers.

Welsh Ministers.

A Northern Ireland Minister.

An NHS trust.

An NHS foundation trust.

[[F1143]A local authority in the exercise of public health functions (within the meaning of the National Health Service Act 2006).**]**

Textual Amendments

F1143 Words in Sch. 22 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(a)** (with Sch. 3 para. 28)

[[F1144]Public Health England.**]**

Textual Amendments

F1144 Words in Sch. 22 inserted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(2)** and words in Sch. 22 inserted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(2)**

[F1144Public Health Agency.**]**

The Common Services Agency.

A health authority or a special health authority.

F1145 . . . . . .

Textual Amendments

F1145 Words in Sch. 22 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(b)** (with Sch. 3 para. 28)

A person other than an excepted person who carries on a business consisting (wholly or partly) of supplying medicinal products in circumstances corresponding to retail sale, or of administering such products, pursuant to an arrangement made with—

(a) an NHS trust or an NHS foundation trust;

(b) the Common Services Agency;

(ba) **[**F648an integrated care board**]**;

[F1146(bb) **[**F649NHS England**]**;**]**

[F1147(bc) a local authority;

(bd) Public Health England;

(be) Public Health Agency; or**]**

(c) a health authority or a special health authority; F1148...

F1148(d) . . . . . .

Textual Amendments

F1146 Words in Sch. 22 inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(c)(i)** (with Sch. 3 para. 28)

F1147 Words in Sch. 22 substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(3)** and words in Sch. 22 substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(3)**

F1148 Words in Sch. 22 omitted (1.4.2013) by virtue of The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), art. 1(2), **Sch. 2 para. 176(8)(c)(ii)** (with Sch. 3 para. 28)

A person other than an excepted person who carries on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of health care by or on behalf of, or under arrangements made by—

(a) a police force in England, Wales or Scotland;

(b) the Police Service of Northern Ireland;

(c) a prison service; F1149...

[F1150(d) Her Majesty's Forces; or

(e) a contractor carrying out helicopter search and rescue operations on behalf of the Maritime and Coastguard Agency.**]**

Textual Amendments

F1149 Word in Sch. 22 omitted (E.W.S.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(4)** and word in Sch. 22 omitted (N.I.) (1.4.2015) by virtue of The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(4)**

F1150 Words in Sch. 22 substituted (E.W.S.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.I. 2015/323), regs. 1, **8(5)** and words in Sch. 22 substituted (N.I.) (1.4.2015) by The Human Medicines (Amendment) Regulations 2015 (S.R. 2015/178), regs. 1, **8(5)**

In this Schedule "excepted person" means—

(a) a doctor or dentist; or

(b) a person lawfully conducting a retail pharmacy business within the meaning of section 69 of the Medicines Act 1968.

SCHEDULE 23

Regulation 253

Particulars in pharmacy records

1. Paragraph 2 applies, subject to paragraph 3, where the sale or supply of a prescription only medicine is—

(a) in pursuance of a prescription given by—

(i) a doctor or dentist,

(ii) a supplementary prescriber,

(iii) a community practitioner nurse prescriber,

(iv) a nurse independent prescriber,

[F1151(v) an optometrist independent prescriber,

(vi) a pharmacist independent prescriber,

(vii) a podiatrist independent prescriber,

(viii) a physiotherapist independent prescriber, F1152...

(ix) a therapeutic radiographer independent prescriber; or**]**

[F1153(x) a paramedic paramedic independent prescriber; or**]**

(b) under regulation 224 (emergency sale etc by pharmacist: prescriber unable to provide prescription).

Textual Amendments

F1151 Sch. 23 para. 1(a)(v)-(ix) substituted for Sch. 23 para. 1(a)(v)(vi) (E.W.S.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **17** and Sch. 23 para. 1(a)(v)-(ix) substituted for Sch. 23 para. 1(a)(v)(vi) (N.I.) (1.4.2016) by The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **17**

F1152 Word in Sch. 23 para. 1(a)(viii) omitted (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **13(2)(a)** and word in Sch. 23 para. 1(a)(viii) omitted (N.I.) (1.4.2018) by virtue of The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **13(2)(a)**

F1153 Sch. 23 para. 1(a)(x) inserted (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.I. 2018/199), regs. 1, **13(2)(b)** and Sch. 23 para. 1(a)(x) inserted (N.I.) (1.4.2018) by The Human Medicines (Amendment) Regulations 2018 (S.R. 2018/64), regs. 1, **13(2)(b)**

2. In such a case, the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine was sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address of the person giving the prescription;

(d) the name and address of the person for whom the prescription only medicine was prescribed;

(e) the date on the prescription; and

(f) in relation to the sale or supply of a prescription only medicine under regulation 224 the date on which the prescription relating to that sale or supply is received.

3. Where the sale or supply is in pursuance of a repeatable prescription and is not the first sale or supply in pursuance of that prescription, the particulars referred to in regulation 253(2)(a) are either—

(a) the date on which the prescription only medicine is sold or supplied and a reference to the entry in the record referred to in regulation 253(1) which was made in respect of the first sale or supply in pursuance of that prescription and which contains the particulars specified in paragraph 2; or

(b) the particulars specified in paragraph 2.

4. Where the sale or supply of a prescription only medicine is a sale or supply under regulation 225 (emergency sale etc by pharmacist: at patient's request), the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine was sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address of the person requiring the prescription only medicine; and

(d) the nature of the emergency.

5. Paragraph 6 applies where—

(a) the sale or supply of a prescription only medicine is by way of wholesale dealing and no order or invoice or copy of the order or invoice has been retained under regulation 224 or 225; or

(b) the sale or supply is one to which regulation 214(1) does not apply by reason of an exemption other than that in regulation 224 or 225.

6. In such a case, the particulars referred to in regulation 253(2)(a) are—

(a) the date on which the prescription only medicine is sold or supplied;

(b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine sold or supplied;

(c) the name and address and trade, business or profession of the person to whom the prescription only medicine is sold or supplied; and

(d) the purpose for which the prescription only medicine is sold or supplied.

SCHEDULE 24 Regulation 257

Packaging information requirements

PART 1

Outer and immediate packaging

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. A statement of the active substances in the product, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.

6. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

7. A list of—

(a) where the product is injectable or is a topical or eye preparation, all excipients; or

(b) in any other case, those excipients known to have a recognized action or effect and included in the guidance **[**[F1154]published under regulation 257D in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive or under regulation 257D that is applicable to such products.**]**.

Textual Amendments

F1154 Words in Sch. 24 para. 7(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

8. The method of administration of the product and if necessary the route of administration.

9. Where appropriate, space for the prescribed dose to be indicated.

10. A warning that the product must be stored out of the reach and sight of children.

11. Any special warning applicable to the product.

12. The product's expiry date (month and year), in clear terms.

13. Any special storage precautions relating to the product.

14. Any special precautions relating to the disposal of an unused product or part of a product, or waste derived from the product, and reference to any appropriate collection system in place.

15. The name and address of the holder of the **[**[F1155]UK marketing authorisation, EU marketing authorisation**]** Article 126a authorisation or traditional herbal registration relating to the product and, where applicable, the name of the holder's representative.

Textual Amendments

F1155 Words in Sch. 24 para. 15 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

16. The number of the **[**F1156UK marketing authorisation, EU marketing authorisation**]** Article 126a authorisation or traditional herbal registration for placing the medicinal product on the market.

Textual Amendments

F1156 Words in Sch. 24 para. 16 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

17. The manufacturer's batch number.

18. In the case of a product that is not a prescription only medicine, instructions for use.

[F1157**18A.** In the case of a medicinal product, other than a radiopharmaceutical, that is required by Article 54a of the 2001 Directive to bear safety features—

(a) a unique identifier which complies with the technical specifications set out in Chapter II of Commission Regulation 2016/161; and

(b) an anti-tampering device allowing verification of whether the packaging of the medicinal product has been tampered with.**]**

Textual Amendments

F1157 Sch. 24 para. 18A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **19** and Sch. 24 para. 18A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **19**

PART 2

Immediate packaging: blister packs

19. The name of the medicinal product.

20. The strength and pharmaceutical form of the product.

21. Where appropriate, whether the product is intended for babies, children or adults.

22. Where the product contains up to three active substances, the common name of each active substance.

23. The name of the holder of the **[**F1158UK marketing authorisation, EU marketing authorisation**]**, Article 126a authorisation or traditional herbal registration relating to the product.

Textual Amendments

F1158 Words in Sch. 24 para. 23 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

24. The product's expiry date (month and year), in clear terms.

25. The manufacturer's batch number.

PART 3

Immediate packaging: small packages

26. The name of the medicinal product.

27. The strength and pharmaceutical form of the product.

28. Where appropriate, whether the product is intended for babies, children or adults.

29. Where the product contains up to three active substances, the common name of each active substance.

30. The method of administration of the product and if necessary the route of administration.

31. The product's expiry date (month and year), in clear terms.

32. The manufacturer's batch number.

33. The contents of the packaging by weight, by volume or by unit.

[F1159PART 4

Outer and immediate packaging: advanced therapy medicinal products for sale or supply in Great Britain only

Textual Amendments

F1159 Sch. 24 Pts. 4, 5 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(5)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

34. The name of the advanced therapy medicinal product which is the international non-proprietary name, or if none, the common name.

35. Where appropriate, whether the product is intended for babies, children or adults.

36. The expiry date in clear terms including the year and month and, if applicable, day.

37. A description of the active substance, expressed qualitatively and quantitatively.

38. Where the product contains tissues and cells of human or animal origin—

(a) a statement that the product contains such cells or tissues; and

(b) a short description of the cells or tissues and of their specific origin, including the species of animal in cases on non-human origin.

39. The pharmaceutical form and the contents by weight, volume or number of doses of the product.

40. A list of excipients, including preservative systems.

41. The method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated.

42. A special warning that the product is to be stored out of the sight and reach and children.

43. Any special warning necessary for the particular product.

44. Any special storage precautions.

45. Specific precautions relating to the disposal of the unused product or of waste derived from the product and, where appropriate, reference to any appropriate collection system.

46. The name and address of the holder of the UK marketing authorisation and, where applicable, the name of the representative appointed by the holder to represent him.

47. The UK marketing authorisation number.

48. The manufacturer's batch number.

49. The unique donation code assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells.

50. Where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words “for autologous use only”.

PART 5

Immediate packaging: blister packs and small packaging (advanced therapy medicinal products for sale or supply in Great Britain only)

51. The information specified in Part 2.

52. The unique donation code assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells.

53. Where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words "for autologous use only".**]**

SCHEDULE 25 Regulation 258

Packaging requirements: specific provisions

PART 1

Medicines on prescription

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.

3. The date on which the product is sold or supplied.

4. Unless paragraph 5, applies, such of the following particulars as the appropriate practitioner who prescribed the product may specify—

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

5. This paragraph applies if the pharmacist, in the exercise of professional skill and judgement, is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 4 is inappropriate.

6. Where paragraph 5 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 4, as the pharmacist thinks appropriate.

PART 2

Transport, delivery and storage

7. Any special requirements for the storage and handling of the product.

8. The expiry date of the product.

9. The manufacturer's batch number.

PART 3

Pharmacy and prescription only medicines

10. Paragraph 11 applies if a pharmacy medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b), or

(d) distributed by way of wholesale dealing.

11. Where this paragraph applies, the capital letter "P" within a rectangle within which there is to be no other matter of any kind.

12. Paragraph 13 applies if a prescription only medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b); or

(d) distributed by way of wholesale dealing.

13. Where this paragraph applies, the capital letters "POM" within a rectangle within which there is to be no other matter of any kind.

PART 4

Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the outer and immediate packaging, the words "Contains paracetamol".

15. If the product contains paracetamol the words "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", which must appear adjacent to either the directions for use or the recommended dosage.

16. If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Do not take anything else containing paracetamol while taking this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Do not give anything else containing paracetamol while giving this medicine" and—

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"; or

(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

18. If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position.

SCHEDULE 26

Regulations 3(13) and 4(5)

Packaging requirements: special provisions

PART 1

Supply by doctors, dentists, nurses and midwives

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.

3. The date on which the product is sold or supplied.

4. Such of the following particulars as the person under whose responsibility the product is sold or supplied considers appropriate—

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

PART 2

Pharmacy exceptions

5. Where the product is to be administered to a particular individual, the name of that individual.

6. The name and address of the person who sells or supplies the product.

7. The date on which the product is sold or supplied.

8. Where the product is prescribed by an appropriate practitioner, such of the following particulars as the appropriate practitioner who prescribed the product may specify, unless paragraph 9 applies —

(a) the name of the product or its common name;

(b) directions for use of the product; and

(c) precautions relating to the use of the product.

9. This paragraph applies if a pharmacist, in the exercise of professional skill and judgement, is of the opinion that the inclusion of one or more of the particulars specified in paragraph 8 by the appropriate practitioner who prescribed the product is inappropriate.

10. Where paragraph 9 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 8, as the pharmacist thinks appropriate.

11. Where the product is not prescribed by an appropriate practitioner, directions for use of the product, but these may be omitted in circumstances where section 10(3) of the Medicines Act 1968 applies.

SCHEDULE 27 Regulation 260

Package leaflets

PART 1

General requirements

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. The pharmaco-therapeutic group, or type of activity, of the product, in terms easily comprehensible for the patient.

6. The product's therapeutic indications.

7. A list of—

(a) contra-indications;

(b) appropriate precautions for use;

(c) interactions with other medicinal products which may affect the action of the product;

(d) interactions with other substances, including alcohol, tobacco and foodstuffs, which may affect the action of the product; and

(e) special warnings, if any, relating to the product.

8. The list mentioned in paragraph 7 must—

(a) take into account the special requirements of particular categories of users (including, in particular, children, pregnant or breastfeeding women, the elderly and persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery; and

(c) list any excipients—

(i) if knowledge of the excipients is important for the safe and effective use of the product, and

(ii) the excipients are included in the guidance published pursuant to **[**F1160published under regulation 257D in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive or under regulation 257D that is applicable to such products.**]**

Textual Amendments

F1160 Words in Sch. 27 para. 8(c)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

9. Instructions for proper use of the product including in particular—

(a) the dosage;

(b) the method and, if necessary, route of administration;

(c) the frequency of administration (including, if necessary, specifying times at which the product may or must be administered);

(d) the duration of treatment if this is to be limited;

(e) symptoms of an overdose and the action, if any, to be taken in case of an overdose;

(f) what to do if one or more doses have not been taken;

(g) an indication, if necessary, of the risk of withdrawal effects; and

(h) a specific recommendation to consult a doctor or pharmacist, as appropriate, for further explanation of the use of the product.

10. A description of the adverse reactions which may occur in normal use of the medicinal product and, if necessary, the action to be taken in such a case.

11. A reference to the expiry date printed on the packaging of the product with—

(a) a warning against using the product after that date;

(b) if appropriate, details of special storage precautions to be taken;

(c) if necessary, a warning concerning visible signs of deterioration;

(d) the full qualitative composition (in active substances and excipients), and the quantitative composition in active substances, using common names, of each presentation of the medicinal product;

(e) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;

(f) the name and address of the holder of the **[**F1161UK marketing authorisation, EU marketing authorisation**]**, Article 126a authorisation or traditional herbal registration relating to the product and, if applicable, the name of the holder's appointed representative; and

(g) the name and address of the manufacturer of the product.

Textual Amendments

F1161 Words in Sch. 27 para. 11(f) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **reg. 204(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

12. Where the product **[**F1162is authorised for sale or supply in Northern Ireland and**]** is authorised under different names in different member States in accordance with Articles 28 to 39 of the 2001 Directive, a list of the names authorised in each member State.

Textual Amendments

F1162 Words in Sch. 27 para. 12 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

13. For medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004**[**F1163in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation 202A, in the case of products for sale or supply in Great Britain,**]** the **[**F1164symbol and **]** statement: "**[**F1165▼**]** This medicinal product is subject to additional F1166... monitoring".

Textual Amendments

F1163 Words in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F1164 Words in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F1165 Symbol in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F1166 Word in Sch. 27 para. 13 omitted (E.W.S.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(2)** and word in Sch. 27 para. 13 omitted (N.I.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(2)**

[F1167**14.** A standardised text relating to adverse event reporting in accordance with the third sub-paragraph of Article 59(1) of the 2001 Directive.**]**

Textual Amendments

F1167 Sch. 27 para. 14 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(3)** and Sch. 27 para. 14 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(3)**

15. The date on which the package leaflet was last revised.

PART 2

Paracetamol

16. If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if your child takes too much of this

medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

[F1168 Part 3

Advanced therapy medicinal products for sale or supply in Great Britain only

Textual Amendments

F1168 Sch. 27 Pt. 3 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

18. The name of the advanced therapy medicinal product.

19. Where appropriate, whether the product is intended for babies, children or adults.

20. The common name of the advanced therapy medicinal product.

21. The therapeutic group, or type of activity, of the product, in terms easily comprehensible for the patient.

22. Where the product contains cells or tissues, a description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.

23. Where the product contains medical devices or active implantable medical devices, a description of those devices and their specific origin.

24. The product's therapeutic indications.

25. A list of information which is necessary before the medicinal product is taken or used, including—

(a) contra-indications;

(b) appropriate precautions for use;

(c) interactions with other medicinal products which may affect the action of the product;

(d) interactions with other substances, including alcohol, tobacco and foodstuffs which may affect the action of the product;

(e) special warnings; if any, relating to the product.

26. The list mentioned in paragraph 25 must—

(a) take into account the special requirements of particular categories of users (including, in particular, children, pregnant or breastfeeding women, the elderly and persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or operate machinery; and

(c) list any excipients—

(i) if knowledge of the excipients is important for the safe and effective use of the product; and

(ii) the excipients are included in the guidance published under regulation 257D.

27. Instructions for proper use of the product including in particular—

(a) the dosage;

(b) the method of use, application, administration or implantation and, if necessary, the route of administration;

(c) the frequency of administration (including, if necessary, specifying the times at which the product may or must be administered);

(d) the duration of treatment if this is to be time limited;

(e) symptoms of an overdose and the action, if any, to be taken in the case of an overdose;

(f) what to do if one or more doses have not been taken;

(g) a specific recommendation to consult a doctor or pharmacist, as appropriate, for further explanation of the use of the product.

28. A description of the adverse reactions which may occur in normal use of the medicinal product and, if necessary, the action to be taken in such a case.

29. A reference to the expiry date printed on the packaging of the product with—

(a) a warning against using the product after that date;

(b) if appropriate, details of special storage precautions to be taken;

(c) if necessary, a warning concerning visible signs of deterioration;

(d) the full qualitative and quantitative composition;

(e) the name and address of the UK marketing authorisation holder and, if applicable, the name of the holder's appointed representative; and

(f) the name and address of the manufacturer.

30. The date on which the package leaflet was last revised.**]**

SCHEDULE 28 Regulation 264

Labelling requirements for registrable homoeopathic medicinal products

PART 1

Outer and immediate packaging

1. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

2. The name and address of the holder of the certificate of registration and, if different, the manufacturer.

3. The method and, if necessary, route of administration.

4. The product's expiry date (month and year), in clear terms.

5. The product's pharmaceutical form.

6. The contents of the presentation, specified by weight, volume or number of doses.

7. Special storage precautions, if any.

8. A special warning, if necessary in relation to the product.

9. The manufacturer's batch number.

10. The number of the certificate of registration.

11. The words “homoeopathic medicinal product without therapeutic indications”.

12. A warning advising the user to consult a doctor if symptoms persist.

PART 2

Blister packs etc contained in outer packaging

13. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

14. The name and address of the holder of the certificate of registration.

15. The product's expiry date (month and year), in clear terms.

16. The manufacturer's batch number.

17. The words “homoeopathic medicinal product without therapeutic indications”.

PART 3

Small immediate packaging

18. The scientific name of the stock or stocks (which may be supplemented by an invented name if the product contains two or more stocks), and the degree of dilution, making use of the symbols

of the European Pharmacopoeia or, in the absence of an entry in the European Pharmacopoeia, of the British Pharmacopoeia.

19. The name and address of the holder of the certificate of registration.

20. The method and, if necessary, route of administration.

21. The product's expiry date (month and year), in clear terms.

22. The contents of the presentation, specified by weight, volume or number of doses.

23. The manufacturer's batch number.

24. The words “homoeopathic medicinal product without therapeutic indications”.

SCHEDULE 29 Regulation 265

Labelling of traditional herbal medicinal products

PART 1

Traditional herbal medicinal products: general

1. A statement to the effect that the product is a traditional herbal medicinal product, for use for specific purposes by reason of long-standing use.

2. A statement that the user should consult a doctor or other health care practitioner if symptoms persist during use of the medicinal product, or if adverse effects not mentioned on the package or package leaflet occur.

PART 2

Traditional herbal medicinal products not subject to general sale

3. Subject to the provisions of regulation 265(2), paragraph 4 applies where a traditional herbal medicinal product that is a pharmacy medicine is—

(a) sold by retail;

(b) supplied in circumstances corresponding to retail sale;

(c) in the possession of a person for the purpose of sale or supply as mentioned in paragraph (a) or (b); or

(d) distributed by way of wholesale dealing.

4. Where this paragraph applies, the outer packaging and the immediate packaging of the product must be labelled to show the capital letter “P” within a rectangle, within which there is to be no other matter of any kind.

SCHEDULE 30

Regulations 294, 295 and 297

Particulars for advertisements to persons qualified to prescribe or supply

1. The number of the **[**F1169UK marketing authorisation, EU marketing authorisation**]**, certificate of registration, traditional herbal registration or Article 126a authorisation for the medicinal product.

Textual Amendments

F1169 Words in Sch. 30 para. 1 substituted (31.12.2020) by S.I. 2019/775, **reg. 216(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 175**)

2. The name and address of the holder of **[**F1170the temporary authorisation or**]** the **[**F1171UK marketing authorisation, EU marketing authorisation**]**, certificate of registration, traditional herbal registration or Article 126a authorisation for the medicinal product or the business name and address of the part of the holder's business that is responsible for its sale or supply.

Textual Amendments

F1170 Words in Sch. 30 para. 2 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(2)** and words in Sch. 30 para. 2 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(2)**

F1171 Words in Sch. 30 para. 2 substituted (31.12.2020) by S.I. 2019/775, **reg. 216(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 175**)

[F1172**2A.** In relation to an advertisement in Great Britain (other than an advertisement falling within the exception in regulation 296) where the medicinal product concerned is authorised under a UKMA(GB), a statement that the product concerned is authorised under a UKMA(GB).**]**

Textual Amendments

F1172 Sch. 30 para. 2A inserted by S.I. 2019/775, regs. 1, **216(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 175**)

3. The classification of the medicinal product as—

(a) a product that is subject to general sale;

(b) a prescription only medicine; or

(c) a pharmacy medicine.

4. The name of the medicinal product.

5. A list of the active ingredients of the medicinal product that uses their common names and is placed immediately adjacent to the most prominent display of the name of the product.

6. One or more of the indications for the medicinal product consistent with the terms of the **[**F1173UK marketing authorisation, EU marketing authorisation**]**, certificate of registration, traditional herbal registration or Article 126a authorisation for the product **[**F1174or, in the case of a product in relation to which there is in force an authorisation by the licensing authority on a temporary basis

under regulation 174, the indications for the medicinal product consistent with the recommendation or requirement of the licensing authority as to the use of that product**]**.

Textual Amendments

F1173 Words in Sch. 30 para. 6 substituted (31.12.2020) by S.I. 2019/775, **reg. 216(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 175**)

F1174 Words in Sch. 30 para. 6 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(3)** and words in Sch. 30 para. 6 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(3)**

7. [F1175The entries or a**]** succinct statement of the entries (if any) in the summary of the product characteristics**[**F1176, or in any equivalent summary published by the holder of a temporary authorisation,**]** relating to—

(a) adverse reactions, precautions and relevant contra-indications;

(b) dosage and method of use so far as relevant to the indications shown in the advertisement, and

(c) where this is not obvious, method of administration so far as relevant to those indications.

Textual Amendments

F1175 Words in Sch. 30 para. 7 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **29** and words in Sch. 30 para. 7 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **29**

F1176 Words in Sch. 30 para. 7 inserted (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125), regs. 1(2), **33(4)** and words in Sch. 30 para. 7 inserted (N.I.) (6.11.2020) by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.R. 2020/349), regs. 1(2), **33(4)**

8. The cost excluding value added tax of—

(a) a specified package of the medicinal product; or

(b) a specified quantity or recommended daily dose of the medicinal product calculated by reference to a specified package of the medicinal product.

This paragraph does not apply to an advertisement inserted in a publication that is printed in the United Kingdom but that has a circulation outside the United Kingdom of more than 15 per cent of its total circulation.

9.—(1) The particulars specified in paragraph 7 must be printed in a clear and legible manner.

(2) Those particulars must be placed in such a position in the advertisement that their relationship to the claims and indications for the product can readily be appreciated by the reader.

SCHEDULE 31

Regulation 328(3)

Sampling

Modifications etc. (not altering text)

C11 Sch. 31 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Introductory

1.—(1) This Schedule has effect where a person authorised by an enforcement authority (in this Schedule referred to as a "sampling officer") obtains a sample of a substance or article—

(a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority ("the relevant enforcement authority") must or may enforce by virtue of regulations 323 and 324; or

(b) otherwise for a purpose connected with the performance of the relevant enforcement authority of its functions under these Regulations.

(2) This Schedule has effect whether the sample is obtained by purchase or in exercise of a power conferred by regulation 327.

(3) In this Schedule "medicines control laboratory" means a laboratory that is—

(a) designated by the licensing authority in accordance with Article 111(1) of the 2001 Directive for the purpose of the analysis of samples of one or more types of medicinal product; and

(b) is so designated in relation to a particular medicinal product that is submitted to it for analysis.

Division of sample

2. The sampling officer must as soon as practicable—

(a) divide the sample into three parts;

(b) mark each part;

(c) seal or fasten each part; and

(d) deal with the parts in accordance with paragraphs 3 to 10.

3. If the sample was purchased by the sampling officer otherwise than from a vending machine the officer must supply one part of the sample to the seller.

4. If the sampling officer obtained the sample from a vending machine—

(a) if a person's name and an address in the United Kingdom are stated on the machine as being the name and address of the owner of the machine, the sampling officer must supply one part of the sample to that person; and

(b) in any other case, the sampling officer must supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

5. If the sample is a sample of goods consigned from outside the United Kingdom, and was taken by the sampling officer before delivery to the consignee, the sampling officer must supply one part of the sample to the consignee.

6. If, in a case not falling within any of paragraphs 3 to 5 of this Schedule, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer must supply one part of the sample to the seller.

7. If, in a case not falling within any of paragraphs 3 to 6 of this Schedule, the sample was taken in transit, the sampling officer must supply one part of the sample to the consignor.

8. In any case not falling within any of paragraphs 3 to 7 of this Schedule, the sampling officer must supply one part of the sample to the person appearing to the sampling officer to be the owner of the substance or article from which the sample was taken.

9. In every case falling within any of paragraphs 3 to 8 of this Schedule, the sampling officer must inform the person to whom the part of the sample in question is supplied that the sample has been obtained for the purpose of analysis or other examination.

10. Unless the sampling officer decides not to submit the sample for analysis or other examination the sampling officer must—

(a) retain one of the two remaining parts for future comparison; and

(b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.

11. If a sample consists of substances or articles in unopened containers, the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them if it appears to the sampling officer that—

(a) it is not reasonably practicable to open the containers and divide the contents into parts; or

(b) opening the containers and dividing the contents into parts might affect the composition or impede the analysis or other examination of the contents.

12. Regulation 343(1)(a) to (d) has effect in relation to supplying a part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.

13. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample should be supplied, the sampling officer may retain that part of the sample.

Notice to person named on container

14.—(1) This paragraph applies where the sampling officer has obtained a sample of a substance or article and it appears to the sampling officer that—

(a) the substance or article was manufactured in the United Kingdom by a person ("M") whose name and address in the United Kingdom are stated on its container or packaging; and

(b) M is not a person to whom a part of the sample must be supplied under the preceding provisions of this Schedule.

(2) Unless the sampling officer decides not to submit the sample for analysis or other examination, the sampling officer must give notice to M—

(a) stating that the sample has been obtained; and

(b) specifying the person from whom the sampling officer purchased it or, if it was obtained otherwise than by purchase, the place from which the sampling officer obtained it.

(3) Notice under sub-paragraph (2) must be given to M within the period of three days beginning immediately after the day on which the sample was obtained.

Analysis or other examination

15. Where the enforcing authority that authorises the sampling officer is the Secretary of State or the Minister for Health, Social Services and Public Safety, if the sampling officer decides to submit the sample for analysis the officer must do so—

(a) to a medicines control laboratory; or

(b) to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

16. Where any other enforcing authority authorises the sampling officer, if the sampling officer decides to submit the sample for analysis the officer must do so to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

17.—(1) Arrangements of the kind mentioned in paragraphs 15(b) and 16 made by an enforcement authority in England, Wales or Scotland other than the Secretary of State must be approved by the Secretary of State.

(2) Arrangements of the kind mentioned in paragraph 15(b) made by a district council in Northern Ireland must be approved by the Minister for Health, Social Services and Public Safety.

18. A laboratory to which a sample is submitted under paragraph 15 or 16 must analyse or examine the sample as soon as practicable,

19. A laboratory that has analysed or examined a sample submitted under the preceding provisions of this Schedule must issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

20. A person to whom a part of the sample is to be supplied in accordance with paragraphs 2 to 8 is entitled, on payment of the required fee, to be given a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19.

Provisions as to evidence

21.—(1) In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document unless sub-paragraph (2) applies.

(2) A party to proceedings, other than the party who produced the document mentioned in paragraph (1), may require that the person who issued the certificate be called as a witness.

(3) In proceedings in Scotland, if the person who issued the certificate is called as a witness, that person's evidence is to be sufficient evidence of the facts stated in the certificate.

22. In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings which has been supplied by another party to the proceedings as a copy of a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document.

23.—(1) If, in proceedings before a magistrates' court for an offence under these Regulations, a defendant intends to produce a certificate issued under paragraph 19, or to require that the person by whom a certificate was issued be called as a witness, the defendant must give notice of that intention and (where a certificate is to be produced) a copy of the certificate to the other party at least three clear days before the day on which the summons is returnable.

(2) If sub-paragraph (1) is not complied with the court may adjourn the hearing on such terms as it thinks fit.

(3) In Scotland, if in proceedings in the sheriff court for an offence under these Regulations the accused intends to produce a certificate under paragraph 19, or to require that the person by whom a certificate was issued be called as a witness, the accused must give notice of that intention and

(where a certificate is to be produced) a copy of the certificate to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.

(4) If sub-paragraph (3) is not complied with the sheriff may adjourn the diet on such terms as the sheriff thinks fit.

Analysis under direction of court

24.—(1) This paragraph applies where proceedings for an offence under these Regulations relate to a substance or article of which a sample has been taken as mentioned in paragraph 1 of this Schedule.

(2) Where this paragraph applies, the part of the sample retained in pursuance of paragraph 10(a) is to be produced as evidence.

(3) The court must, if requested by a party to the proceedings, and may, in the absence of such a request, cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, to the Government Chemist in Northern Ireland) or to be sent for other examination to a laboratory specified by the court.

(4) If, in a case where an appeal is brought, no action has been taken under sub-paragraph (3), that sub-paragraph applies to the court by which the appeal is heard.

(5) A person or laboratory to whom or to which a part of a sample is sent under this paragraph for analysis or other examination must—

(a) analyse or examine it; and

(b) issue and give to the court a certificate specifying the results of the analysis or examination.

(6) A certificate under sub-paragraph (5)(b) is to be evidence (and, in Scotland, is to be sufficient evidence) of the facts stated in the certificate unless a party to the proceedings requires that the person by whom it was issued be called as a witness.

(7) In Scotland, if the person by whom a certificate is issued is called as a witness that person's evidence is sufficient evidence of the facts stated in the certificate.

25. The costs of analysis or examination under paragraph 24 are to be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

Proof by written statement

26.—(1) In relation to England and Wales section 9 of the Criminal Justice Act 1967 [M107] does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

(2) In relation to Northern Ireland any enactment corresponding to section 9 of the Criminal Justice Act 1967 does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

Marginal Citations
M107 1967 c.80.

Payment for sample taken under compulsory powers

27.—(1) Where a sampling officer takes a sample in the exercise of a power conferred by regulation 327, the officer must, if payment is required, pay the value of the sample to the person to whom a part of the sample is required to be supplied under paragraph 5, 7 or 8 (as the case may be) of this Schedule.

(2) If the sampling officer and the person mentioned in sub-paragraph (1) are unable to agree, the value of the sample is to be determined—

(a) by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question; or

(b) if they are unable to agree on an arbitrator, by the county court for the district (or in Northern Ireland the division) in which the sample was taken.

(3) In the application of this paragraph to Scotland for references to the county court there is to be substituted a reference to the sheriff.

SCHEDULE 32

Regulation 347

Transitional provisions and savings

Continuity of the law

1.—(1) This paragraph applies where any provision of these Regulations re-enacts (with or without modification) an enactment or instrument repealed or revoked by these Regulations.

(2) The repeal and re-enactment do not affect the continuity of the law.

(3) Anything done, or having effect as if done, under or for the purposes of the repealed provision that could have been done under or for the purposes of the corresponding provision of these Regulations, if in force or effective immediately before the commencement of that corresponding provision, has effect thereafter as if done under or for the purposes of that corresponding provision.

(4) Any reference (express or implied) in these Regulations or any other enactment, instrument or document to a provision of these Regulations is to be construed (so far as the context permits) as including, as respects times, circumstances or purposes in relation to which the corresponding repealed provision had effect, a reference to that corresponding provision.

(5) Any reference (express or implied) in any enactment, instrument or document to a repealed provision is to be construed (so far as the context permits), as respects times, circumstances and purposes in relation to which the corresponding provision of these Regulations has effect, as being or (according to the context) including a reference to the corresponding provision of these Regulations.

(6) This paragraph has effect subject to any specific transitional provision or saving in this Schedule.

Product licences

2.—(1) This paragraph applies to a marketing authorisation that—

(a) became a marketing authorisation on 1st January 1995 by virtue of paragraph 1 of Schedule 6 [M108] to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (conversion of existing product licences); and

(b) by virtue of paragraph 1 of this Schedule, has effect from the coming into force of these Regulations as a marketing authorisation granted under these Regulations.

(2) The following provisions do not apply in relation to the marketing authorisation—

(a) regulation 68(7) (revocation etc of marketing authorisation because the holder has ceased to be established in the EU); and

(b) regulation 258 (packaging requirements: specific provisions).

(3) Paragraph (4) applies if the marketing authorisation has not been renewed in the period beginning with 1st January 1995 and ending when these Regulations come into force.

(4) The Medicines (Labelling) Regulations 1976 [M109] and the Medicines (Leaflets) Regulations 1977 [M110] (and subsequent regulations amending those regulations) in so far as they relate to medicinal products continue to have effect in relation to the product to which the marketing authorisation relates until the marketing authorisation is renewed.

Marginal Citations

M108 S.I. 1994/3144, as amended by S.I. 2004/3224 and S.I. 2005/2759. There are other amendments to those regulations that are not relevant to this paragraph..

M109 S.I. 1976/1726, as amended by S.I. 1977/996 and 2168, S.I. 1978/41 and 1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558 and 2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104 and 3144, S.I. 2002/236, S.I. 2004/1031 and S.I. 2005/2745 and 2753.

M110 S.I. 1977/1055, as amended by S.I. 1992/3274, 1994/104 and 3144, and 2005/2753..

Product licences of right

3.—(1) This paragraph applies to a product licence of right.

(2) In this paragraph, "product licence of right" means a licence of right within the meaning of section 25(4) of the Medicines Act 1968 that—

(a) has been issued in relation to the requirements to hold a product licence contained in section 7(2) of that Act; and

(b) is in force immediately before the coming into force of these Regulations.

(3) A product licence of right shall continue in force, subject to the following sub-paragraphs.

(4) Parts 4 to 11, 13 and 14 of these Regulations shall not apply in relation to a medicinal product that is the subject of a product licence of right, except as provided in the following sub-paragraphs.

(5) A medicinal product to which a product licence of right relates shall—

(a) continue to be classified as a prescription only medicine, a medicinal product not subject to general sale, or a medicinal product subject to general sale, as the case may be, in accordance with the provisions of the Medicines Act 1968 and any statutory instrument made under that Act that was in force immediately before the coming into force of these regulations; and

(b) shall be treated as a prescription only medicine, a pharmacy medicine not subject to general sale, or a medicine subject to general sale respectively, as the case may be, for the purposes of Part 12 of these Regulations.

(6) The provisions listed in sub-paragraph (7), and any provisions to which they refer, shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to a product licence of right and to the product to which it relates.

(7) Those provisions are—

(a) section 28(1), (2) and (3)(a) to (e) and (g) to (j) (general power to suspend, revoke or vary licences) of the Medicines Act 1968 [M111];

(b) the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975 [M112];

(c) the Medicines (Labelling) Regulations 1976 [M113];

(d) the Medicines (Leaflets) Regulations 1977 [M114]; and

(e) the Medicines (Labelling and Advertising to the Public) Regulations 1978 [M115].

(8) Part 1 of Schedule 11 (advice and representations) shall have effect where the licensing authority proposes to exercise any power conferred by section 28 of the Medicines Act referred

to in sub-paragraph 7(a) in relation to a product licence of right, as if that proposal concerned the suspension, revocation or variation of a UK marketing authorisation, certificate of registration or traditional herbal registration under these Regulations.

(9) Without prejudice to any requirement of Part 1 of Schedule 11 as to the service of notices, where in the exercise of any such power the licensing authority suspends, revokes or varies a product licence of right, it must serve a notice on the holder a notice giving particulars of the suspension, revocation or variation and of the reasons for its decision to suspend, vary or revoke the product licence of right.

(10) Regulations **[**F1177268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**]** and 271 (offences: penalties) shall have effect in relation to the provisions in sub-paragraph (7)(d) as if—

(a) references to the holder of a marketing authorisation included reference to the holder of a product licence of right; and

(b) the provisions in sub-paragraph (7)(d) were requirements of Part 13.

(11) A product licence of right shall cease to be in force at the same time that a marketing authorisation, certificate of registration or traditional herbal registration is granted in respect of the product to which the product licence of right relates.

Textual Amendments

F1177 Words in Sch. 32 para. 3(10) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZD** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

Marginal Citations

M111 Section 28(3) was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (1984 c.40), regulation 4(5) of S.I. 1977/1050, regulation 2(2) of S.I. 1975/1169, regulation 6(2) of S.I. 1994/276, regulation 2(a)(iii) of S.I. 2002/236 and paragraph 14 of Schedule 8 to S.I. 2006/2407.

M112 S.I. 1975/1326, as amended by S.I. 1979/1760 and S.I. 1994/1932.

M113 S.I. 1976/1726, as amended by S.I. 1977/996, S.I. 1977/2168, S.I. 1978/41, S.I. 1978/1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558, S.I. 1985/2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104S.I. 1994/3144, S.I. 2002/236, S.I. 2004/1031, S.I. 2005/2745 and S.I. 2005/2753.

M114 S.I. 1977/1055, as amended by S.I. 1992/3274, S.I. 1994/104, S.I. 1994/3144, and S.I. 2005/2753.

M115 S.I. 1978/41, as amended by S.I. 2004/1771.

Classification of UK marketing authorisation and certificate of registration

4.—(1) Sub-paragraph (3) applies to a UK marketing authorisation granted before 1st April 2002 if—

(a) the authorisation contains a statement that the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2); or

(b) the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2) by virtue of any enactment in force immediately before the coming into force of these Regulations.

(2) Those bases are that the product is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(3) It is a condition of the UK marketing authorisation that the product is only to be available on that basis or those bases.

Advanced therapy medicinal products

5. No provision of these Regulations that applies only to advanced therapy medicinal products shall apply until 30th December 2012 to advanced therapy medicinal products which—

(a) are tissue engineered products; and

(b) were legally on the market in the United Kingdom in accordance with United Kingdom or European Union legislation on 30th December 2008.

*Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (*S.I. 2010/1882*)*

6. Regulation 9 (amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004) of the Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 [M116] remains in force.

Marginal Citations

M116 S.I. 2010/1882.

Section 60 of the Medicines Act 1968 etc

7.—(1) Section 60 of the Medicines Act 1968 ("the Act") shall continue to have effect insofar as it relates to the making of, and continued operation of, the Medicines (Administration of Radioactive Substances) Regulations 1978 [M117] ("the 1978 Regulations").

(2) The following provisions of the Act shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to the following provisions of the 1978 Regulations—

(a) section 22A(2) to (9) and 10(b) (hearing before person appointed) of the Act, in relation to regulation 7 (hearings and written representations) of the 1978 Regulations;

(b) section 67(2) and (4) (offences under Part III) of the Act, as they relate to section 60 of the Act, in relation to regulation 8 (application of provisions of the Act) of the 1978 Regulations; and

(c) paragraphs 7, 8, 9(3) and 10 to 12 of Schedule 1A (provisions relating to Commission and committees) to the Act [M118], in relation to the committee established under regulation 3 (advisory committee) of the 1978 Regulations.

Marginal Citations

M117 S.I. 1978/1006, as amended by S.I. 1995/2147, S.I. 2005/2754. S.I. 2006/2407 and S.I. 2006/2806.

M118 1968 c.67. Schedule 1A was inserted by regulation 7(2) of S.I. 2005/1094.

SCHEDULE 33

Regulation 212

Transitional arrangements: pharmacovigilance

Pharmacovigilance system master file

F1178**1.** . . . . . .

Textual Amendments

F1178 Sch. 33 para. 1 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178**; 2020 c. 1, Sch. 5 para. 1(1)

F1179**2.** . . . . . .

Textual Amendments

F1179 Sch. 33 para. 2 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178**; 2020 c. 1, Sch. 5 para. 1(1)

Post-authorisation safety studies

3. Regulations 198, 199, 200, 201 and 202 (provisions relating to post authorisation safety studies) do not apply to post authorisation safety studies commenced before 21st July 2012.

4. Regulation 210(3)(g) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) does not apply to post authorisation safety studies commenced before 21stJuly 2012.

Reporting obligations

F1180**5.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

F1180**6.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

F1180**7.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

F1180**8.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

Periodic safety update reports

F1180**9.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

F1180**10.** . . . . . .

Textual Amendments

F1180 Sch. 33 paras. 5-10 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **178** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 140); 2020 c. 1, Sch. 5 para. 1(1)

[F1181SCHEDULE 33A

Regulation 347A

Transitional provision in relation to EU Exit

Textual Amendments

F1181 Sch. 33A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 7** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 193**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 1

Interpretation

1. In this Schedule—

"the COMP" means the Committee for Orphan Medicinal Products of the EMA, established under Article 4 of the Orphan Regulation;

"converted EU marketing authorisation" has the meaning given in paragraph 6(1) and (2);

"the Paediatric Regulation" means Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, as it has effect in EU law;

"the Paediatric Committee" means the committee of the EMA established under Article 3 of the Paediatric Regulation;

"the Pharmacovigilance Risk Assessment Committee" means the Committee of the EMA established by Article 56(1)(aa) of Regulation (EC) No 726/2004; and

"Regulation (EC) No 507/2006" means Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council, as it has effect in EU law.

PART 2

Manufacturing, wholesale dealing and brokering

Wholesale dealer's licence used to distribute a medicinal product imported from an EEA State before IP completion day

2.—(1) Subject to sub-paragraphs (2) and (3), a person ("P") who is the holder of a wholesale dealer's licence which—

(a) was granted before IP completion day by the licensing authority;

(b) was in force immediately before IP completion day and remains in force on IP completion day (whether or not it is suspended); and

(c) was used by P to distribute a medicinal product, which was imported from an EEA State, by way of wholesale dealing, or to possess a medicinal product imported from an EEA State for such a purpose,

is deemed on and after IP completion day to hold a wholesale dealing licence granted under Part 3 (manufacture and distribution of medicinal products and active substances) that permits the operation of importing medicinal products from an approved country for import for the purposes specified in paragraph (c).

(2) After the end of the period of 6 months beginning with IP completion day, P is deemed to continue hold a wholesale dealer's licence that permits the operation of importing medicinal products from an approved country for import by virtue of sub-paragraph (1) only if, before the end of that period, P has notified the licensing authority in writing of—

(a) P's intention to continue to import medicinal products from an approved country for import; and

(b) either—

(i) P's intention to appoint a responsible person (import) who will carry out the functions under regulation 45AA(4) (requirement as to responsible persons where licence holder imports from an approved country for import) in respect of the licence, or

(ii) that P will only import medicinal products from an approved country for import to which an exemption in regulation 45AA(2) applies.

(3) Unless P has notified the licensing authority as provided for in sub-paragraph (2)(b)(ii), after the end of the period of 2 years beginning with IP completion day, P is deemed to continue to hold a wholesale dealer's licence that permits the operation of importing medicinal products from an approved country for import by virtue of sub-paragraph (1) only if, before the end of that period, P has notified the licensing authority in writing of the name, address and qualifications of a person who—

(a) is included in the register under regulation 45AB(1); and

(b) will carry out the functions under regulation 45AA(4) in respect of the licence.

(4) From IP completion day, until the date on which P notifies the licensing authority of the information specified in sub-paragraph (3), the responsible person in respect of that licence under regulation 45 must carry out the functions under regulation 45AA(4).

(5) As soon as reasonably practicable after receipt of the information specified in paragraph (3), the licensing authority must provide P with written notice that the responsible person (import) is named on the licence.

(6) Where P has notified the licensing authority as provided for in sub-paragraph (2)(b)(ii), the licensing authority must, as soon as reasonably practicable, notify P in writing that the wholesale dealer's licence includes import of a medicinal product from an approved country for import limited to medicinal products to which an exemption in regulation 45AA(2) applies.

Approved country for import list on IP completion day (regulation 18A)

3.—(1) For the purposes of regulation 18A(1) (approved country for import), during the transitional period, the licensing authority must publish an approved country for import list that includes each EEA State in it.

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 18A(3) to remove an EEA State from the approved country for import list.

(3) In this paragraph, "the transitional period" is the period of two years beginning with IP completion day.

Qualified persons and approved country for batch testing list on IP completion day (Schedule 7)

4.—(1) Sub-paragraph (2) applies to a person who—

(a) is acting as a qualified person immediately before IP completion day; and

(b) satisfies the requirements of Part 1 of Schedule 7 (qualification requirements for qualified persons) immediately before IP completion day as they had effect at that time.

(2) The person is to be treated on and after IP completion day as continuing to satisfy the requirements of Part 1 of Schedule 7 if the person would otherwise fail to do so as a result of amendments made to that Part by the EU Exit Regulations.

(3) For the purposes of paragraph 14(1)(b) of Schedule 7 (obligations of qualified person), for the transitional period, the licensing authority is deemed to have made appropriate arrangements with—

(a) each EEA State;

(b) Australia;

(c) Canada;

(d) Israel;

(e) Japan;

(f) New Zealand;

(g) Switzerland; and

(h) the United States of America,

and the licensing authority must, on IP completion day, publish a list that includes those countries under paragraph 14(3) of Schedule 7.

(4) The licensing authority may, in respect of any country specified in sub-paragraph (3)(b) to (h), include that country in the list subject to a condition or restriction as provided for in paragraph 14(4) of Schedule 7, insofar as that condition or restriction was reflected in the appropriate arrangements that existed immediately before IP completion day under Article 51(2) of the 2001 Directive.

(5) The licensing authority must not, before the end of the transitional period, exercise its powers under paragraph 14(6) of Schedule 7 to remove an EEA State from the list it publishes.

(6) In this regulation, "the transitional period" is the period of two years beginning with IP completion day.

List of countries with equivalent regulatory standards as to the manufacturing of active substances on IP completion day (regulation 45O(6) to (9))

5.—(1) For the purposes of regulation 45O(6) (requirements for registration as an importer, manufacturer or distributor of active substances), for the transitional period, the licensing authority must publish a list that includes the following countries—

(a) each EEA State;

(b) Australia;

(c) Brazil;

(d) Israel;

(e) Japan;

(ea) Republic of Korea;

(f) Switzerland; and

(g) the United States of America.

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 45O(9) to remove an EEA State from the list it publishes.

(3) In this paragraph, "the transitional period" is the period of two years beginning with IP completion day.

PART 3

Transitional provision in respect of conversion of EU marketing authorisations in force immediately before IP completion day

Conversion of EU marketing authorisations in force before IP completion day

6.—(1) This paragraph applies in relation to an EU marketing authorisation which was in force immediately before IP completion day.

(2) An EU marketing authorisation to which this paragraph applies—

(a) insofar as it authorises sale or supply of a medicinal product in Great Britain, has effect on and after IP completion day as a UKMA(GB) granted under regulation 49(1) of these Regulations (but, insofar as it authorises sale or supply of a medicinal product in Northern Ireland, continues to operate in Northern Ireland as an EU marketing authorisation); and

(b) is referred to in this Part as a "converted EU marketing authorisation".

(3) If the holder of an EU marketing authorisation to which this paragraph applies notifies the licensing authority in writing before the end of the period of 21 days beginning with IP completion day that it does not wish to be the holder of a converted EU marketing authorisation, the licensing authority must revoke the converted EU marketing authorisation with effect from the date of receipt of the notification.

(4) A converted EU marketing authorisation—

(a) is treated as if it had been granted by the licensing authority under regulation 49(1) on the same terms as those on which the EU marketing authorisation was granted, including any conditions or restrictions subject to which the EU marketing authorisation was granted and which remain in force immediately before IP completion day;

(b) is treated, for the purposes of regulations 65 or 65B (validity of UK marketing authorisation), as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(c) is treated for the purposes of regulation 67(1) (failure to place on the market) as if it had been granted on IP completion day, and the period of three years referred to in regulation 67(2) is treated as having started on IP completion day;

(d) is treated for the purposes of determining the relevant fee period for the purposes of Schedule 4 to the Fees Regulations (periodic fees for marketing authorisations) as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(e) is treated, for the purposes of the reference to the date of grant in regulation 27A(a) of the Fees Regulations (fees for renewals of a marketing authorisation) as if it had been granted on the date that the EU marketing authorisation took effect;

(f) retains, for the purposes of regulation 51A(1) and (6), the benefit of any remaining periods of data or marketing exclusivity (if any) from which the holder benefitted immediately before IP completion day;

(g) retains the benefit of any decision by the EMA to exempt the holder from Articles 14(4) or (5) of Regulation (EC) No 726/2004 (failure to place on the market), and that decision is treated as if it had been made by the licensing authority under regulation 67(3); and

(h) remains subject to—

(i) any suspension of the EU marketing authorisation that is in force immediately before IP completion day,

(ii) any post-authorisation obligations imposed after it was granted, and which remain in force immediately before IP completion day, and

(iii) any variation to its terms which were granted or accepted before IP completion day.

(5) For the purposes of this paragraph, an EU marketing authorisation is in force, even if that authorisation is suspended immediately before IP completion day.

(6) A converted EU marketing authorisation to which this paragraph applies which—

(a) was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006; and

(b) remains such a conditional marketing authorisation immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58F.

(7) A converted EU marketing authorisation to which this paragraph applies which relates to a medicinal product which—

(a) was designated as an orphan medicinal product by the European Commission pursuant to Article 5 of the Orphan Regulation; and

(b) remains in the Community register of Orphan Medicinal Products as referred to in that Article immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58C and retains, for the purposes of regulation 58D, the benefit of any period of marketing exclusivity from which the holder benefitted immediately before IP completion day under Article 8 of the Orphan Regulation.

Classification of converted EU marketing authorisations

7. For the purposes of regulation 62 (classification of UK marketing authorisation), it is a term of a converted EU marketing authorisation that the product to which the authorisation relates is to be available—

(a) in a case where the product was classified in its EU marketing authorisation immediately before IP completion day as a prescription only medicine, the product is to be available only on prescription;

(b) in a case where the product was not so classified and the licensing authority has determined that the product should be available on general sale, the product is to be available on general sale; or

(c) in any other case, the product is to be available only from a pharmacy.

Obligations of licensing authority in connection with converted EU marketing authorisations

8.—(1) The licensing authority must, before the end of the period of 7 days beginning with IP completion day, notify the holders of converted EU marketing authorisations—

(a) that the EU marketing authorisation is converted to a UK marketing authorisation; and

(b) that the holder may notify the licensing authority in accordance with paragraph 6(3) that it does not wish to be the holder of a UK marketing authorisation.

(2) The licensing authority must, as soon as reasonably practicable after the end of the period referred to in paragraph 6(3), publish a list of converted EU marketing authorisations.

(3) The list mentioned in sub-paragraph (2) must specify which converted EU marketing authorisations have been revoked in accordance with paragraph 6(3).

Obligations of holders of converted EU marketing authorisations

9.—(1) A holder of a converted EU marketing authorisation must submit to the licensing authority, before the end of the period of one year beginning with IP completion day, the information described in sub-paragraph (3).

(2) The obligation in sub-paragraph (1) is subject to any requirement imposed by the licensing authority to provide that information before the end of a shorter period specified by the licensing authority under paragraph 10(1).

(3) The information which must be submitted in accordance with sub-paragraph (1) (referred to in this paragraph as the "baseline data") is—

(a) such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing for this purpose and published by the licensing authority on or before IP completion day;

(b) notification of whether or not the product to which the converted EU marketing authorisation relates—

(i) is on the market in the United Kingdom at the time the notification is given, or

(ii) if not, whether the product has been on the market in the United Kingdom at any time on or after IP completion day and if so, the date on which it was withdrawn from the United Kingdom market.

(4) In this Part, the date on which the holder of a converted EU marketing authorisation complies with the obligation in sub-paragraph (1), or with any requirement imposed by the licensing authority under paragraph 10(1) to provide all of the baseline data before the end of a period shorter than the period of one year beginning with IP completion day, is referred to as "the data submission date".

Powers of licensing authority in connection with provision of information

10.—(1) If the licensing authority requests a holder of a converted EU marketing authorisation to submit all or part of the baseline data at any time before the expiry of the period of one year beginning with IP completion day, the holder must supply the information within the time period specified by the licensing authority in its request.

(2) If the licensing authority requests a holder of a converted EU marketing authorisation to provide any other information relating to the EU marketing authorisation, the holder must supply the information within the time period specified by the licensing authority in its request.

Variations of converted EU marketing authorisations notified or applied for before IP completion day

11.—(1) This paragraph applies where, before IP completion day—

(a) a holder of a converted EU marketing authorisation has notified the EMA of, or made an application to the EMA for, a variation of the EU marketing authorisation to which the converted EU marketing authorisation applies under Chapter III of Regulation (EC) No 1234/2008, or has made an application to the EMA for an extension of that EU marketing authorisation in accordance with Article 19 of that Regulation;

(b) the procedures specified in Article 17 of that Regulation (measures to close the procedures of Articles 14 to 16) have not concluded, or, in the case of an extension, no final decision has been made by the European Commission in relation to the application; and

(c) the holder of the converted EU marketing authorisation wishes the variation to be made to the converted EU marketing authorisation.

(2) Where the variation is a minor variation of Type IA—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13), include in the baseline data—

(i) a summary of the variation, and

(ii) if the notification has been rejected by the EMA, an indication of that fact; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing before the end of the period of 30

days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(3) Where the variation is a minor variation of Type IB—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) if the variation has not been rejected by the EMA, the holder of the converted EU marketing authorisation must (subject to paragraph 13) include a copy of the notification in the baseline data; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing before the end of the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(4) Sub-paragraph (5) applies where—

(a) the variation is a major variation of Type II or an extension; and

(b) before IP completion day the Committee for Medicinal Products for Human Use gave a positive final opinion in relation to the application with which the United Kingdom concurred.

(5) Where this sub-paragraph applies—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13) include a copy of the application in the baseline data; and

(c) the licensing authority must either—

(i) treat the variation as accepted, and, if the variation affects the terms of the converted EU marketing authorisation, amend those terms accordingly; or

(ii) notify the holder of the converted EU marketing authorisation before the end of the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(6) Sub-paragraph (7) applies where—

(a) the variation is a major variation of Type II or an extension; and

(b) before IP completion day the Committee for Medicinal Products for Human Use had not given any opinion in relation to the application, or had given a negative final opinion in relation to it, or had given a positive final opinion but the United Kingdom recorded a divergent opinion.

(7) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must submit to the licensing authority—

(i) the application for the variation; and

(ii) (subject to paragraph 13) the baseline data; and

(b) the licensing authority must consider the application in accordance with Schedule 10A.

(8) In this paragraph and paragraph 12, "minor variation of Type IA", "minor variation of Type IB", "major variation of Type II" and "extension" have the meanings given in paragraph 1 of Schedule 10A.

Variations of converted EU marketing authorisations submitted to EMA after IP completion day but before the data submission date

12.—(1) This paragraph applies where a holder of a converted EU marketing authorisation—

(a) notifies the EMA of, or applies to the EMA for, a variation of the EU marketing authorisation to which the converted EU marketing authorisation relates during the period beginning with IP completion day and ending on the day before the data submission date; and

(b) wishes the variation to be made in relation to the converted EU marketing authorisation.

(2) Where the variation is a minor variation of Type IA—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at the same time as it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13), include in the baseline data—

(i) a summary of the variation, and

(ii) if the notification has been rejected by the EMA, an indication of that fact; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(3) Where the variation is a minor variation of Type IB, a major variation of Type II or an extension which has not been rejected by the EMA—

(a) the holder of the converted EU marketing authorisation must submit to the licensing authority—

(i) the notification of, or application for, the variation, and

(ii) (subject to paragraph 13) the baseline data; and

(b) the licensing authority must consider the application in accordance with Schedule 10A.

Variations of converted EU marketing authorisations sought in advance of the data submission date

13.—(1) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a notification of, or an application for, a variation to the authorisation before the data submission date, the holder must—

(a) submit the notification or application to the licensing authority; and

(b) unless sub-paragraph (2) applies, provide to the licensing authority at the same time such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a notification of, or an application for, a variation to the authorisation before the data submission date but does not provide the information described in sub-paragraph (1)(b) with

the notification or application, the licensing authority may agree to consider the notification or application if it is satisfied that—

(a) the variation may be necessary on urgent safety grounds;

(b) the variation may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the variation in advance of the submission of the information described in sub-paragraph (1).

(3) Where the licensing authority considers a notification of, or an application for, a variation in advance of the data submission date in accordance with this paragraph, the references in paragraphs 11(2)(c), (3)(c) and (5)(c)(ii) and 12(2)(c) to the data submission date are to be read as references to the date on which—

(a) the notification of, or the application for, the variation is submitted to the licensing authority in accordance with sub-paragraph (1); or

(b) the licensing authority notifies the holder that it will consider the notification or application, in accordance with sub-paragraph (2), without the information referred to in sub-paragraph (2)(b).

Applications for renewals of converted EU marketing authorisations made before IP completion day

14.—(1) This paragraph applies where a holder of a converted EU marketing authorisation has, before IP completion day, made an application to the EMA for renewal of the EU marketing authorisation in accordance with Article 14 of Regulation (EC) No 726/2004 but no final decision has been made in relation to that application by the European Commission before IP completion day.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the application for renewal to the licensing authority with the baseline data; and

(b) the licensing authority must—

(i) where before IP completion day the Committee for Medicinal Products for Human Use has given a positive final opinion in relation to the application with which the United Kingdom concurred, treat the renewal application as accepted for the purposes of regulation 66 (application for renewal of authorisation), or

(ii) where before IP completion day the Committee for Medicinal Products for Human Use has not given any opinion or has given a negative final opinion in relation to the application, or where a positive final opinion has been given but the United Kingdom recorded a divergent opinion, treat the application as an application made in relation to the converted EU marketing authorisation under regulation 66 and consider the application in accordance with that regulation.

Applications for renewals of conditional marketing authorisations made before IP completion day

15.—(1) This paragraph applies where before IP completion day—

(a) a holder of a converted EU marketing authorisation which was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006 has made an application to the EMA for renewal of the authorisation in accordance with Article 6 of that Regulation; but

(b) no final decision has been made in relation to that application by the European Commission.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the application for renewal to the licensing authority with the baseline data; and

(b) the licensing authority must—

(i) where before IP completion day the Committee for Medicinal Products for Human use has given a positive final opinion in relation to the application with which the United Kingdom concurred, treat the renewal application as accepted for the purposes of regulation 66B, or

(ii) where before IP completion day the Committee for Medicinal Products for Human Use has not given any opinion or has given a negative final opinion in relation to the application, or where a positive final opinion has been given but the United Kingdom recorded a divergent opinion, treat the application as an application made in relation to the converted EU marketing authorisation under regulation 66B (renewal of conditional marketing authorisation) and consider the application in accordance with that regulation.

Applications for renewals of converted EU marketing authorisations made after IP completion day

16.—(1) This paragraph applies where a holder of a converted EU marketing authorisation is due to make an application for renewal of the authorisation in accordance with regulation 66 (application for renewal of authorisation) during the period of one year beginning with IP completion day.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the baseline data so that it is received by the licensing authority at the same time as the application for renewal is made;

(b) the licensing authority must consider the renewal application in accordance with regulation 66; and

(c) the converted EU marketing authorisation remains in force until the licensing authority notifies the holder of its decision on the renewal application.

Applications for renewals of conditional marketing authorisations made after IP completion day

17.—(1) This paragraph applies where the holder of a converted EU marketing authorisation which was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006 is due to make an application for renewal of the authorisation in accordance with regulation 66B during the period beginning with IP completion day and ending on the data submission date.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the baseline data so that it is received by the licensing authority at the same time as the application for renewal is made;

(b) the licensing authority must consider the renewal application in accordance with regulation 66B (renewal of conditional marketing authorisation); and

(c) the authorisation remains in force until the licensing authority notifies the holder of its decision on the renewal application.

Renewals of converted EU marketing authorisations sought in advance of the data submission date

18.—(1) If a holder of a converted EU marketing authorisation submits an application for renewal in accordance with regulation 66 or 66B before the data submission date, it must, unless sub-paragraph (2) applies, provide to the licensing authority with the application such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a renewal application before the data submission date but does not provide the information described in sub-paragraph (1) with the application, the licensing authority may agree to consider the application if it is satisfied that—

(a) the renewal may be necessary on urgent safety grounds;

(b) the renewal may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the renewal in advance of the data submission date.

Article 61(3) notifications made before IP completion day in relation to converted EU marketing authorisations

19.—(1) This paragraph applies where, before IP completion day—

(a) a holder of a converted EU marketing authorisation has, in accordance with Article 61(3) of the 2001 Directive, notified the EMA of a proposed change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates; but

(b) the period of 90 days referred to in Article 61(3) has not elapsed and the EMA has not objected to the proposed change.

(2) Where this paragraph applies, and where the holder wishes the proposed change to apply in relation to the converted EU marketing authorisation—

(a) the holder may put the change into effect in relation to the converted EU marketing authorisation at the same time as it may be put into effect in relation to the EU marketing authorisation;

(b) the holder must (subject to paragraph 21) include with the baseline data—

(i) a copy of the notification, and

(ii) an indication of whether the EMA has opposed the proposed change; and

(c) the proposed change to the labelling or the package leaflet of the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the proposed change is opposed, in which case the holder must cease to apply the opposed change immediately after receipt of the notification.

Article 61(3) notifications made in relation to converted EU marketing authorisations after IP completion day but before the data submission date

20.—(1) This paragraph applies where, during the period beginning with IP completion day and ending on the day before the data submission date, a holder of a converted EU marketing authorisation notifies the EMA in accordance with Article 61(3) of the 2001 Directive of a proposed

change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates.

(2) Where this paragraph applies, and where the holder wishes the proposed change to apply in relation to the converted EU marketing authorisation—

(a) the holder of the converted EU marketing authorisation may put the change into effect at the same time as it may be put into effect in relation to the EU marketing authorisation;

(b) the holder must (subject to paragraph 21) include with the baseline data—

(i) a copy of the notification, and

(ii) an indication of whether the EMA has opposed the proposed change; and

(c) the proposed change to the labelling or the package leaflet of the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the proposed change is opposed, in which case the holder must cease to apply the opposed change immediately after receipt of the notification.

Article 61(3) notifications sought in advance of the data submission date

21.—(1) If a holder of a converted EU marketing authorisation wishes to notify the licensing authority of a proposed change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates in advance of the data submission date, the holder must—

(a) submit the notification of the proposed change to the licensing authority; and

(b) unless sub-paragraph (2) applies, at the same time provide the licensing authority with such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a proposed change before the data submission date but does not provide the information described in sub-paragraph (1)(b) with the notification, the licensing authority may agree to consider the notification if it is satisfied that—

(a) the proposed change may be necessary on urgent safety grounds;

(b) the proposed change may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the proposed change in advance of the data submission date.

(3) Where the licensing authority considers a proposed change in accordance with this paragraph, the references in paragraph 19(2)(c) and 20(2)(c) to the data submission date are to be read as references to the date on which—

(a) the proposed change is notified to the licensing authority in accordance with sub-paragraph (1); or

(b) the licensing authority notifies the holder that it will consider the notification, in accordance with sub-paragraph (2), without the information referred to in sub-paragraph (1)(b).

Place of establishment for converted EU marketing authorisation holder established in EEA state before IP completion day

22.—(1) Subject to sub-paragraph (2), a person who—

(a) holds a converted EU marketing authorisation on IP completion day (whether or not it is suspended); and

(b) was, immediately before IP completion day, established in an EEA State, and remains established there on and after IP completion day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 49(3) or 66(2) (as the case may be), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) But sub-paragraph (1) continues to apply to a person after the end of the specified period only if the person has, before the end of that period, notified the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom who the licensing authority may contact in respect of any matter relating to the converted EU marketing authorisation during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) In this paragraph—

"the specified period" means 4 weeks beginning with IP completion day; and

"the transitional period" means the period of 24 months beginning with IP completion day.

Temporary exemption as to packaging requirements for converted EU marketing authorisations

23.—(1) A holder of a converted EU marketing authorisation does not commit an offence under regulation 268 during the period of 36 months beginning with IP completion day to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 by reason only of the fact that the outer or immediate packaging, or the package leaflet, do not include the correct information as to—

(i) the name and address of the holder of the UK marketing authorisation, or, where applicable, the name of the holder's representative,

(ii) the number of the UK marketing authorisation, or

(iii) the name and address of the manufacturer of the product; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the number of the marketing authorisation is the number of the EU marketing authorisation to which the converted EU marketing authorisation relates, or

(ii) the UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 49(3), and the information specified in paragraph (a)(i) or (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in sub-paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the holder of the converted EU marketing authorisation, having been notified of the number of the UK marketing authorisation and having established itself in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, during the period referred to in sub-paragraph (1).

Referrals made under Article 20 of Regulation (EC) No 726/2004 that have not concluded or been implemented before IP completion day

24.—(1) Sub-paragraph (2) applies where—

(a) the European Commission has requested the opinion of the EMA in accordance with Article 20(2) of Regulation (EC) No 726/2004 in relation to a specified matter; but

(b) no final decision has been adopted by the European Commission in accordance with Article 20(3) of that Regulation immediately before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 68 (revocation, variation and suspension of UK marketing authorisation) as soon as reasonably practicable.

(3) In making a decision under regulation 68 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in the procedure under Article 20 of Regulation (EC) No 726/2004;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member State in the making of that decision or agreement, under any procedure provided for in the Council Decision of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission; and

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11.

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 68 in accordance with sub-paragraph (2) in a case where the Committee for Medicinal Products for Human Use has given a final opinion in relation to the specified matter.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11.

(6) Sub-paragraph (7) applies where—

(a) the European Commission has requested the opinion of the EMA in accordance with Article 20(2) of Regulation (EC) No 726/2004 in relation to a specified matter;

(b) a final decision has been adopted by the European Commission in accordance with Article 20(3) of that Regulation immediately before IP completion day; but

(c) the necessary steps to give effect to the decision referred to in paragraph (b) have not been taken before IP completion day.

(7) Where this sub-paragraph applies, the licensing authority must, where a Commission decision or opinion requires steps to be taken in respect of an EU marketing authorisation that is a converted EU marketing authorisation, take the steps necessary as a result of the decision or opinion to suspend, revoke or vary a converted EU marketing authorisation as soon as reasonably practicable.

(8) In this paragraph, "specified matter" means a matter in relation to which the opinion of the EMA has been requested by the European Commission under Article 20(2) of Regulation (EC) No 726/2004 before IP completion day that might result in the suspension, revocation or variation of an EU marketing authorisation which is a converted EU marketing authorisation.

Enforcement

25. If a holder of a converted EU marketing authorisation fails to comply with an obligation imposed on the holder by or under this Part, the licensing authority may suspend the authorisation until the holder complies with the obligation.

PART 4

Transitional provision in respect of UK marketing authorisations, parallel import licences and parallel distribution notices

Status of certain UK marketing authorisations granted before IP completion day

26ZA.—(1) This paragraph applies in relation to a UK marketing authorisation granted by the licensing authority under Chapter 4 of Title III to the 2001 Directive that was in force immediately before IP completion day.

(2) A UK marketing authorisation to which this paragraph applies—

(a) has effect on and after IP completion day as a UKMA(UK) granted under regulation 49(1) of these Regulations; and

(b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).

Place of establishment for UK marketing authorisation holder or parallel import licence holder established in an EEA State before IP completion day

26.—(1) Subject to sub-paragraphs (2) and (3), any person—

(a) who—

(i) holds a UK marketing authorisation immediately before IP completion day which remains in force on IP completion day (whether or not it is suspended),

(ii) holds a parallel import licence immediately before IP completion day which remains in force on IP completion day (whether or not it is suspended),

(iii) has made an application for, or to renew, a UK marketing authorisation or parallel import licence before IP completion day, which has not been determined before that date,

(iv) makes such an application on or after IP completion day but before the end of the transitional period; or

(v) is deemed to hold a parallel import licence under paragraph 28(2); and

(b) who was, immediately before IP completion day, established in an EEA State and remains established there on and after IP completion day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 49(3), 66(2) or 66A(2) (as the case may be), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) But sub-paragraph (1) continues to apply to a person where the UK marketing authorisation or parallel import licence authorises sale or supply of the medicinal product in Great Britain only if the person has notified the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom who the licensing authority may contact in respect of any matter relating to the UK marketing authorisation

or parallel import licence, or application for a UK marketing authorisation or parallel import licence (as the case may be), during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) to (iii) applies, within the period of 4 weeks beginning with IP completion day; or

(b) where sub-paragraph (1)(a)(iv) applies, at the time of making the application.

(4) This paragraph does not apply to a UK marketing authorisation that is a converted EU marketing authorisation within the meaning of paragraph 6.

(5) In this paragraph "the transitional period" means the period of 24 months beginning with IP completion day.

Temporary exemption as to packaging requirements: change of place of establishment

27.—(1) Subject to sub-paragraph (2), a person to whom paragraph 26 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets in Great Britain: holder of authorisation etc) during the transitional period to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) by reason only of the fact that the outer or immediate packaging, or the package leaflet (as the case may be), do not include the correct information as to—

(i) the name and address of the holder of the UK marketing authorisation, or, where applicable, the name of that holder's representative,

(ii) the number of the UK marketing authorisation, or

(iii) the name and address of the manufacturer of the product; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 49(3), and

(ii) the information specified in paragraph (a)(i) to (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the UK marketing authorisation holder, having established itself in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 36 months beginning with IP completion day.

Status of parallel import licences granted before IP completion day

27A.—(1) This paragraph applies in relation to a parallel import licence granted by the licensing authority that was in force immediately before IP completion day.

(2) A parallel import licence to which this paragraph applies—

(a) has effect on and after IP completion day as a parallel import licence in force in the whole United Kingdom granted under regulation 49(1) of these Regulations; and

(b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).

Conversion of parallel distribution notices in to parallel import licences

28.—(1) Sub-paragraph (2) applies where—

(a) a person holds a parallel distribution notice, issued by the EMA, for a medicinal product in respect of which there is an EU marketing authorisation;

(b) that distribution notice, and that EU marketing authorisation, are in force immediately before IP completion day; and

(c) that parallel distribution notice specifies the United Kingdom as a member state of destination in respect of that medicinal product.

(2) Subject to sub-paragraph (3), a person who falls within sub-paragraph (1) is deemed, on and after IP completion day, to have a parallel import licence granted under Part 5, in force in Great Britain only, in respect of the medicinal product specified in the parallel distribution notice.

(3) A person who falls within sub-paragraph (1) continues to hold a parallel import licence pursuant to sub-paragraph (2) only if that person notifies the licensing authority—

(a) before the end of the period of 21 days beginning with IP completion day, of each medicinal product, and each country from which it is intended to import that product on or after IP completion day; and

(b) of any other information that the licensing authority requests, within such time period as the licensing authority may specify.

(4) The licensing authority must as soon as reasonably practicable after receipt of the information specified in sub-paragraph (3), issue a parallel import licence to the holder of the parallel distribution notice.

Inclusion of the batch testing condition in relevant UK marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60A)

29.—(1) Sub-paragraph (2) applies where—

(a) a marketing authorisation was in force before IP completion day,

(b) that authorisation is in force as a UK marketing authorisation on IP completion day (whether or not it is suspended); and

(c) that authorisation is for a medicinal product of a type that is specified in regulation 60A(2)(a) to (e) (condition as to the submitting of samples and other information to the appropriate authority).

(2) Where this sub-paragraph applies, the UK marketing authorisation is deemed to include the batch testing condition on and after IP completion day.

(3) Sub-paragraph (4) applies where a holder of a UK marketing authorisation has, before IP completion day, submitted to a competent authority of an EEA State samples for testing from a batch of a medicinal product ("the relevant batch") that—

(a) is the subject of that authorisation; and

(b) is of a type specified in regulation 60A(2)(a) to (e).

(4) Where this sub-paragraph applies, the holder of the UK marketing authorisation is deemed to have satisfied the batch testing condition in respect of the relevant batch if, before IP completion day—

(a) the competent authority of that EEA State examines the sample from the relevant batch; and

(b) that authority declared it to be in conformity with the approved specifications (within the meaning of Article 114 of the 2001 Directive) before IP completion day.

(5) The appropriate authority—

(a) must include each EEA State on the list it publishes under regulation 60A(5) on IP completion day; and

(b) must not, before the end of the transitional period, exercise its powers under regulation 60A(8) to remove an EEA State from the list it publishes under regulation 60A(5).

(6) For the purposes of regulation 60A(9), the appropriate authority must, on IP completion day—

(a) include Switzerland and Israel in the list it publishes under that paragraph; and

(b) include in respect of those countries any conditions or restrictions in the arrangement with those countries that affect the applicability of the batch testing exemption.

(7) In this paragraph—

(a) "the transitional period" means the period of 24 months beginning with IP completion day; and

(b) "the batch testing condition" and "the batch testing exemption" have the same meaning as in regulation 60A.

(8) This paragraph, with the exception of sub-paragraphs (3) and (4), applies equally to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this paragraph (other than in this sub-paragraph) to—

(a) a marketing authorisation or a UK marketing authorisation is to be read as a reference to a parallel import licence for a medicinal product, and

(b) the holder of a UK marketing authorisation is to be read as a reference to the holder of a parallel import licence.

Application of the batch testing requirement to relevant EU marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60B)

29A.—(1) Sub-paragraph (2) applies where—

(a) an EU marketing authorisation was in force before IP completion day,

(b) that authorisation is in force on IP completion day (whether or not it is suspended); and

(c) that authorisation is for a medicinal product of a type that is specified in regulation 60B(2) (requirement to submit samples and other information to the appropriate authority).

(2) Where this sub-paragraph applies, the EU marketing authorisation is deemed to be subject to the batch testing requirement in regulation 60B on and after IP completion day.

(3) Sub-paragraph (4) applies where a holder of an EU marketing authorisation has, before IP completion day, submitted to a competent authority of an EEA State samples for testing from a batch of a medicinal product ("the relevant batch") that—

(a) is the subject of that authorisation; and

(b) is of a type specified in regulation 60B(2).

(4) Where this sub-paragraph applies, the holder of the EU marketing authorisation is deemed to have satisfied the batch testing requirement in regulation 60B in respect of the relevant batch if, before IP completion day—

(a) the competent authority of that EEA State examines the sample from the relevant batch; and

(b) that authority declared it to be in conformity with the approved specifications (within the meaning of Article 114 of the 2001 Directive) before IP completion day.

(5) Sub-paragraphs (5) and (6) of paragraph 29 apply in relation to the appropriate authority's management of the list published under regulation 60A(5) for the purposes of this paragraph and regulation 60B.

Existing data and marketing exclusivity and global marketing authorisations

30.—(1) Sub-paragraph (2) applies in relation to a UK marketing authorisation which, immediately before IP completion day, is part of a global marketing authorisation with one or more EU marketing authorisations or marketing authorisations granted by the competent authority of an EEA state.

(2) Where this sub-paragraph applies, the provisions of regulation 48(5) (definitions for Part 5), in so far as they describe a global marketing authorisation by reference to UK marketing authorisations only, do not affect the periods of data and marketing exclusivity to which the holder of a UK marketing authorisation to which this paragraph applies is entitled immediately before IP completion day.

Applications for EU marketing authorisations made before IP completion day

31.—(1) Sub-paragraph (2) applies where, before IP completion day—

(a) an application has been made to the EMA for an EU marketing authorisation; but

(b) no final decision has been made by the European Commission in relation to the grant of an EU marketing authorisation under Article 10 of Regulation (EC) No 726/2004.

(2) Where this sub-paragraph applies, the applicant may apply to the licensing authority for the grant of a UK marketing authorisation by submitting to the licensing authority—

(a) a copy of the application for the EU marketing authorisation; and

(b) if requested by the licensing authority, such material or information that the licensing authority reasonably considers necessary for dealing with the application.

(3) Sub-paragraph (4) applies where, before IP completion day and in relation to an application to which sub-paragraph (2) applies, a final opinion favourable to the granting of an EU marketing authorisation has been given by the Committee for Medicinal Products for Human Use and the United Kingdom concurred with that opinion.

(4) Where this sub-paragraph applies, the licensing authority must grant a UK marketing authorisation in response to an application as described in sub-paragraph (2) as soon as reasonably practicable after it is received.

(5) Sub-paragraph (6) applies where before IP completion day, in relation to an application to which sub-paragraph (2) applies—

(a) no final opinion favourable to the granting of an EU marketing authorisation has been given by the Committee for Medicinal Products for Human Use; or

(b) such an opinion has been given but the United Kingdom recorded a divergent opinion.

(6) Where this sub-paragraph applies, the licensing authority must consider an application made under sub-paragraph (2) in accordance with Part 5 of these Regulations (marketing authorisations).

Place of establishment for UK marketing authorisation holder established in EEA state before IP completion day (pre-exit EU marketing authorisation applications)

32.—(1) Subject to sub-paragraph (2), a person—

(a) who applied to the EMA for an EU marketing authorisation before IP completion day;

(b) to whom the licensing authority grants a UK marketing authorisation on or after IP completion day in response to that application in accordance with paragraph 31; and

(c) who was, immediately before IP completion day, established in an EEA State, and remains established there on and after IP completion day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 49(3), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) Sub-paragraph (1) applies to a person only if, when submitting a copy of the application for the EU marketing authorisation to the licensing authority in accordance with paragraph 31, the person notifies the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom whom the licensing authority may contact in respect of any matter relating to the UK marketing authorisation during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) In this paragraph, "the transitional period" means the period which beginning with the date on which the licensing authority grants a UK marketing authorisation as described in paragraph 31(4) and ending 24 months after IP completion day.

Packaging in relation to UK marketing authorisations granted in response to application for EU marketing authorisation made before IP completion day

33.—(1) Subject to sub-paragraph (2), a person to whom paragraph 32(1) applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets in Great Britain: holder of authorisation etc) during the transitional period to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) by reason only of the fact that the outer or immediate packaging, or the package leaflet, do not include the correct information as to—

(i) the name and address of the holder of the marketing authorisation, or, where applicable, the name of the holder's representative,

(ii) the number of the marketing authorisation, or

(iii) the name and address of the manufacturer of the product; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the number of the marketing authorisation is the number of the EU marketing authorisation to which the application for the EU marketing authorisation related, or

(ii) the UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 49(3), and the information specified in paragraph (a)(i) or (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in sub-paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the UK marketing authorisation holder, being aware of the number of the UK marketing authorisation and having established in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, as the case may be, during the transitional period.

(3) In this paragraph, "the transitional period" means the period beginning with the date on which the licensing authority grants a UK marketing authorisation as described in paragraph 31(4) and ending 36 months after IP completion day.

Applications made for a UK marketing authorisation before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied

34.—(1) Sub-paragraph (2) applies where an application for a UK marketing authorisation has been made before IP completion day and—

(a) regulation 58(6) and (7) of the 2012 Regulations (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before IP completion day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before IP completion day in relation to that application, grant a UK marketing authorisation in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with IP completion day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before IP completion day, determine that application in accordance with Part 5 of these Regulations (marketing authorisations) as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive; and

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11 (advice and representations).

(4) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a UK marketing authorisation in the time period specified in regulation 58(1) (consideration of application) as if it had applied to that application on the date on which the application was submitted.

Transitional provision in respect of Plasma Master Files

35.—(1) This paragraph applies in relation to a UK marketing authorisation or EU marketing authorisation—

(a) which was granted before IP completion day;

(b) the application for which made reference to a Plasma Master File within the meaning of paragraph 1.1(a), first indent, of Part III of Annex I to the 2001 Directive which was certified by the EMA in accordance with paragraph 1.1(c) of that Part of the Annex; and

(c) which remains in force as a UK marketing authorisation on and after IP completion day.

(2) A holder of the UK marketing authorisation to which this paragraph applies may, subject to complying with the obligations in sub-paragraph (3), continue to refer to the Plasma Master File as certified by the EMA, notwithstanding the modifications to paragraph 1.1(c) of Part III of Annex I to the 2001 Directive in Schedule 8B, subject which that paragraph is to be read on and after IP completion day.

(3) The holder of a UK marketing authorisation to which this paragraph applies must notify the licensing authority of—

(a) the outcome of the annual update and recertification of the Plasma Master File by the EMA within 4 weeks beginning with the completion of that update and recertification;

(b) any application for changes to the terms of the Plasma Master File which the holder seeks from the EMA, within 4 weeks beginning with the date of the application; and

(c) the outcome of any application referred to in paragraph (b), within 4 weeks beginning with the date on which the holder is notified of that outcome.

(4) The licensing authority may at any time review the terms of a Plasma Master File to which reference is made in accordance with sub-paragraph (2), with a view to exercising its powers under these Regulations in relation to the UK marketing authorisation.

Suspensions of UK marketing authorisations that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive or Regulation (EC) No 726/2004

36. Where, immediately before IP completion day, a marketing authorisation, which is a UK marketing authorisation on IP completion day, has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive or Regulation (EC) No 726/2004, the suspension—

(a) continues to have effect on and after IP completion day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 5 (marketing authorisations).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of an EU marketing authorisation or a UK marketing authorisation that have not concluded before IP completion day

37.—(1) Sub-paragraph (2) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day; but

(b) that procedure has not concluded before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 68 (revocation, variation and suspension of UK marketing authorisation) as soon as reasonably practicable.

(3) In making a decision under regulation 68 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive; and

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11.

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 68 in accordance with sub-paragraph (2) in a case where the Committee for Medicinal Products for Human Use or the Co-ordination Group for Mutual Recognition and Decentralised Procedures (as the case may be) has given a final opinion in relation to the matter referred under Article 31 of the 2001 Directive.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11 (advice and representations).

(6) Sub-paragraph (7) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day;

(b) that referral has concluded before IP completion day; but

(c) the licensing authority has not, before IP completion day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the UK marketing authorisation—

(a) as soon as reasonably practicable; and

(b) in the case of a UK marketing authorisation that is not a converted EU marketing authorisation, within the period specified in Article 34(3) of the 2001 Directive (if relevant).

(8) In this paragraph—

"concluded before IP completion day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before IP completion day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before IP completion day; and

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before IP completion day that concerns a proposal to suspend, revoke or otherwise vary a UK marketing authorisation or an EU marketing authorisation; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

PART 5

Transitional provision in relation to variations of marketing authorisations other than converted EU marketing authorisations

Application or notification made before IP completion day in respect of a variation under Chapter IIa of Regulation (EC) No 1234/2008 (variations to purely national marketing authorisations)

38.—(1) Sub-paragraph (2) applies where—

(a) an application or notification in respect of a variation to a UK marketing authorisation has been submitted to the licensing authority under Chapter IIa of Regulation (EC) No 1234/2008 before IP completion day; but

(b) the procedures specified in Article 13e of that Regulation (measures to close the variation procedures in Chapter IIa of that Regulation) have not concluded before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) determine which of the provisions specified in Schedule 10A that are relevant to that application or notification need to be taken on or after IP completion day, having regard to the steps that have already been undertaken under Chapter IIa of Regulation (EC) No 1234/2008 before IP completion day;

(b) assess the application or notification in accordance with the provisions of that Schedule the authority has determined are relevant to the application, as if the application or notification had been made under them; and

(c) take all reasonable steps to ensure that it assesses the notification or application in accordance with any relevant time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before IP completion day.

(3) Paragraphs 15 and 16 of Schedule 10A apply to any variation that falls under sub-paragraph (1)(a) or (b).

Application or notification made before IP completion day in respect of a variation under Chapter II of Regulation (EC) No 1234/2008 (variations to marketing authorisations granted in accordance with Chapter 4 of the 2001 Directive)

39.—(1) This paragraph applies where an application or notification in respect of a variation to a marketing authorisation has been submitted to the licensing authority, as a relevant authority, under Chapter II of Regulation (EC) No 1234/2008 before IP completion day.

(2) If the procedures specified in Article 11(1) of Regulation (EC) No 1234/2008 have not concluded before IP completion day, the licensing authority must—

(a) assess the application or notification in accordance with regulation 65C and Schedule 10A to these Regulations, as if the application or notification had been made under those provisions; and

(b) make such an assessment having regard to the matters specified in sub-paragraph (5).

(3) If the procedures specified in Article 11(1) of Regulation (EC) No 1234/2008 have concluded before IP completion day—

(a) the licensing authority must take the steps specified in Article 11(2) of Regulation (EC) No 1234/2008 within the time limit specified in Article 23(1) of that Regulation; and

(b) paragraphs 15 and 16 of Schedule 10A apply to the variation.

(4) In making a determination under sub-paragraph (2), the licensing authority must—

(a) determine which steps of the procedures specified in Schedule 10A that are relevant to that application or notification need to be taken on or after IP completion day, having regard to the matters specified in sub-paragraph (5); and

(b) take all reasonable steps to ensure that it assesses the notification or application in accordance with any time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before IP completion day.

(5) In making a determination under sub-paragraph (2), the licensing authority must have regard to—

(a) any recommendation in relation to that application or notification given before IP completion day pursuant to Article 5 of Regulation (EC) No 1234/2008;

(b) any relevant information obtained by it before IP completion day, as a relevant authority, in relation to the application or notification by virtue of any procedure provided for in Chapter II of that Regulation; and

(c) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a relevant authority, including any matter referred under the procedure specified in Article 13 of that Regulation.

Application or notification in respect of a variations made before IP completion day under Article 20 of Regulation (EC) No 1234/2008 (work-sharing procedure)

40.—(1) Sub-paragraph (2) applies where—

(a) an application or notification in respect of a variation to a UK marketing authorisation has been submitted to the licensing authority, as a relevant authority or the reference authority, under Article 20 of Regulation (EC) No 1234/2008;

(b) the marketing authorisation is one to which Chapter II or IIa of that Regulation applied; and

(c) the procedure in Article 20(8) has not been completed before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) determine which of the provisions specified in Schedule 10A that are relevant to that application or notification need to be taken on or after IP completion day, having regard to the steps that have already been undertaken under Article 20 of Regulation (EC) No 1234/2008 before IP completion day;

(b) assess the application or notification in accordance with the relevant provisions in that Schedule, as if the application or notification had been made under them; and

(c) take all reasonable steps to ensure that it assesses the notification or application in accordance with any relevant time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before IP completion day.

(3) In making a determination or assessment under sub-paragraph (2), the licensing authority must have regard to—

(a) any opinion given by the reference authority before IP completion day in relation to that application;

(b) any relevant information obtained by it before IP completion day, as a reference authority or relevant authority, in relation to the application or notification by virtue of any procedure provided for in regulation 20 of Regulation (EC) No 1234/2008; and

(c) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a relevant authority.

(4) Paragraphs 15 and 16 of Schedule 10A apply to any variation that falls under sub-paragraph (1).

PART 6

Transitional provision in relation to the Paediatric Regulation

Transitional provision in relation to applications made to EMA before IP completion day under the Paediatric Regulation

41.—(1) Where a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before IP completion day, that plan, including any modifications agreed by the EMA before IP completion day, has effect on and after IP completion day as an agreed paediatric investigation plan.

(2) Sub-paragraph (3) applies where—

(a) a paediatric investigation plan has been submitted to the EMA with a request for agreement before IP completion day;

(b) the proposed paediatric plan is valid in accordance with the provisions of Article 15(2) of the Paediatric Regulation; but

(c) the EMA has not adopted a decision to agree the plan before IP completion day.

(3) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the paediatric investigation plan has been given by the Paediatric Committee before IP completion day, treat the plan as an agreed paediatric investigation plan;

(b) where an opinion against agreeing the paediatric investigation plan has been given by the Paediatric Committee before IP completion day, decide that it cannot agree the plan under regulation 50B(5) (agreement and modification of paediatric investigation plan); or

(c) where before IP completion day no opinion in relation to the paediatric investigation plan has been given by the Paediatric Committee treat it as a request for agreement under regulation 50B(1) and determine that request as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they do not want the application to proceed as a request for agreement of a paediatric investigation plan under these Regulations.

(4) Sub-paragraph (5) applies where—

(a) a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before IP completion day;

(b) the person to whom the EMA's decision to agree the plan was addressed has, before IP completion day, made a proposal under Article 22 of the Paediatric Regulation to modify the plan, or to request a waiver; but

(c) the EMA has not adopted a decision to agree to the modification or waiver before IP completion day.

(5) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the modification or waiver has been given by the Paediatric Committee before IP completion day, agree to the modification or waiver as if it had been requested under regulation 50B(6);

(b) where an opinion against agreeing the modification or waiver has been given by the Paediatric Committee before IP completion day, decide that it cannot agree to the modification or waiver as if it had been requested under regulation 50B(6); or

(c) where before IP completion day no opinion in relation to the modification or waiver has been given by the Paediatric Committee treat the proposal as one made under regulation 50B(6) and consider it accordingly, unless the applicant notifies the licensing

authority in writing that they do not want the proposal to proceed as a proposal under regulation 50B(6).

(6) Where the EMA has adopted a decision to grant, and has not revoked, a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before IP completion day, that waiver has effect on and after IP completion day as a waiver granted by the licensing authority under regulation 50D (waiver of production of information in a paediatric investigation plan).

(7) Sub-paragraph (8) applies where—

(a) an application has been made to the EMA for a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before IP completion day;

(b) the application has been accepted as valid by the EMA; but

(c) the EMA has not adopted a decision to grant the waiver before IP completion day.

(8) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the waiver has been given by the Paediatric Committee before IP completion day, grant the waiver under regulation 50D(2);

(b) where an opinion against agreeing the waiver has been given by the Paediatric Committee before IP completion day, decide that it cannot grant the waiver under regulation 50D(2); or

(c) where before IP completion day no opinion in relation to the waiver has been given by the Paediatric Committee treat the proposal as one made under regulation 50D and consider it accordingly, unless the applicant notifies the licensing authority in writing that they do not want the proposal to proceed as a proposal under regulation 50D.

Transitional provision in relation to global marketing authorisations under the 2001 Directive

41A. Where a relevant medicinal product is subject to a global marketing authorisation as described in Article 6 of the 2001 Directive before IP completion day, a paediatric investigation plan does not need to be carried out in relation to that product.

PART 8

Transitional provision in respect of homoeopathic medicinal products

List of countries for the purposes of the definition of "homoeopathic medicinal product" on IP completion day

43.—(1) For the purposes of the definition of "homoeopathic medicinal product" in regulation 8 (general interpretation: accepted Pharmacopoeias for homoeopathic manufacturing procedures), during the transitional period, the licensing authority must publish a list of countries that includes each EEA State in it.

(2) The licensing authority must not, before the end of the transitional period, remove an EEA State from the list described in sub-paragraph (1).

(3) In this paragraph, "the transitional period" is the period of two years beginning with IP completion day.

Place of establishment for holders of certificates of registration established in EEA before IP completion day

44.—(1) Subject to sub-paragraph (2), any person—

(a) who—

(i) holds a certificate of registration immediately before IP completion day which remains in force on IP completion day (whether or not it is suspended),

(ii) has made an application for, or to renew, a certificate of registration before IP completion day, which has not been determined by the licensing authority before that date, or

(iii) makes such an application on or after IP completion day but before the end of the transitional period; and

(b) who was, immediately before IP completion day, established in an EEA State and who remains there on and after that day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 103(4) or 108(2) (as the case may be), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) But sub-paragraph (1) continues to apply to a person, in relation to a certificate of registration in force in Great Britain, only if the person has notified the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom who the licensing authority may contact in respect of any matter relating to the certificate of registration, or application for a certificate of registration, during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) or (ii) applies, within the period of 4 weeks beginning with IP completion day; or

(b) where sub-paragraph (1)(a)(iii) applies, at the time of making the application.

(4) In this paragraph "the transitional period" means the period of 24 months beginning with IP completion day.

Temporary exemption as to packaging requirements: change of place of establishment

45.—(1) Subject to sub-paragraph (2), a person to whom paragraph 44 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets in Great Britain) during the transitional period in relation to a product to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) by reason only of the fact that the outer or immediate packaging, or the package leaflet (as the case may be), do not include the correct information as to—

(i) the name and address of the holder of the certificate of registration,

(ii) the number of the certificate of registration, or

(iii) the name and address of the manufacturer of the product if different from the holder of the certificate of registration; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the holder of the certificate of registration has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 103(4) or 108(2), and

(ii) the information specified in paragraph (a)(i) to (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in sub-paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the certificate of registration holder, having established itself in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 36 months beginning with IP completion day.

Applications made for a certificate of registration for a registrable homoeopathic product before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied

46.—(1) Sub-paragraph (2) applies where an application for a certificate of registration has been made before IP completion day and—

(a) regulation 104(5) and (6) (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before IP completion day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before IP completion day in relation to that application, grant a certificate of registration in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with IP completion day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before IP completion day, determine that application in accordance with Part 6 of these Regulations as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive; and

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive.

(4) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration in the time period specified in regulation 104(1) as if it had applied to that application on the date on which the application was submitted.

Suspensions of certificates of registration that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive

47. Where, immediately before IP completion day, a certificate of registration has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive, the suspension—

(a) continues to have effect on and after IP completion day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 6 of these Regulations (certification of homoeopathic medicinal products).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a certificate of registration that have not concluded before IP completion day

48.—(1) Sub-paragraph (2) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day; but

(b) the procedure has not concluded before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 110 (revocation, variation and suspension of certificate of registration) as soon as reasonably practicable.

(3) In making a decision under regulation 110 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11 (advice and representations).

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 110 in accordance with sub-paragraph (2) in a case where the Co-ordination Group for Mutual Recognition and Decentralised procedures has given an opinion in relation to the matter under Article 31 of the Directive.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11.

(6) Sub-paragraph (7) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day;

(b) the referral has concluded before IP completion day; but

(c) the licensing authority has not, before IP completion day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) The licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the certificate of registration within the time period specified in Article 34(3) of the 2001 Directive where the decision or opinion requires steps to be taken in relation to a certificate of registration.

(8) In this paragraph—

"concluded before IP completion day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before IP completion day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before IP completion day;

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before IP completion day that concerns a proposal to suspend, revoke or otherwise vary a certificate of registration; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

PART 9

Transitional provision in respect of traditional herbal registrations

Place of establishment for holders of traditional herbal registrations established in EEA before IP completion day

49.—(1) Subject to sub-paragraph (2), any person—

(a) who—

(i) holds a traditional herbal registration immediately before IP completion day which remains in force on IP completion day (whether or not it is suspended),

(ii) has made an application for, or to renew, a traditional herbal registration before IP completion day, which has not been determined by the licensing authority before that date, or

(iii) makes such an application on or after IP completion day but before the end of the transitional period; and

(b) who was, immediately before IP completion day, established in an EEA State and who remains there on and after that day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 127(3) or 133(2) (as the case may be), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) But sub-paragraph (1) continues to apply to a person, only in relation to a registration in force in Great Britain, and only if the person notifies the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom who the licensing authority may contact in respect of any matter relating to the traditional herbal registration, or application for a traditional herbal registration, during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) or (ii) applies, within the period of 4 weeks beginning with IP completion day; or

(b) where sub-paragraph (1)(a)(iii) applies, at the time of making the application.

(4) In this paragraph "the transitional period" means the period of 24 months beginning with IP completion day.

Temporary exemption as to packaging requirements: change of place of establishment

50.—(1) Subject to sub-paragraph (2), a person to whom paragraph 49 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets in Great Britain) during the transitional period in relation to a product to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) by reason only of the fact that the outer or immediate packaging, or the package leaflet (as the case may be), do not include the correct information as to—

(i) the name and address of the holder of the traditional herbal registration, or, if applicable, the holder's representative,

(ii) the number of the traditional herbal registration, or

(iii) the name and address of the manufacturer of the product; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the holder of the traditional herbal registration has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 127(3) or 133(2), and

(ii) the information specified in paragraph (a)(i) to (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in sub-paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the holder of the traditional herbal registration, having established itself in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 36 months beginning with IP completion day.

List of approved countries for traditional use of a herbal medicinal product on IP completion day

51.—(1) For the purpose of regulation 125A (list of approved countries for traditional use of a herbal medicinal product), the licensing authority must, for the transitional period, include each EEA State in the list it publishes under regulation 125A(1).

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 125A(3) to remove an EEA State from the list.

(3) In this paragraph, the transitional period is two years beginning with IP completion day.

Applications made for a traditional herbal registration before IP completion day to which Chapter 4 of Title III of the 2001 Directive applied

52.—(1) Sub-paragraph (2) applies where an application for a traditional herbal registration to be in force in Great Britain only has been made before IP completion day and—

(a) regulation 130(12) and (13) (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before IP completion day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before IP completion day in relation to that application, grant a traditional herbal registration in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with IP completion day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before IP completion day, determine that application in accordance with Part 7 of these Regulations as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11 (advice and representations).

(4) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration in the time period specified in regulation 130(1) as if it had applied to that application on the date on which the application was submitted.

Suspensions of traditional herbal registrations that have effect immediately before IP completion day that were imposed under Chapter 4 of Title III of the 2001 Directive

53. Where, immediately before IP completion day, a traditional herbal registration in force in Great Britain only has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive, the suspension—

(a) continues to have effect on and after IP completion day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 7 of these Regulations (traditional herbal registrations).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a traditional herbal registration that have not concluded before IP completion day

54.—(1) Sub-paragraph (2) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day; but

(b) the procedure has not concluded before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 135 (revocation, variation and suspension of traditional herbal registration) as soon as reasonably practicable.

(3) In making a decision under regulation 135 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11 (advice and representations).

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 135 of these Regulations in accordance with sub-paragraph (2) in a case where the Co-ordination Group for Mutual Recognition and Decentralised procedures has given an opinion in relation to the matter under Article 31 of the Directive.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11.

(6) Sub-paragraph (7) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before IP completion day;

(b) the referral has concluded before IP completion day; but

(c) the licensing authority has not, before IP completion day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the traditional herbal registration within the time period specified in Article 34(3) of the 2001 Directive where the decision or opinion requires steps to be taken in relation to a traditional herbal registration.

(8) In this paragraph—

"concluded before IP completion day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before IP completion day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before IP completion day; and

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before IP completion day that concerns a proposal to suspend, revoke or otherwise vary a traditional herbal registration; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

Proposals to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products and the procedure in Part 3 of Schedule 11 that were on-going at IP completion day

55.—(1) This paragraph applies where—

(a) the licensing authority has proposed to refer an application for a traditional herbal registration to be in force in Great Britain only to the Committee on Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive before IP completion day; but

(b) that application has not been determined in accordance with Part 7 of these Regulations before IP completion day.

(2) Where the licensing authority has received an opinion of the Committee for Herbal Medicinal Products before IP completion day in relation to the application, it must take that decision in to account and determine that application.

(3) Where the licensing authority has not received an opinion of the Committee for Herbal Medicinal Products before IP completion day, notwithstanding the amendments made to Part 3 of Schedule 11 by the EU Exit Regulations, it may—

(a) proceed to determine the application, taking into account any proceedings that took place before IP completion day under Part 3 of Schedule 11 (prior to its amendment by the EU Exit Regulations), or any opinion of the Committee on Herbal Medicinal Products in relation to the application that is given on or after IP completion day; or

(b) it may refer the matter under regulation 130A in order to obtain the findings and advice of the appropriate committee before determining the application.

PART 10

Transitional provision in respect of pharmacovigilance

Referrals made under Article 107i of the 2001 Directive concerning the evaluation of data from pharmacovigilance activities which are not concluded before IP completion day

58.—(1) Sub-paragraph (2) applies where—

(a) a specified matter in relation to a UKMA(GB) or a THR(GB) has been referred under Article 107i of the 2001 Directive (urgent Union procedure) before IP completion day; but

(b) that procedure has not concluded before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 68 or 135 (revocation, variation and suspension of UKMA(GB) or THR(GB)) as soon as reasonably practicable.

(3) In making a decision under regulation 68 or 135 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in any procedure provided for by, or referred to in, Section 4 of Chapter 3 of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for by, or referred to in, Section 4 of Chapter 3 of the 2001 Directive; and

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11 (advice and representations).

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 68 or 135 in accordance with sub-paragraph (2) in a case where the Committee for Medicinal Products for Human Use or the Co-ordination Group for Mutual Recognition and Decentralised Procedures (as the case may be) has given a final opinion in relation to the matter.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11 (advice and representations).

(6) In making a determination under regulation 68 or 135 in accordance with sub-paragraph (2), the licensing authority may adopt or have regard to any decision made, or agreement reached, in relation to the specified matter under Section 4 of Chapter 3 of the 2001 Directive on or after IP completion day, notwithstanding that the United Kingdom did not participate in the making of that decision or agreement.

(7) Sub-paragraph (8) applies where—

(a) a specified matter in relation to a UKMA(GB) or a THR(GB) has been referred under Article 107i of the 2001 Directive before IP completion day; and

(b) that referral has concluded before IP completion day; but

(c) the licensing authority has not, before IP completion day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(8) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the UK marketing authorisation or traditional herbal registration—

(a) as soon as reasonably practicable, and, where relevant, within the time period specified in Article 34(3) of the 2001 Directive where a Commission decision requires steps to be taken in relation to a UK marketing authorisation that is not a converted EU marketing authorisation, or traditional herbal registration; or

(b) as soon as reasonably practicable, where a Commission decision or opinion requires steps to be taken in respect of a UK marketing authorisation that is a converted EU marketing authorisation.

(9) In this paragraph—

"concluded before IP completion day", in relation to an Article 107i referral, means—

(a) a Commission decision as provided for in Article 107k of the 2001 Directive has been taken before IP completion day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 107i referral procedure in accordance with Article 107k(2), has been given before IP completion day;

"specified matter" means a referral made under Article 107i of the 2001 Directive on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities.

Matters on-going at IP completion day in respect of periodic safety update reports

59.—(1) Sub-paragraph (2) applies where—

(a) a holder of a UKMA(GB) or a THR(GB) has submitted a periodic safety update report under regulation 191 before IP completion day;

(b) that periodic safety report is, immediately before IP completion day, to be assessed in accordance with the single assessment procedure in Article 107e of the 2001 Directive;

(c) the procedure described in Article 107e(3) of the 2001 Directive has been completed before IP completion day; but

(d) the licensing authority has not yet taken the steps described in regulation 194 before IP completion day.

(2) Where this sub-paragraph applies, notwithstanding the amendment of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive) by the EU Exit Regulations, the licensing authority must take the steps specified in regulation 194 in respect of the UKMA(GB) or THR(GB) as soon as reasonably practicable.

(3) Sub-paragraph (4) applies where—

(a) a holder of a UKMA(GB) or a THR(GB) has submitted a periodic safety update report under regulation 191 before IP completion day;

(b) that periodic safety report is, immediately before IP completion day, to be assessed in accordance with the single assessment procedure in Article 107e of the 2001 Directive; and

(c) the procedure described in Article 107e(3) of the 2001 Directive has not been completed before IP completion day.

(4) Where this sub-paragraph applies, the licensing authority—

(a) may notify a holder falling within sub-paragraph (3)(a) of the need to provide to it such further information that the licensing authority specifies; and

(b) must, subject to sub-paragraph (5), assess the periodic safety update report in accordance with regulation 195 (obligations on licensing authority to assess PSURs) (as amended by the EU Exit Regulations) as soon as reasonably practicable.

(5) Information required under sub-paragraph (4)(a) must be provided before the end of whatever period the licensing authority may specify.

(6) In making a determination under regulation 195, where sub-paragraph (4) applies, the licensing authority may adopt or have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the periodic safety report and the assessment of that report as a consequence of its involvement in any procedure provided for in Section 2 of Chapter III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, in relation to the periodic safety update report or its assessment before IP completion day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Section 2 of Chapter III of the 2001 Directive;

(c) any decision made, or agreement reached, in relation to that marketing authorisation or certificate of registration under Section 2 of Chapter III of the 2001 Directive on or after IP completion day, notwithstanding that the United Kingdom did not participate in the making of that decision or agreement.

Matters on-going at IP completion day in relation to draft study protocols under Article 107n and 107o of the 2001 Directive (submission of, and amendment to, draft study protocols for required studies)

60.—(1) Where the Pharmacovigilance Risk Assessment Committee has, before IP completion day—

(a) issued a letter endorsing a draft study protocol under Article 107n(2)(a) of the 2001 Directive;

(b) informed a holder of a UKMA(GB) or a THR(GB) that the study is a clinical trial under Article 107n(2)(c) of the 2001 Directive; or

(c) informed a holder of its endorsement of a substantial amendment to that protocol under Article 107o of the 2001 Directive,

the licensing authority is deemed to have accepted the draft study protocol, or the amended draft study protocol, or made that decision (as the case may be) under regulation 199(5) (submission of draft study protocols for required studies) or 200(5)(b) (amendment to study protocols for required studies).

(2) Where sub-paragraph (1) applies, the licensing authority may request the holder of a UKMA(GB) or a THR(GB) to provide to it any information in relation to the procedures under Article 107n or 107o of the 2001 Directive within a specified time period, and that holder must provide that information within that time period.

(3) Sub-paragraph (4) applies where, before IP completion day—

(a) a holder of a UKMA(GB) or a THR(GB) is proposing to, or, pursuant to Article 21a or 22a of the 2001 Directive, is under a duty to, undertake a non-interventional post-authorisation safety study; and

(b) the procedure specified in Article 107n or 107o of the 2001 Directive has not concluded before IP completion day.

(4) Where this sub-paragraph applies, on and after IP completion day, the holder must—

(a) submit any further information that has been required of it by the Pharmacovigilance Risk Assessment Committee to the licensing authority; and

(b) submit to the licensing authority such further information that it may request in relation to the procedures under Article 107n or 107o of the 2001 Directive within a time period specified by the licensing authority, whether or not that information has already been submitted to, or received from, that Committee before IP completion day,

and the licensing authority must assess that information in accordance with regulation 199 or 200 (as the case may be).

(5) In this paragraph, "not concluded before IP completion day" means that—

(a) a holder of a UKMA(GB) or a THR(GB) is proposing to, or, pursuant to Article 21a or 22a of the 2001 Directive, is under a duty to, undertake a non-interventional post-authorisation safety study;

(b) the Pharmacovigilance Risk Assessment Committee has not taken any of the steps specified in sub-paragraph (1)(a) to (c).

Matters on-going at IP completion day in respect of the follow up of final study reports

61.—(1) Sub-paragraph (2) applies where—

(a) a final study report has been submitted to the Pharmacovigilance Risk Assessment Committee under Article 107p of the 2001 Directive; but

(b) that committee has not, before IP completion day, made recommendations under Article 107q(1) of the 2001 Directive.

(2) Where this sub-paragraph applies—

(a) the licensing authority may, on or after IP completion day, request the holder of a UKMA(GB) or a THR(GB) to submit to it the information specified in regulation 201(2) (submission and evaluation of final study reports for required studies), and such further information relating to the final study report, or the procedure provided for in Chapter 4 of Title IX of the 2001 Directive, as the licensing authority may require; and

(b) that holder of a UKMA(GB) or a THR(GB) must, in any event, undertake the steps specified in regulation 201(5) in respect of that final study report.

(3) Sub-paragraph (4) applies where—

(a) regulation 202(1) (follow-up of final study reports) applied before IP completion day in respect of a final study report; but

(b) the licensing authority has not, before IP completion day, taken the steps specified in regulation 202(2).

(4) Where this paragraph applies, notwithstanding the amendment of regulation 202 by the EU Exit Regulations, the licensing authority must take the steps specified in regulation 202(2) in accordance with the time period specified in that paragraph.

(5) Sub-paragraph (6) applies where—

(a) regulation 202(3) applied before IP completion day; but

(b) the holder of a UKMA(GB) or a THR(GB) has not taken the steps specified in regulation 202(4) before IP completion day.

(6) Where this sub-paragraph applies, notwithstanding the amendment of regulation 202—

(a) the holder of a UKMA(GB) or a THR(GB) must take the steps specified in regulation 202(4); and

(b) the licensing authority must determine that application for a variation in accordance with Part 5 (marketing authorisations) or 7 (traditional herbal registrations).

PART 11

Transitional provision in respect of Part 12

Approved country health professional list on IP completion day (regulation 214(6A))

62.—(1) For the purposes of regulation 214(6A), for the transitional period, the licensing authority must include on the list published under that paragraph, professions of equivalent professional status to an appropriate practitioner under regulation 214(3) to (5D) in each EEA State.

(2) In this paragraph, "transitional period" is the period of one year beginning with IP completion day.

PART 12

General provision in relation to transitional provisions

Licensing authority power to require information

63.—(1) Notwithstanding any other power to require information under this Schedule, the licensing authority may require in writing that a holder of, or an applicant for, a UK marketing authorisation, parallel import licence, manufacturing licence, wholesale dealing licence, certificate of registration or traditional herbal registration provides it with any information which—

(a) is relevant to the exercise of the licensing authority's functions under this Schedule; and

(b) is either in the holder's or applicant's possession or is information which the holder or applicant may reasonably access,

within such time period as the licensing authority specifies in that written request.

(2) If the holder of an authorisation, licence, certificate or registration mentioned in sub-paragraph (1) fails to comply with a request made pursuant to that sub-paragraph, the licensing authority may suspend the authorisation, licence, certificate or registration until the holder complies with the obligation.

(3) Nothing in this Schedule requires a person to supply information in contravention of requirements imposed under the data protection legislation (within the meaning of Part 1 of the Data Protection Act 2018).**]**

SCHEDULE 34 Regulation 348

Amendments to existing law

PART 1

The Medicines Acts 1968 and 1971

1. The Medicines Act 1968 is amended as follows.

2. For the text of section 1 (Ministers responsible for the administration of Act) substitute—

"**1.** In this Act, "the Ministers" has the meaning given by regulation 6(6) to (8) of the 2012 Regulations (but as if references in that regulation to those Regulations were references to this Act).".

3. In section 10 [M119] (exemptions for pharmacists)—

(a) in subsection (1) for "a practitioner" substitute " an appropriate practitioner ";

(b) in subsections (1) and (4) for "sections 7 and 8 of this Act" substitute " regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations ";

(c) in subsection (5) for "section 7 of this Act" substitute " regulation 46 of the 2012 Regulations ";

(d) in subsection (6) for "section 8(2) of this Act" substitute " regulation 17(1) of the 2012 Regulations ";

(e) omit subsection (7); and

(f) in subsection (8) for the words from "section 92" to the end of the subsection substitute " regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations ".

Marginal Citations

M119 1968, c.67. Section 10(1), 10(3) and 10(7A) were amended and 10(2) repealed by Part 1 paragraphs 1 and 10 of Schedule 8 to S.I. 2006/2407, section 10(1), 10(4) were amended and 10(5) to (7) and 10(8) inserted by article 3 of S.I. 1971/1445, section 10(1) was amended and section 10(9) inserted by paragraph 5 Schedule 1 to the Regulations of Care (Scotland) Act 2001, and section 10(7A) to (7C) were inserted by section 26(1) of the Health Act 2006.

4. In section 15 (provision for extending or modifying exemptions)—

(a) omit subsections (1) and (2); and

(b) in subsection (3) [M120] for "sections 9 to 14" substitute " section 10 ".

Marginal Citations

M120 Section 15(3) was amended by paragraphs 1 and 11(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

5. In section 58 [M121] (medicinal products on prescription only)—

(a) in subsection (1) for the words from the first occurrence of "for the purposes" to the end of the subsection substitute " as prescription only medicines ";

(b) omit subsections (1A), (2) and (3);

(c) in the opening words of subsection (4) for "the last preceding subsection" substitute " regulation 223(1) of the 2012 Regulations ";

(d) in subsection (4)(a)—

(i) for "paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs," substitute " regulation 214(1) or (2) of the 2012 Regulations ", and

(ii) for the words from "or, where" to "of this section" substitute " or, in the case of an appropriate practitioner, other than a doctor or dentist, ";

(e) in subsection (4)(b) for "paragraph (a) of that subsection" substitute " regulation 214(1) of the 2012 Regulations ";

(f) in subsection (4A) for "a person who is an appropriate practitioner by virtue of subsection (1)(d) or (e)" substitute " an appropriate practitioner, other than a doctor or dentist ";

(g) in subsection (4C) for "subsection (2)(a) or (b) of this section" substitute " regulation 214(1) or (2) of the 2012 Regulations "; and

(h) after subsection (6) insert—

"(7) In subsection (6) "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

Marginal Citations

M121 Section 58((1), (4) and (6) was amended by paragraph 29 of Part 1 of Schedule 8 to S.I. 2006/2407. Section 58(4) was amended by paragraph 2(b) of Schedule 5 to S.I. 2002/53. Section 58(4) was amended by section 63(1 and (4) of, and section 58(4A) and (4C) inserted by section 63(1) and (5) of, the Health and Social Care Act 2001.

6. In section 58A(1) [M122] (requirement to specify certain products as prescription-only products) —

(a) omit paragraphs (a) and (b) and the word "and" following paragraph (b); and

(b) for the words following paragraph (c) to the end of the subsection substitute "is specified as a prescription only medicine".

Marginal Citations

M122 Section 58A was inserted by regulation 2 of S.I. 1992/3271, and the heading substituted by and subsection (1) amended by paragraph 30 Part 1 of Schedule 8 to S.I. 2006/2407.

7. In section 62 [M123] (prohibition of sale or supply, or importation, of medicinal products of specified description), after subsection (7) add—

"(8) In this section "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.".

Marginal Citations

M123 Section 62(7) was substituted by paragraph 12(5) of Schedule 1 to S.I. 2005/1094.

8. In section 64(5) (protection for purchasers of medicinal products) for "a practitioner" substitute " an appropriate practitioner ".

9.—(1) Section 67 [M124] (offences under Part III) is amended as follows.

(2) In subsection (1B)(a) for "by virtue of provision made under section 58(1) of this Act" substitute " within the meaning of regulation 214 of the 2012 Regulations ";

(3) in subsection (2)—

(a) for "52, 58, 63, 64 and 65", substitute " 63 and 64 "; and

(b) omit "any regulations made under section 60 or section 61 or".

(4) Omit subsection (3A).

(5) In subsection (4) for "subsection (1A), (1B), (2), (3) or (3A)" substitute " subsection (1A), (1B), (2) or (3) ".

(6) Omit subsections (5) and (6).

Marginal Citations

M124 Section 67(1B) was inserted by section 63(7) of the Health and Social Care Act 2001, and section 67(3A) inserted and section 67(4) amended by paragraph 8 of Schedule 5 to S.I. 2005/2789

10. In section 72 (representative of pharmacist in case of death or disability)—

(a) in paragraph (1)(c) [M125], for the words from "a committee" to the end of paragraph (c) substitute "a controller is appointed in his case under the Mental Health (Northern Ireland) Order 1986 [M126] "; and

(b) in paragraph (4)(c) for "committee" substitute " controller ".

Marginal Citations

M125 Section 72(1)(c) was amended by paragraph 12(a) of Schedule 5 to the Adults with Incapacity (Scotland) Act 2000 and paragraph 14(a) of Schedule 6 to the Mental Capacity Act 2005, and section 72(4)(c) by paragraph 14(d) of Schedule 6 to the Mental Capacity Act 2005.

M126 S.I. 1986/594 (N.I. 4).

11. In section 82(4) (pharmacies: procedure relating to disqualification) for "Pharmaceutical Society" substitute—

(a) in the first place it appears, "General Pharmaceutical Council or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland"; and

(b) in the second place it appears, "Council or the Society".

12. In section 87 [M127] (requirements as to containers)—

(a) in subsection (1) for "section 85(2) of this Act" substitute " subsection (3) "; and

(b) after subsection (2) insert—

"(3) The purposes mentioned in subsection (1) are—

(a) securing that medicinal products are correctly described and readily identifiable;

(b) securing that any appropriate warning or other appropriate instruction or information is given, and that false or misleading information is not given, with respect to medicinal products;

(c) promoting safety in relation to medicinal products.”

Marginal Citations

M127 Section 87(1) was amended by paragraph 44 of Part 1 of Schedule 8 to S.I. 2006/2407.

13. In section 88(1) [M128] (distinctive colours, shapes and markings of medicinal products) for “section 85(2)” substitute “ section 87(3) ”.

Marginal Citations

M128 Section 88(1) was amended by paragraph 45 of Part 1 of Schedule 8 to S.I. 2006/2407.

14. In section 91 [M129] (offences under Part V, and supplementary provisions)—

(a) omit subsection (1);

(b) in subsection (2) omit “section 85(3), section 86(2) or”; and

(c) in subsection (3) for “sections 85 to” substitute “ section ”.

Marginal Citations

M129 Section 91(2) and (3) was amended by paragraph 48(b) and (c) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 91(2) was amended by section 32(2) of the Magistrates' Courts Act 1980.

15. In section 104 (application of Act to certain articles and substances)—

(a) in the heading to the section for “Act” substitute “ the 2012 Regulations ”; and

(b) in paragraph (1) for “this Act” substitute “ the 2012 Regulations ”.

16. In section 105 (application of Act to certain other substances which are not medicinal products)—

(a) in the heading to the section for “Act” substitute “ the 2012 Regulations ”; and

(b) in paragraph (1) for “this Act” substitute “ the 2012 Regulations ”.

17. In section 107 (validity of decisions and proceedings relating thereto)—

(a) in subsection (1)—

(i) omit “of the licensing authority under Part II of this Act or”, and

(ii) for “licence or certificate granted or issued” substitute “ certificate issued ”;

(b) in subsection (4)—

(i) for “grant a licence or certificate” substitute “ issue a certificate ”,

(ii) for “licence or certificate granted” substitute “ certificate issued ”, and

(iii) for “grant of the licence or” substitute “ issue of the ”;

(c) in subsection (6) omit “of Justice”.

18.—(1) Section 108 [M130] (enforcement in England and Wales) is amended as follows.

(2) In subsection (2)—

(a) in paragraph (a) for the words from "sections 64" to "and 89(2)" substitute " section 64 and sections 87(2) and 88(3) ";

(b) omit paragraphs (b) and (c); and

(c) in the words following those paragraphs—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ",

(ii) for "the Society" substitute " the Council ",

(iii) for "that Society" substitute " that Council "

(iv) for "paragraphs (a) and (b)" substitute " paragraph (a) ",

(v) for "those paragraphs" substitute " that paragraph ", and

(vi) omit the words from ", and the provisions" to the end of the subsection.

(3) Omit subsections (3) to (5).

(4) In subsection (6)—

(a) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ";

(b) omit paragraph (a); and

(c) in paragraph (b) omit "or section 61".

(5) In subsections (6A) and (6B) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ".

(6) Omit subsection (7).

(7) In subsection (9) for "(7)" substitute " (6D) ".

(8) In subsection (10)—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ", and

(ii) for the words from "or any" to "that duty" substitute " has in relation to any matter failed to perform a duty imposed on it by subsections (6A) or (6B) to enforce any provisions mentioned in those subsections ".

(9) In subsection (12) for paragraphs (a) and (b) substitute—

"(a) in relation to an area in England other than the City of London, the council of a non-metropolitan county, metropolitan district or London borough;

(b) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London; and

(c) in relation to an area in Wales, the council of a county or county borough.".

Marginal Citations

M130 Section 108(2) was amended and 108(12) inserted by paragraph 8 of Schedule 3 to the Food Safety Act 1990, section 108(6A) to (6D) was inserted and section 108(9) and (10) amended by section 31(1) of the Health Act 2006, section 108(9) was amended by paragraph 56(c), section 108(10) by paragraph 56(d) and section 108(11) by paragraph 56(e) of Part 1 of Schedule 8 to S.I. 2006/2407, and section . 108(12) was amended by paragraph 33 of Schedule 16 to the Local Government (Wales) Act 1994.

19. In section 109 [M131] (enforcement in Scotland)—

(a) in subsection (2)—

(i) for the words from "(2)" to "(10)" substitute " (2), (6) to (6D), (9) and (10) ", and

(ii) in paragraph (a) omit the words from "or" to "jointly"; and

(b) omit subsection (3).

Marginal Citations

M131 Section 109(2)(c) was repealed by paragraph 9(a) of Schedule 3 to the Food Safety Act 1990, and section 109(2)(d) was repealed by paragraph 57 of Part 1 of Schedule 8 to S.I. 2006/2407.

20. In section 110 [M132] (enforcement in Northern Ireland)—

(a) in subsection (1), for "Minister of Health and Social Services for Northern Ireland" substitute " Minister for Health, Social Services and Public Safety ";

(b) in subsection (2)—

(i) for "paragraphs (a) and (b)" substitute " paragraph (a) " in both places where it occurs,

(ii) for the words from "those paragraphs" to "subsection" substitute " that paragraph ",

(iii) for "area" substitute " district "[M133] ,

(iv) for "health authority" in both places where it occurs substitute " district council ",

(v) omit the words "and the provisions and regulations specified in the said paragraph (c)";

(c) omit subsection (3);

(d) in subsections (3A) and (3B), after "the Pharmaceutical Society" insert " of Northern Ireland ";

(e) in subsection (5)—

(i) for "Subsections (9) and (10)" substitute " Subsection (9) ",

(ii) in paragraph (a) for "(2) to (7)" substitute " (2) to (6D) ", and

(iii) omit paragraph (b) and the word "and" preceding that paragraph;

(f) omit subsections (6) and (7); and

(g) for subsection (8) substitute—

"(8) In this section "district council" means a council established under the Local Government Act (Northern Ireland) 1972 [M134]."."

Marginal Citations

M132 Section 110(1) was amended by paragraph 58(a) and section 110(5)(a) was amended by paragraph 58(c)(i) of Part 1 of Schedule 8 to S.I. 2006/2407, and section 110(3A) and (3B) were inserted by section 31(3)(b) and section 110(5)(a) amended by section 31(3)(c) of the Health Act 2006. In relation to Northern Ireland,

M133 The amendments in paragraph 19(b)(iii) and (iv), (f) and (g) reproduce amendments already made with effect in Northern Ireland by article 2 and the Schedule to S.R. (NI) 1973 No 211.

M134 1972 c. 9 (N.I.).

21. In section 111 [M135] (rights of entry)—

(a) in subsection (1) omit paragraph (aa) except for the word "or";

(b) in subsection (2) omit paragraph (a);

(c) omit subsection (3);

(d) in subsection (6) omit—

(i) "aircraft," in both places where it occurs, and

(ii) ", commander"; and

(e) for subsection (9) substitute—

"(9) References in this section to a justice of the peace—

(a) in relation to England, include a reference to a district judge (magistrates' courts);

(b) in relation to Scotland, are to be read as references to a sheriff, stipendiary magistrate or justice of the peace, and

(c) in relation to Northern Ireland, are to be read as references to a lay magistrate or a district judge (magistrates' courts).".

Marginal Citations

M135 Section 111(1)(aa) was inserted by paragraph 9 of Schedule 5 to S.I. 2005/2789.

22. In section 113(1) (application of sampling procedure to substance or article seized under section 112), omit the words from "(including" to the end of the subsection.

23. In section 114(1) (supplementary provisions as to rights of entry and related rights), omit—

(a) "aircraft," in both places where it occurs; and

(b) ", commander".

24. In section 121(4) [M136] (contravention due to default of other person), for the words from "63" to "96" substitute " 63, 64, 87 and 88 ".

Marginal Citations

M136 Section 121(4) was amended by paragraph 61 of Part 1 of Schedule 8 to S.I. 2006/2407.

25. In section 122(2) [M137] (warranty as defence), for the words "section 63(b), sections 64 and 65, sections 85 to 88" substitute " sections 63(b), 64, 87 and 88 ".

Marginal Citations

M137 Section 122(2) was amended by paragraph 62 of Part 1 of Schedule 8 to S.I. 2006/2407.

26. In section 123(1)(b) (offences in relation to warranties and certificates of analysis), omit "section 115 of this Act, or under".

27. In section 125 [M138] (prosecutions)—

(a) in subsection (4)—

(i) for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council ", and

(ii) for "that Society" substitute " the Council ";

(b) in subsections (6) and (7) for "Minister of Health and Social Services for Northern Ireland" substitute " Minister for Health, Social Services and Public Safety ".

Marginal Citations

M138 Section 125(4) was amended by paragraph 63 of Part 1 of Schedule 8 to S.I. 2006/2407.

28. In section 126 [M139] (presumptions)—

(a) in subsection (1), omit paragraph (b) and the word "or" following it;

(b) in subsection (3), omit "subsections (3) and (5) of section 85,"; and

(c) omit subsection (4).

Marginal Citations

M139 Section 126(3) was amended by paragraph 64(c) of Part 1 of Schedule 8 to S.I. 2006/2407.

29. In section 128 (financial provisions)—

(a) in subsection (1), for the words from "any of" to "section 1(1) of this Act" substitute " either of the Ministers ";

(b) in subsections (4) and (5), for "the Pharmaceutical Society" substitute " the General Pharmaceutical Council or (as the case may be) the Pharmaceutical Society of Northern Ireland ";

(c) in subsection (5), for "a Minister" substitute " either of the Ministers "; and

(d) in subsection (6), for the words from "any of the Ministers" to "Ireland" substitute " the Secretary of State ".

30. In section 129 [M140] (orders and regulations)—

(a) in subsection (2), omit the words from "or any regulations" to "section 120 of this Act";

(b) in subsection (3)—

(i) in paragraph (a), for the words from "13" to "and 130(5)(c)" substitute " 58, 62, 79 and 106 ", and

(ii) omit paragraph (b);

(c) in subsection (4) omit the words from ", other" to "69(3),", and

(d) in subsection (7)—

(i) omit "Part V or Part VI", and

(ii) for the words "a committee established under section 4 of this Act" substitute " an expert committee appointed by themselves, or by one of them acting alone ".

Marginal Citations

M140 Section 129(2) was amended by paragraph 65(a) of and section 129(3) was amended by paragraph 65(b) of Part 1 of Schedule 8 to S.I. 2006/2407.

31. In section 130 [M141] (meaning of medicinal product and related expressions)—

(a) for subsection (1) substitute—

"(1) In this Act, "medicinal product" has the meaning given by regulation 2 of the 2012 Regulations."; and

(b) omit subsections (2) to (8) and (10).

Marginal Citations

M141 Section 130(1) was amended by paragraph 66(a) of Part 1 of Schedule 8 to S.I. 2006/2407.

32. In section 131(5) [M142] (meaning of "wholesale dealing", "retail sale" and related expressions) for "or the Health and Personal Social Services (Northern Ireland) Order1972" substitute " , the Health and Personal Social Services (Northern Ireland) Order 1972 or the Health and Social Care (Reform) Act (Northern Ireland) 2009 ".

Marginal Citations

M142 Section 131(5) was amended by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006, paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978 and paragraph 128(2) of Schedule 4 to the National Health Service Reorganisation Act 1973.

33. In section 132 (general interpretation provisions)—

(a) for subsection (1) substitute—

"(1) In this Act—

(a) unless the context otherwise requires, any expression defined by any provision of the 2012 Regulations, and not defined in this Act, has the same meaning as it has for the purposes of those Regulations; and

(b) "the 2012 Regulations" means the Human Medicines Regulations 2012.";

(b) omit subsections (2) and (3);

(c) in subsection (4) omit "licence or" in each place it appears; and

(d) omit subsection (5).

34. In Schedule 3 [M143] (sampling)—

(a) omit paragraphs 5 to 7;

(b) in paragraph 8 for "3 to 7" substitute " 3 or 4 ";

(c) in paragraph 9 for "3 to 8" substitute " 3, 4, or 8 "; and

(d) in paragraph 17, in the words following paragraph (c)—

(i) for the words "a health authority" substitute " the Pharmaceutical Society of Northern Ireland ", and

(ii) for "the Minister of Health and Social Services for Northern Ireland" substitute " the Minister for Health, Social Services and Public Safety ".

Marginal Citations

M143 Paragraph 17 of Schedule 3 was amended by paragraph 66 of Part 1 of Schedule 8 to S.I. 2006/2407.

35. In Schedule 4 [M144] (provisions relating to Northern Ireland)—

(a) for every reference to "the Minister of Health and Social Services for Northern Ireland" substitute " the Minister for Health, Social Services and Public Safety ";

(b) in paragraph 6 omit the words from "(except" to "Act)";

(c) in paragraph 8 omit the words from ", and every regulation made solely" to "this Act,"; and

(d) in paragraph 10 for "the Ministry of Health and Social Services for Northern Ireland" substitute " the Department of Health, Social Services and Public Safety ".

Marginal Citations

M144 Paragraphs 2 to 5, 7 and 9(b) and (c) and following words of Schedule 4 were omitted by paragraphs 69(a), (c) and (e)(iii) and (iv) of Part 1 of Schedule 8 to S.I. 2006/2407. Paragraph 6 was amended by paragraph 69(b), paragraph 8 by paragraph 69(d), paragraph 9 by paragraph 69(e) and paragraph 10 by paragraph 69(f) of that Part.

Medicines Act 1971

36.—(1) The Medicines Act 1971 [M145] shall have effect as follows.

(2) In section 1 (fees)—

(a) in subsection (1), the reference to any application in pursuance of the Medicines Act 1968 for a licence or certificate under Part II of that Act, or for the variation or renewal of such a licence or certificate, shall have effect as a reference to any application under Parts 3 to 8 of these Regulations for the grant, variation or renewal of—

(i) a manufacturer's licence,

(ii) a wholesale dealer's licence,

(iii) a marketing authorisation,

(iv) a certificate of registration,

(v) a traditional herbal registration, or

(vi) an Article 126a authorisation; and

(b) in subsection (2)(b), the reference to any licence or certificate under the Medicines Act 1968 shall have effect as a reference to a manufacturer's licence, a wholesale dealer's licence, a marketing authorisation, a certificate of registration, a traditional herbal registration, or an Article 126a authorisation under these Regulations.

(3) Paragraph (2) has effect in relation to references of the kind mentioned in that paragraph in regulations made under section 1.

Marginal Citations

M145 1971 c.69.

PART 2

Other primary legislation

Trade Descriptions Act 1968

37. In section 2(5)(b) (trade descriptions) of the Trade Descriptions Act 1968 [M146] for the words from "made under Part V" to "that Act)" substitute " of Chapter 1 of Part 13 of the Human Medicines Regulations 2012 ".

Marginal Citations

M146 1968 c.29. Paragraph (b) of section 2(5) was inserted by paragraph 16 of Schedule 5 to the Medicines Act 1968.

House of Commons Disqualification Act 1975

38. In Part II (bodies of which all members are disqualified) of Schedule 1 to the House of Commons Disqualification Act 1975 [M147] for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Marginal Citations

M147 1975 c.24.

Northern Ireland Assembly Disqualification Act 1975

39. In Part II (bodies of which all members are disqualified) of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 [M148] for the entry for the Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968 substitute—

"The Commission on Human Medicines.".

Marginal Citations

M148 1975 c.25.

Consumer Protection Act 1987

40. Section 19(1) (interpretation of Part II) of the Consumer Protection Act 1987 [M149] shall have effect as if, in the definition "licensed medicinal product", the reference to any medicinal product within the meaning of the Medicines Act 1968, in respect of which a product licence within the meaning of that Act is for the time being in force, included a reference to a medicinal product, in respect of which a marketing authorisation or a traditional herbal registration within the meaning of these Regulations is for the time being in force.

Marginal Citations

M149 1987 c.43. Section 19(1) was amended by paragraph 7 of Part 1 of Schedule 9 to S.I. 2006/2407; there are other amendments to that subsection, but none is relevant.

Environmental Protection Act 1990

41. In section 142(7) (powers to obtain information about potentially hazardous substances) of the Environmental Protection Act 1990 [M150], for the entry relating to the Medicines Act 1968 substitute " Parts 3 to 8 and 16 of the Human Medicines Regulations 2012 ".

Marginal Citations

M150 1990 c.43. Section 142(7) was amended by paragraph 8 of Schedule 4 to the Radioactive Substances Act 1993 (1993 c.12), in relation to England and Wales by paragraph 5(1) and (12) of Part 1 of Schedule 26 to S.I. 2010/675, and by paragraph 8 of Part 1 of Schedule 9 to S.I. 2006/2407.

Value Added Tax Act 1994

42. In Part II of Schedule 8 (zero-rating) to the Value Added Tax Act 1994 [M151]—

(a) in note (2B) to Group 12 (drugs, medicines, aids for the handicapped etc) for the words "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 "; and

(b) in note (11) to Group 15 (charities etc)—

(i) for paragraph (a) substitute—

"(a) "medicinal product" has the meaning assigned to it by regulation 2(1) of the Human Medicines Regulations 2012;", and

(ii) omit paragraphs (b) and (c).

Marginal Citations

M151 1994 c.23. In Part II of Schedule 8, note (2B) to Group 12 was inserted by S.I. 2009/2972, and note (11)(a) to Group 15 was amended by paragraph 10(a), and (11)(d) inserted by paragraph 10(b), of Schedule 9 to S.I. 2006/2407.

Health Act 1999

43. In section 60(2A)(c) (regulation of health care and associated professions) of the Health Act 1999 [M152], after "that Act" insert " or the Human Medicines Regulations 2012 ".

Marginal Citations

M152 1999 c.8. Subsection (2A) was inserted by paragraph 1 of Schedule 8 to the Health and Social Care Act 2008 (2008 c.14).

Communications Act 2003

44. In section 368R(1) (interpretation of Part 4A) of the Communications Act 2003 [M153], for the definition "prescription-only medicine" substitute the following definition—

""prescription-only medicine" means a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012;".

Marginal Citations

M153 2003 c.21. Section 368R was inserted by regulation 2 of S.I. 2009/2979.

Christmas Day and New Year's Day Trading (Scotland) Act 2007

45. In section 7 (interpretation) of the Christmas Day and New Year's Day Trading (Scotland) Act 2007 [M154]—

(a) omit the definition "appropriate person"; and

(b) for the definition "on prescription" substitute the following definition—

""on prescription" means in accordance with a prescription given by an appropriate practitioner, within the meaning of regulation 214(1) and (3) to (6) (sale or supply of prescription only medicines) of the Human Medicines Regulations 2012;".

Marginal Citations

M154 2007 asp 13.

PART 3

Northern Ireland Orders in Council

Health and Personal Social Services (Northern Ireland) Order 1972

46. The Health and Personal Social Services (Northern Ireland) Order 1972 [M155] is amended as follows—

(a) in article 2(2), in the definition "pharmacist" for "Medicines Act 1968" substitute " Human Medicines Regulations 2012 "; and

(b) in article 57D—

(i) in paragraphs (3) and (5) for "Community" substitute " EU ", and

(ii) in paragraph (5) for "regulation 1 of the Medicines for Human Use (Marketing Authorisations etc Regulations 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M155 S.I. 1972/1265 (N.I. 14). Article 57D was inserted by article 4 of the Primary Medical Services (Northern Ireland) Order 2004 (S.I. 2004/311 (N.I. 2))

Pharmacy (Northern Ireland) Order 1976

47. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976 [M156], in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M156 S.I. 1976/1213 (N.I. 22).

Poisons (Northern Ireland) Order 1976

48. In article 2(2) of the Pharmacy (Northern Ireland) Order 1976 [M157]—

(a) in the definition "pharmacist" after "Medicines Act" insert " or the Human Medicines Regulations 2012 "; and

(b) in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M157 S.I. 1976/1214 (N.I. 23).

Diseases of Animals (Northern Ireland) Order 1981

49. In article 38 of the Diseases of Animals (Northern Ireland) Order 1981 [M158] in the definition "retail pharmacy business" for "section 132(1) of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M158 S.I. 1981/1115 (N.I. 22).

Waste and Contaminated Land (Northern Ireland) Order 1997

50. In article 33(6) of the Waste and Contaminated Land (Northern Ireland) Order 1997 [M159] for the entry relating to the Medicines Act 1968 substitute " Parts 3 to 8, 12 and 16 of the Human Medicines Regulations 2012 ".

Marginal Citations

M159 S.I. 1997/2778 (N.I. 19). Article 33(6) was amended by S.R. (NI) 2006 No 45.

Shops (Sunday Trading &c.) (Northern Ireland) Order 1997

51. In article 4(3) of the Shops (Sunday Trading &c.) (Northern Ireland) Order 1997 [M160] for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M160 S.I. 1997/2779 (N.I. 20).

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004 [M161] are amended as follows.

Marginal Citations

M161 S.I. 2004/1031, as amended by S.I. 2005/2754. There are other amendments, but none is relevant.

53. In regulation 2(1) (interpretation)—

(a) before the definition "the Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;";

(b) for the definition "appropriate committee" substitute—

""appropriate committee" for the purposes of any provision of these Regulations under which a function falls to be performed means whichever the licensing authority considers to be appropriate of—

(a) the Commission on Human Medicines; or

(b) an expert committee appointed by the licensing authority;";

(c) insert in the appropriate position in alphabetical order the following definition—

""the Commission on Human Medicines" means the Commission on Human Medicines within the meaning of regulation 9 of the 2012 Regulations;";

(d) in the definition "licensing authority" for "section 6 of the Act" substitute " regulation 6 of the 2012 Regulations ";

(e) for sub-paragraph (a) of the definition "marketing authorisation" substitute—

"(a) a UK marketing authorisation granted by the licensing authority under the 2012 Regulations,"; and

(f) for the definition "medicinal product" substitute—

""medicinal product" means a medicinal product within the meaning of regulation 2(1) of the 2012 Regulations."

54. In regulation 4(3) (responsibility for functions under the Directive) for "the Act" substitute " the 2012 Regulations ".

55. In regulation 19(10) (authorisation procedure for clinical trials involving medicinal products for gene therapy etc) omit "established by section 2A of the Act".

56. In regulation 46(2)(c) (labelling) for words from "Schedule 5" to the end of the sub-paragraph substitute " Part 13 of the 2012 Regulations that apply in relation to medicinal products sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner within the meaning of regulation 214(3) to (6) of those Regulations ".

57. In regulation 47 (application of enforcement provisions of the Act)—

(a) for "the Act" in the heading substitute " the 2012 Regulations "; and

(b) for paragraph (1) substitute—

"(1) Regulations 2, 8(1), 322, 323(1), 324(1), 325 to 330, 332 to 339, 343 and Schedule 31 of the 2012 Regulations ("those provisions") shall apply for the purposes of these Regulations as they apply for the purposes of the 2012 Regulations, but with the modifications specified in Schedule 9, and any reference in those provisions to the 2012 Regulations includes a reference to these Regulations."; and

(c) after paragraph (2) insert the following paragraph—

"(3) In those provisions as applying by virtue of paragraph (1), any reference to, or relating to, a requirement, a power, a function, a right, a duty, an entitlement, or a protection

shall be read as a reference to, or relating to, that requirement, power, function, right, duty, entitlement, or protection as applied by this regulation.".

58. In regulation 48(5) (infringement notices) for "sections 108 to 110 of the Act" substitute " regulation 323(1) or 324(1) of the 2012 Regulations ".

59. In regulation 49(5) (offences) for "the Act" substitute " the 2012 Regulations ".

60. In regulation 53(3) (construction of references to specified publications) for "section 103(1) of the Act" substitute " regulation 321(1) of the 2012 Regulations ".

61. In paragraph 4(2) of Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

62. In Schedule 7 (standard provisions for manufacturing authorisations)—

(a) in Part 2—

(i) in paragraph 5 for "the Act" substitute " the 2012 Regulations ",

(ii) in paragraph 9 for "the Act or any regulations under the Act" substitute " or the 2012 Regulations ", and

(iii) in paragraph 13—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations "; and

(b) in Part 3—

(i) in paragraph 6 for "the Act" in the first place where it occurs substitute " the 2012 Regulations ", and

(ii) in paragraph 8—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations ".

63. In paragraph 5(2) of Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

64. For Schedule 9 substitute the following Schedule—

"SCHEDULE 9 Regulation 47(1)

MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE 2012 REGULATIONS SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

1. The modifications of the 2012 Regulations mentioned in regulation 47 are as follows.

2. In regulation 2 (medicinal products)—

(a) at the beginning of paragraph (1) insert " Subject to paragraph (3), "; and

(b) after paragraph (2) insert the following paragraph—

"(3) "Medicinal product" includes any investigational medicinal product.".

2. In regulation 8(1) (interpretation)—

(a) the definition "assemble" is substituted by the definition of that expression in regulation 2(1) of these Regulations; and

(b) there is inserted in the appropriate position in alphabetical order a definition "container" in the same terms as the definition of that expression in regulation 2(1) of these Regulations; and

(c) the definition "qualified person" is substituted by the definition of that expression in regulation 2(1) of these Regulations.

3. In regulation 322(1) (validity of decisions and proceedings) omit "or" and insert a comma before " 8 (Article 126a authorisations) ", and after those words insert " or the Clinical Trials Regulations ".

4. In regulation 325(1) (rights of entry) insert after sub-paragraph (b) the following sub-paragraph—

"(ba) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations;".

5.—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (b) omit "; or";

(b) after sub-paragraph (c) insert " ; or " and the following sub-paragraph—

"(d) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations.".

(3) After paragraph (2)(g) insert the following sub-paragraph—

"(h) information and documents relating to clinical trials".

(4) In paragraph (3)—

(a) omit "or" following sub-paragraph (a); and

(b) following paragraph (b) insert " ; or " and the following sub-paragraph—

"(c) a medicinal product used, or intended to be used, in a clinical trial".

(5) In paragraph (4)—

(a) after "require" insert " — (a) "; and

(b) after "control" insert " ; or " and the following sub-paragraph—

"(b) a person associated with a clinical trial to produce information or documents relating to the clinical trial which are in the person's possession or under the person's control".

(6) In paragraph (5)(a) for "(2)(f) or (g)" substitute " (2)(f), (g) or (h) ".

(7) After paragraph (9) insert the following paragraph—

"(10) In this regulation, "a person associated with a clinical trial means any of the following—

(a) the sponsor of a clinical trial (within the meaning of regulation 3 of the Clinical Trials Regulations);

(b) any person who, under arrangements made with the sponsor of a clinical trial, carries out functions of the sponsor of the trial;

(c) in investigator for a clinical trial (within the meaning of regulation 2(1) of the Clinical Trials Regulations);

(d) any person, other than an investigator, who conducts a clinical trial;

(e) any person occupying premises at which a clinical trial is being conducted; or

(f) any person who, in the course of employment with a person listed in any of sub-paragraphs (a) to (e), undertakes activities in connection with a clinical trial.".

(8) In regulation 335(6) (contravention due to fault of another person) omit "and" after sub-paragraph (e) and after sub-paragraph (f) insert " ; and " and the following sub-paragraph—

"(g) any obligation or prohibition under the Clinical Trials Regulations".

(9) In regulation 336(3) (warranty as defence) omit "and" after sub-paragraph (c) and after sub-paragraph (d) insert " ; and " and the following sub-paragraph—

"(e) regulation 46 of the Clinical Trials Regulations (labelling)"."

PART 5

Other United Kingdom, Scotland and Wales Secondary legislation

Medicines (Administration of Radioactive Substances) Regulations 1978

65. In regulation 8(1) of the Medicines (Administration of Radioactive Substances) Regulations 1978 [M162]—

(a) for "Section 6(2) of the Act" substitute "Regulation 6(3) of the Human Medicines Regulations 2012 ("the 2012 Regulations"); and

(b) for "by or under the Act" substitute " by the 2012 Regulations ".

Marginal Citations

M162 S.I. 1978/1006, as amended by S.I. 1995/2147 and S.I. 2006/2407. There are other amendments, but none is relevant.

Importation of Animal Products and Poultry Products Order 1980

66. In the Schedule to the Importation of Animal Products and Poultry Products Order 1980 [M163], for "or the Medicines for Human Use (Marketing Authorisations Etc. Regulations) 1994" substitute " or the Human Medicines Regulations 2012 ".

Marginal Citations

M163 S.I. 1980/14, as amended by S.I. 1994/2920, S.I. 1994/3142 and S.I. 1994/3144.

Medicines Act (Hearings by Persons Appointed) (Scotland) Rules 1986

67. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986 [M164]—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "the appropriate Ministers as defined in section 1(2)" substitute " the Ministers as defined in regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012 ".

Marginal Citations

M164 S.I. 1986/1700. There are amendments, but none is relevant.

Medicines Act (Hearings by Persons Appointed) Rules 1986

68. In rule 2 of The Medicines Act (Hearings by Persons Appointed) Rules 1986 [M165]—

(a) in the definition "applicant" omit the words "a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or";

(b) in the definition "person appointed" omit—

(i) sub-paragraphs (i), (ii), (iii), (v) and (vi), and

(ii) the words following sub-paragraph (vii), from "including" until the end of the definition; and

(c) in the definition "relevant Minister"—

(i) omit sub-paragraph (i), and

(ii) in sub-paragraph (ii) for "section 1(1)" substitute " regulation 6(6) and (7) (the licensing authority and the Ministers) of the Human Medicines Regulations 2012 ".

Marginal Citations

M165 S.I. 1986/1761, as amended by S.I. 2006/2407. There are other amendments, but none is relevant.

Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989

69.—(1) The Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989 [M166] is amended as follows.

(2) In article 1(2) insert after the definition " the 1987 Act " the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(3) In Schedule 1—

(a) in paragraph 1 omit ", II" and ", VI";

(b) after paragraph 1 insert the following paragraph—

"**1A.** Functions of the Ministers under the 2012 Regulations (except those under Part 15 (British Pharmacopeia) of those Regulations), subject to paragraph 11 below.".

(c) in paragraph 2 for "Part II of the 1968 Act " substitute "Parts 3 to 8 of the 2012 Regulations";

(d) for paragraph 3 substitute—

"**3.** Functions of the Commission on Human Medicines, whose continuation is provided for in regulation 9 of the 2012 Regulations (except those under Part 15 (British Pharmacopoeia) of those Regulations).";

(e) for paragraph 4 substitute—

"**4.** Functions of any expert committee appointed by the licensing authority under the 2012 Regulations.".

(f) for paragraph 8 substitute—

"**8.** Functions of reviewers appointed under the 2012 Regulations.".

(g) omit paragraphs 9A, 9C and 9D;

(h) in paragraph 10(c) for "and of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " and of the 2012 Regulations " and

(i) in paragraph 11—

(i) after "Paragraphs 1" insert " , 1A ", and

(ii) after "under it" insert " or under the 2012 Regulations ".

Marginal Citations

M166 S.I. 1989/684, as amended by S.I. 1995/871, S.I. 2004/1031 and S.I. 2005/2754. There are other amendments, but none is relevant.

Medical Devices (Consultation Requirements) (Fees) Regulations 1995

70. In regulation 1(2) of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995 [M167]—

(a) in the definition "authorised medicinal product"—

(i) in sub-paragraph (b) before "under" insert " the Human Medicines Regulations 2012 or ", and

(ii) in sub-paragraph (c) for "those" substitute " the latter "; and

(b) in the definition "product licence of right" for "section 25(4) of that Act" substitute " paragraph 3(2) of Schedule 32 to the Human Medicines Regulations 2012 ".

Marginal Citations

M167 S.I. 1995/449

Prescription Only Medicines (Human Use) Order 1997

71.—(1) The Prescription Only Medicines (Human Use) Order 1997 [M168] is amended as follows.

(2) In article 1—

(a) in paragraph (2) omit all the defined expressions except "inhaler" and "maximum strength";

(b) for paragraph (2A) substitute—

"(2A) In this Order, unless the context otherwise requires, any expression defined by any provision of the Human Medicines Regulations 2012 has the same meaning as it has for the purposes of those Regulations.";

(c) in paragraph (5) for "Schedules 1, 2, 3A and 5" substitute " Schedules 1 and 2 "; and

(d) omit paragraphs (6) to (9).

(3) In article 5(1) for the words from the beginning of the paragraph until sub-paragraph (a) substitute "A medicinal product that is not the subject of a marketing authorisation is a prescription only medicine for the purposes of the Human Medicines Regulations 2012 if it, or a substance in it, is listed in column 1 of Schedule 1, unless there".

(4) In paragraphs (1) and (2) of article 10 for the words "The restrictions" to "administration of" substitute " A medicinal product is not a prescription only medicine for the purposes of the Human Medicines Regulations 2012 by virtue of Article 5(1) if it is ".

Marginal Citations

M168 S.I. 1997/1830, as amended by S.I. 1997/2044, S.I. 1998/108, S.I. 1998/1178, S.I. 1998/2081, S.I. 1999/1044, S.I. 1999/3463, S.I. 2000/1917, S.I. 2000/2899, S.I. 2000/3231, S.I. 2001/2777, S.I. 2001/3942, S.I. 2003/696, and S.I. 2006/915. There are other amendments, but none is relevant.

General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999

72. In rule 7B(b) of the Schedule to the General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999 [M169], for the words from "article" to the end of the paragraph substitute " regulation 215 (prescribing and administration by supplementary prescribers) " of the Human Medicines Regulations 2012.

Marginal Citations

M169 S.I. 1999/3267, as amended by S.I. 2005/1476. There are other amendments, but none is relevant.

National Health Service (Charges for Drugs and Appliances) Regulations 2000

73. The National Health Service (Charges for Drugs and Appliances) Regulations 2000 [M170] are amended as follows—

[F1182](a) . . . . . .

(b) in regulation 6A(6) for the words from "the Medicines" to the end of the paragraph substitute " the Human Medicines Regulations 2012 ".

Textual Amendments

F1182 Sch. 34 para. 73(a) revoked (E.) (1.4.2015) by The National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570), reg. 1, **Sch. 3**

Marginal Citations

M170 S.I. 2000/620, as amended by S.I. 2000/3189 and S.I. 2009/1166. There are other amendments, but none is relevant.

Biocidal Products Regulations 2001

74. In Schedule 2 to the Biocidal Products Regulations 2001 [M171]—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations

M171 S.I. 2001/880, as amended by S.I. 2010/745. There are other amendments, but none is relevant.

Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001

75. In article 4(4) of the Medicines (Aristolochia and Mu Tong etc) (Prohibition Order) 2001 [M172], for the words following "marketing authorisation" to the end of the paragraph substitute " , certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. "

Marginal Citations

M172 S.I. 2001/1841, as amended by S.I. 2005/2750 and S.I. 2008/548.

Misuse of Drugs Regulations 2001

76. In regulation 2(1) of the Misuse of Drugs Regulations 2001 [M173]—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "pharmacist independent prescriber", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in the definitions "pharmacist" and "registered pharmacy" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M173 S.I. 2001/3998, as amended by S.I. 2003/2429, S.I. 2005/271, S.I. 2006/986, S.I. 2006/1450, S.I. 2007/2154 and 2012/973. There are other amendments, but none is relevant.

Medicines for Human Use (Kava-kava) (Prohibition Order) 2002

77. In paragraph (d) of article 3 of the Medicines for Human Use (Kava-kava) (Prohibition Order) 2002 [M174], for the words following "subject" to the end of the article substitute " of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. ".

Marginal Citations

M174 S.I. 2002/3170, as amended by S.I. 2005/2750 and S.I. 2008/548.

Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003

[F1183]**78.** . . . . . .

Textual Amendments

F1183 Sch. 34 para. 78 revoked (1.4.2022) by The Medicines and Healthcare Products Regulatory Agency Trading Fund (Revocation) Order 2022 (S.I. 2022/90), art. 1, **Sch.**

Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003

79. In the column "specified UK laws" of the Schedule to the Enterprise Act 2002 (Part 8 Community Infringements Specified UK Laws) Order 2003 [M175] for "the Medicines (Advertising) Regulations 1994" substitute " Chapters 1 and 2 of Part 14 (advertising) of the Human Medicines Regulations 2012 ".

Marginal Citations

M175 S.I. 2003/1374. There are amendments, but none is relevant.

Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003

80. In the Schedule to the Enterprise Act 2002 (Part 8 Notice to OFT of Intended Prosecution Specified Enactments, Revocation and Transitional Provision) Order 2003 [M176]—

(a) in the first column, insert in the appropriate position in alphabetical order " Human Medicines Regulations 2012 ";

(b) in the second column, insert adjacent to the entry " Human Medicines Regulations 2012 " in the first column "regulation 303 (advertising offences)"; and

(c) omit "Medicines (Advertising) Regulations 1994" in the first column and the adjacent entry "regulation 23 (offences)" in the second column.

Marginal Citations

M176 S.I. 2003/1376. There are amendments, but none is relevant.

Health Professions (Parts of and Entries in the Register) Order of Council 2003

81. In article 6 of the Health Professions (Parts of and Entries in the Register) Order of Council 2003 [M177]—

(a) for sub-paragraph (b) of paragraph (2), up to and including the word "analgesics", substitute—

"(b) referred to in the following provisions of Schedule 17 (exemption for sale, supply or administration by certain persons) to the Human Medicines Regulations 2012 —

(i) in Part 1 (exemption from restrictions on sale or supply of prescription only medicines), paragraph 11 (certificate of competence in the use of specified medicines), or

(ii) in Part 3 (exemptions from the restriction on administration of prescription only medicines), paragraph 1 (certificate in the use of analgesics),"; and

(b) in paragraph (3) for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M177 S.I. 2003/1571, as amended by S.I. 2006/1996. There are other amendments, but none is relevant.

Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

82.—(1) The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [M178] (interpretation) are amended as follows.

(2) In regulation 1(2)—

(a) omit the following definitions—

(i) "the 1994 Regulations", and

(ii) "herbal remedy";

(b) before the definition of "the appropriate committee" insert—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(c) for the definition of "the appropriate committee" substitute—

""the appropriate committee" means whichever the appropriate Minister considers to be the appropriate body of the following—

(a) the Commission; or

(b) an expert committee appointed by the appropriate Minister, or by the appropriate Ministers for Great Britain and for Northern Ireland acting jointly;";

(d) after the definition of "the appropriate Minister" insert—

""the Commission" means the Commission on Human Medicines continued in existence by regulation 9 of the 2012 Regulations;";

(e) for the definition of "excluded medicine" substitute—

""excluded medicine" means a medicinal product to which the restrictions in regulation 46 (requirement for authorisation) of the 2012 Regulations do not apply by virtue of regulation 3(6) (scope of these Regulations: special provisions) or 4(1) (special provisions for pharmacies etc) of those Regulations;";

(f) in the definition of "market" for the words from "have the same meaning" to the end substitute " are to be construed in accordance with the 2012 Regulations; ";

(g) for the definition of "medicinal product" substitute—

""medicinal product" has the meaning given by regulation 2 of the 2012 Regulations;"; and

(h) in the definition of "unlicensed product"—

(i) in paragraph (a)(i), for "the 1994 Regulations" substitute " the 2012 Regulations ",

(ii) omit paragraph (b) and the word "or" following it,

(iii) for paragraph (c) substitute—

"(c) no traditional herbal registration has been granted by the licensing authority under the 2012 Regulations;", and

(iv) after that paragraph insert the word " or " and the following paragraph —

"(d) no Article 126a authorisation has been granted by the licensing authority under those regulations;".

Marginal Citations

M178 S.I. 2003/1680, as amended by S.I. 2004/3224, S.I. 2005/2750 and S.I. 2005/2754.

National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004

83.—(1) The National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004 [M179] are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 ".

(3) In paragraph 41(2)(a) of Schedule 5—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M179 S.S.I. 2004/115, as amended by S.S.I. 2005/337. There are other amendments, but none is relevant.

National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004

84.—(1) The National Health Service (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 [M180] are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition "the POM Order"; and

(b) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 ".

(3) In paragraph 13(2)(a) of Schedule 1—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M180 S.S.I. 2004/116, as amended by S.S.I. 2005/336. There are other amendments, but none is relevant.

National Health Service (General Medical Services Contracts) Regulations 2004

[F1184]**85.** . . . . . .

Textual Amendments

F1184 Sch. 34 para. 85 revoked (E.) (7.12.2015) by The National Health Service (General Medical Services Contracts) Regulations 2015 (S.I. 2015/1862), reg. 1(2), **Sch. 5** (with reg. 2)

National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

86.—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 [M181] are amended as follows.

(2) In regulation 2—

(a) in paragraph (1)—

(i) omit the definition "the POM Order"; and

(ii) in the definition "prescription only medicine" for the words from "article" to the end of the definition substitute " regulation 5(3) (classification of medicinal products) of the Human Medicines Regulations 2012 "; and

(b) in paragraph (3) for "the POM Order" substitute " the Human Medicines Regulations 2012 ".

(3) In paragraph 43(2)(a) of Schedule 6—

(a) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(b) for "that Order" substitute " those Regulations ".

Marginal Citations

M181 S.I. 2004/478, as amended by S.I. 2006/358 and S.I. 2010/1647. There are other amendments, but none is relevant.

National Health Service (Personal Medical Services Agreements) Regulations 2004

[F1185]**87.** . . . . . .

Textual Amendments

F1185 Sch. 34 para. 87 revoked (E.) (7.12.2015) by The National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879), reg. 1(2), **Sch. 4** (with regs. 2, 88)

National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004

88. In Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004 [M182] for "article 12F of the Prescription Only Medicines (Human Use) Order 1997 or article 8 of the Medicines (Pharmacy and General Sale-Exemptions) Order 1980", in both places where those words occur, substitute " regulation 247 (exemption for supply in the event or anticipation of pandemic disease) of the Human Medicines Regulations 2012 ".

Marginal Citations

M182 S.I. 2004/1022, as amended by S.I 2005/366 and S.I. 2009/1977. There are other amendments, but none is relevant.

Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004

89.—(1) The Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004 [M183] is amended as follows.

(2) In article 2(1)—

(a) omit the definition "the 1994 Regulations"; and

(b) after the definition "the 2003 Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;".

(3) In article 7—

(a) in paragraph (1) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations "; and

(b) in paragraph (2)—

(i) for "the 1994 Regulations" substitute " the 2012 Regulations ", and

(ii) for the words from "the following" to the end of the paragraph substitute " regulation 314 of the 2012 Regulations ".

(4) In article 8(3)(d) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations ".

(5) In article 11—

(a) in paragraph (2) for "the 1994 Regulations" substitute " the 2012 Regulations "; and

(b) in paragraph (3)—

(i) for "section 1(1)(a) of the Medicines Act 1968" substitute " regulation 6(6) of the 2012 Regulations ", and

(ii) for "the 1994 Regulations" substitute " Chapter 3 (monitoring of advertising) of Part 14 of the 2012 Regulations ".

Marginal Citations

M183 S.I. 2004/1975.

General Optical Council (Registration Rules) Order of Council 2005

90. In the Table in rule 10 of the Schedule to the General Optical Council (Registration Rules) Order of Council 2005 [M184]—

(a) in entry B column 3—

(i) in paragraph (a) for "paragraph 6A of Schedule 5 to the Prescription Only Medicines (Human Use) Order 1997" substitute " paragraph 8 of Part 1 of Schedule 17 of the Human Medicines Regulations 2012 ", and

(ii) in paragraph (b) for "6B" substitute " 9 ";

(b) in entry C column 3 for "article 3B of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(c) in entry D column 3 for "article 3 of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations

M184 S.I. 2005/1478, as amended by S.I. 2008/1940. There are other amendments, but none is relevant.

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007

91.—(1) The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 [M185] are amended as follows.

(2) In regulation 2(1) omit the definition of "the POM Order".

(3) In regulation 2(2A) for "the POM Order" substitute " the Human Medicines Regulations 2012 ".

(4) In regulation 7(2) for the words from "the Medicines" to the end of the regulation substitute " the Human Medicines Regulations 2012 ".

(5) In regulation 7A(1)(b) for the words from "article 12F" to the end of the regulation substitute " regulation 247 of the Human Medicines Regulations 2012 ".

Marginal Citations

M185 S.I. 2007/121, as amended by S.I. 2009/1175 and S.I. 2010/1647. There are other amendments, but none is relevant.

Human Tissue (Quality and Safety for Human Application) Regulations 2007

92. In regulation 2(3) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 [M186]—

(a) omit sub-paragraph (a); and

(b) for sub-paragraph (b) substitute—

"(b) the Human Medicines Regulations 2012;".

Marginal Citations

M186 S.I. 2007/1523.

Legislative and Regulatory Reform (Regulatory Functions) Order 2007

93.—(1) The Schedule to the Legislative and Regulatory Reform (Regulatory Functions) Order 2007 [M187] is amended as follows.

(2) In Part 2 under the heading "Medicines"—

(a) omit the entries—

"Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994",

"Medicines (Advertising) Regulations 1994",

"Medicines (Monitoring of Advertising) Regulations 1994",

"Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994",

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005", and

"Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012".

(3) In Part 3 under the heading "Public health and safety"—

(a) omit the entries—

"Medicines (Advertising) Amendment Regulations 2004", and

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(4) In Part 6—

(a) omit the entry—

"Medicines (Advertising) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(5) In Part 8—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(6) In Part 13—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Marginal Citations

M187 S.I. 2007/3544, as amended by S.I. 2009/2981. There are other amendments, but none is relevant.

Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008

94. In paragraph (d) of article 3 of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 [M188], for the words following "subject" to the end of

the article substitute " of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation within the meaning of the Human Medicines Regulations 2012. ".

Marginal Citations
M188 S.I. 2008/548.

Specified Animal Pathogens Order 2008

95. In article 5(2) of the Specified Animal Pathogens Order 2008 [M189]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 "; and

(b) omit sub-paragraph (c).

Marginal Citations
M189 S.I. 2008/944. There are amendments, but none is relevant.

Specified Animal Pathogens (Wales) Order 2008

96. In article 5(2) of the Specified Animal Pathogens (Wales) Order 2008 [M190]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 "; and

(b) omit sub-paragraph (c).

Marginal Citations
M190 S.I. 2008/1270. There are amendments, but none is relevant.

Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008

97. In regulation 1(2) of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No 2) Regulations 2008 [M191] in the definition "prescription only medicine", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M191 S.I. 2008/3258. There are amendments, but none is relevant.

Specified Animal Pathogens (Scotland) Order 2009

98. In article 5(2) of the Specified Animal Pathogens (Scotland) Order 2009 [M192]—

(a) in sub-paragraph (b) for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;" substitute " the Human Medicines Regulations 2012. "; and

(b) omit sub-paragraph (c).

Marginal Citations
M192 S.S.I. 2009/45. There are amendments, but none is relevant.

National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

99.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 [M193] are amended as follows.

(2) In regulation 2(1)—

(a) in the definition "clinical management plan" for the words from "article" to the end of the definition substitute " regulation 8(1) of the Human Medicines Regulations 2012 ";

(b) in the definition "non-proprietary name"—

(i) for "section 103(5) of the 1968 Act" in both places where it occurs substitute "regulation 321(3) of the Human Medicines Regulations 2012, and

(ii) for "section 100 of that Act" substitute " regulation 318 of those Regulations ";

(c) in the definition "Patient Group Direction" for the words from "Article" to the end of the definition substitute " regulation 213 of the Human Medicines Regulations 2012 "; and

(d) in the definition "supply form" for the words from "Article" to the end of the definition substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012 ".

(3) In Schedule 1—

(a) in paragraph 4—

(i) in sub-paragraph (23) for "Article 12C of the Prescription Only Medicines (Human Use) Order 1997 (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012 "; and

(ii) in sub-paragraph (29) for "paragraph (4) of article 8 of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 225 (emergency sale etc by pharmacist: at patient's request) of the Human Medicines Regulations 2012 "; and

(b) in paragraph 10(8) for "article 12C of the Prescription Only Medicines (Human Use) Order 1997, (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction)" substitute " regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) of the Human Medicines Regulations 2012, ".

Marginal Citations
M193 S.S.I. 2009/183.

Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009

100.—(1) The Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009 [M194] is amended as follows.

(2) In Part 1 of Schedule 1, to the entry "Medicines Act 1968 (section 109)" add "or Human Medicines Regulations 2012 (regulation 323)".

(3) In Part 2 of Schedule 1—

(a) omit the entry—

"Medicines (Advertising) Regulations 1994"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Chapters 1 and 2 of Part 14 (advertising) of those Regulations".

(4) In Part 4 of Schedule 1—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for human use) Regulations 2005"; and

(b) add in the appropriate place the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

(5) In Part 2 of Schedule 2—

(a) omit the entry—

"Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005"; and

(b) add the entry—

"Human Medicines Regulations 2012, in relation to Part 7 (traditional herbal registrations) of those Regulations".

Marginal Citations

M194 S.I. 2009/669. There are amendments, but none is relevant.

Single Use Carrier Bags Charge (Wales) Regulations 2010

101. In Schedule 1(3) to the Single Use Carrier Bags Charge (Wales) Regulations 2010 [M195]—

(a) in the definition "EEA health professional" for the words from "1(2)" to the end of the definition substitute " 213(1) of the Human Medicines Regulations 2012 ";

(b) in the definition "pharmacy medicine" for the words from "means" to the end of the definition substitute " has the meaning given in regulation 5(5) of the Human Medicines Regulations 2012 ";

(c) in the definition "prescription only medicine" for the words from "means" to the end of the definition substitute " has the meaning given in regulation 5(3) of the Human Medicines Regulations 2012 "; and

(d) in the definition beginning "supplementary prescriber" for "article 1(2) of the Prescription Only Medicines (Human Use) Order 1997" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations

M195 S.I. 2010/2880. There are amendments, but none is relevant.

PART 6

Northern Ireland statutory rules

Control of Pesticides Regulations (Northern Ireland) 1987

102. For regulation 3(2)(b)(i) of the Control of Pesticides Regulations (Northern Ireland) 1987 [M196] substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations

M196 S.R. (NI) 1987 No 414, as amended by S.R. (NI) 1997 No 469.

Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995

103. In rule 4 of the Prison and Young Offenders Centre (Amendment) Rules (Northern Ireland) 1995 [M197]—

(a) omit the definition "the 1997 Order";

(b) in the definitions "nurse independent prescriber" and "pharmacist independent prescriber" for "article 1(2) of the 1997 Order" substitute " regulation 8(1) of the Human Medicines Regulations 2012 "; and

(c) in the definition "prescription only medicine" for "article 1(2) of the 1997 Order" substitute " regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations

M197 S.R. (NI) 1995 No 8, as amended by S.R. (NI) 2009 No 429. There are other amendments, but none is relevant.

Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996

104. In the Schedule to the Diseases of Animals (Importation of Bird Products) Order (Northern Ireland) 1996 [M198] for "Medicines Act 1968" substitute " Human Medicines Regulations 2012 ".

Marginal Citations

M198 S.R. (NI) 1996 No 81.

Pharmaceutical Services Regulations (Northern Ireland) 1997

105. In Part 2 of Schedule 2 to the Pharmaceutical Services Regulations (Northern Ireland) 1997 [M199], in paragraph 2(12) for the words from "Articles" to the end of the paragraph substitute regulation 224 of the Human Medicines Regulations 2012".

Marginal Citations

M199 S.R. (NI) 1997 No 381, as amended by S.R. (NI) 1999 No 405. There are other amendments, but none is relevant.

Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998

106. In Schedule 1, Chapter 4, Section 4.8, Part C of the Industrial Pollution Control (Prescribed Processes and Substances) Regulations (Northern Ireland) 1998 [M200], for the words from "means" to the end of the Part substitute " has the meaning given in regulation 2 of the Human Medicines Regulations 2012 ".

Marginal Citations

M200 S.R. (NI) 1998 No 28.

Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998

107. The Products of Animal Origin (Import and Export) Regulations (Northern Ireland) 1998 [M201] are amended as follows—

(a) in regulation 10(1)(a) for "section 8 of the Medicines Act 1968" substitute " regulation 17 of the Human Medicines Regulations 2012 "; and

(b) in regulation 11(1) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M201 S.R. (NI) 1998 No 45, as amended by S.R. (NI) 2011 No 124.

Importation of Animal Pathogens Order (Northern Ireland) 1999

108. In article 5(a) of the Importation of Animal Pathogens Order (Northern Ireland) 1999 [M202] for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M202 S.R. (NI) 1999 No 433.

Biocidal Products Regulations (Northern Ireland) 2001

109. In Schedule 2 to the Biocidal Products Regulations (Northern Ireland) 2001 [M203]—

(a) omit entry (f); and

(b) for entry (i) substitute—

"(i) the Human Medicines Regulations 2012;".

Marginal Citations

M203 S.R. (NI) 2001 No 422.

Misuse of Drugs Regulations (Northern Ireland) 2002

110.—(1) The Misuse of Drugs Regulations (Northern Ireland) 2002 [M204] are amended as follows.

(2) In regulation 2(2)—

(a) in the definitions "clinical management plan", "nurse independent prescriber", "patient group direction", "registered chiropodist", "registered midwife", "registered nurse", "registered occupational therapist", "registered optometrist", "registered orthoptist", "registered orthotist and prosthetist", "registered paramedic", "registered physiotherapist", "registered radiographer" and "supplementary prescriber", for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in the definition "medicinal product" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 "

(3) In regulation 6A(1)(e) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

(4) In regulation 8(2)—

(a) in sub-paragraph (h) after the first occurrence of "the Medicines Act 1968" insert " or of Schedule 31 to the Human Medicines Regulations 2012 "; and

(b) in sub-paragraph (j) after "the Medicines Act 1968" insert " or of regulation 324 of the Human Medicines Regulations 2012 ".

(5) In regulation 9(2)—

(a) in sub-paragraph (f) after "the Medicines Act 1968" insert " or of Schedule 31 to the Human Medicines Regulations 2012 "; and

(b) in sub-paragraph (h) after "the Medicines Act 1968" insert " or of regulation 324 of the Human Medicines Regulations 2012 ".

(6) In regulation 11(1) for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

(7) In regulation 17—

(a) after "the Medicines Act 1968" insert " or of the Human Medicines Regulations 2012 "; and

(b) after "that Act" insert " or of those Regulations ".

(8) In regulation 18 for paragraph (3) substitute—

"(3) In this regulation, "clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004.".

Marginal Citations

M204 S.R. (NI) 2002 No 1, as amended by S.R. (NI) 2003 No 324, S.R. (NI) 2003 No 420, S.R. (NI) 2005 No 119, S.R. (NI) 2005 No 564, S.R. (NI) 2006 No 214, S.R. (NI) 2006 No 264, and S.R. (NI) 2007 No 348.

Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003

111. In regulation 5(2)(c) of the Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 [M205] for "section 58 of the Medicines Act 1968" substitute " regulation 214 of the Human Medicines Regulations 2012 ".

Marginal Citations

M205 S.R. (NI) 2003 No 34.

Waste Management Licensing Regulations (Northern Ireland) 2003

112. In paragraph 2 of Schedule 1 to the Waste Management Licensing Regulations (Northern Ireland) 2003 [M206], in the definition "hazardous waste" for the words following " "medicinal product" means" to the end of the definition substitute " a prescription only medicine within the meaning of regulation 5(3) of the Human Medicines Regulations 2012 ".

Marginal Citations

M206 S.R. (NI) 2003 No 493.

Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004

113.—(1) The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 [M207] are amended as follows.

(2) In regulation 2—

(a) in the definition "licensing authority" for "section 6(3) of the Medicines Act 1968" substitute " regulation 6 of the Human Medicines Regulations 2012 ";

(b) omit the definition "the POM Order" and

(c) in the definition "prescription only medicine" for the words from "referred" to the end of the definition substitute " within the meaning of regulation 5(3) of the Human Medicines Regulations 2012 ".

(3) In regulation 47(2) for the words from "Part 3" to the end of the regulation substitute " Part 12 of the Human Medicines Regulations 2012 ".

(4) In Schedule 5—

(a) in paragraph 11A(1) in the definition "Patient Group Direction" for "the Prescription Only Medicines (Human Use) Order 1997" substitute " the Human Medicines Regulations 2012 "; and

(b) in paragraph 41(2)(a)—

(i) for "article 3B(3) of the POM Order" substitute " regulation 215 of the Human Medicines Regulations 2012 "; and

(ii) for "that Order" substitute " those Regulations ".

Marginal Citations

M207 S.R. (NI) 2004 No 140, as amended by S.R. (NI) 2005 No 368.

Nursing Homes Regulations (Northern Ireland) 2005

114. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005 [M208] for "section 58 of the Medicines Act 1968" substitute " regulation 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations

M208 S.R. (NI) 2005 No 160.

Residential Care Homes Regulations (Northern Ireland) 2005

115. In regulation 13(6)(b) of the Nursing Homes Regulations (Northern Ireland) 2005 [M209] for "section 58 of the Medicines Act 1968" substitute " regulation 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations

M209 S.R. (NI) 2005 No 161.

Children's Homes Regulations (Northern Ireland) 2005

116. In regulation 20(4)(b) of the Children's Homes Regulations (Northern Ireland) 2005 [M210], for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations

M210 S.R. (NI) 2005 No 176.

Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006

117. In regulation 3(1) of the Healthy Start Scheme and Day Care Food Scheme Regulations (Northern Ireland) 2006 [M211] in the definition "Pharmacist" for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations

M211 S.R. (NI) 2006 No 478.

Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007

118. In regulation 71(3)(a) of the Avian Influenza and Influenza of Avian Origin in Mammals Regulations (Northern Ireland) 2007 [M212], for "section 8(2) of the Medicines Act 1968" substitute " regulation 17 of the Human Medicines Regulations 2012 ".

Marginal Citations
M212 S.R. (NI) 2007 No 68.

Day Care Setting Regulations (Northern Ireland) 2007

119. In regulation 13(6)(b) of the Day Care Setting Regulations (Northern Ireland) 2007 [M213] for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations
M213 S.R. (NI) 2007 No 234.

Residential Family Centres Regulations (Northern Ireland) 2007

120. In regulation 13(4)(b) of the Residential Family Centres Regulations (Northern Ireland) 2007 [M214] for "section 58 of the Medicines Act 1968" substitute " regulations 214 or 215 of the Human Medicines Regulations 2012 ".

Marginal Citations
M214 S.R. (NI) 2007 No 236.

Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007

121. In regulation 3(1)(a) of the Natural Mineral Water, Spring Water and Bottled Drinking Water Regulations (Northern Ireland) 2007 [M215] for "the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M215 S.R. (NI) 2007 No 420.

Specified Animal Pathogens Order (Northern Ireland) 2008

122. In article 5(2)(b) of the Specified Animal Pathogens Order (Northern Ireland) 2008 [M216] for "the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M216 S.R. (NI) 2008 No 336.

Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

123. In regulation 2(2) of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 [M217], in the definition "retail pharmacy business" for "section 132 of the Medicines Act 1968" substitute " regulation 8(1) of the Human Medicines Regulations 2012 ".

Marginal Citations
M217 S.R. (NI) 2009 No 225.

Private Water Supplies Regulations (Northern Ireland) 2009

124. In regulation 4(b) of the Private Water Supplies Regulations (Northern Ireland) 2009 [M218] for "the Medicines Act 1968" substitute " the Human Medicines Regulations 2012 ".

Marginal Citations
M218 S.R. (NI) 2009 No 413.

SCHEDULE 35 Regulation 349

Repeals and revocations

Enactment or instrument	*Extent of repeal or revocation*
Medicines Act 1968 (c. 67)	Sections 2A to 9. Section 10(7). Sections 11 to 14. Section 15(1) and (2). Sections 16 to 57. Section 58(1A), (2) and (3). Sections 59 to 61. Sections 65 and 66. Section 67(3A), (5) and (6). Section 68. Sections 85 and 86. Section 89. Section 91(1). Sections 92 to 103. Section 108(3) to (5) and (7). Section 109(3). Section 110(3). Section 111(3).

	Section 112(7). Sections 115 and 116. Section 126(4). Section 130(2) to (8) and (10). Section 132(2), (3) and (5). Schedules 1A and 2. In Schedule 3, paragraphs 5 to 7.
Medicines (Extension to Antimicrobial Substances) Order 1973 (S.I. 1973/367)	The whole Order.
Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968)	The whole Order.
Medicines (Fluted Bottles) Regulations 1978 (S.I. 1978/40)	The whole of the Regulations.
Medicines (Medicines Act 1968 Amendment) Regulations 1983 (S.I. 1983/1724)	The whole of the Regulations.
Medicines (Products Other than Veterinary Drugs) (General Sale List) Amendment Order 1990 (S.I. 1990/1129)	The whole Order.
Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605)	The whole of the Regulations.
Medicines Act 1968 (Amendment) Regulations 1993 (S.I. 1993/834)	The whole of the Regulations.
Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994/105)	The whole of the Regulations.
Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1994 (S.I. 1994/899)	The whole of the Regulations.
Medicines (Advertising) Regulations 1994 (S.I. 1994/1932)	The whole of the Regulations.
Medicines (Monitoring of Advertising) Regulations 1994 (S.I. 1994/1933)	The whole of the Regulations.
Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144)	The whole of the Regulations.
Medicines Act 1968 (Amendment) Regulations 1995 (S.I. 1995/2321)	The whole of the Regulations.
Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1996 (S.I. 1996/482)	The whole of the Regulations.
Prescription Only Medicines (Human Use) Order 1997 (S.I. 1997/1830)	The whole of the Order except articles 1(1) to (5), 5 and 10 and Schedules 1 and 2.

Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 1998 (S.I. 1998/3105)	The whole of the Regulations.
Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 (S.I. 1999/267)	The whole of the Regulations.
Medicines (Monitoring of Advertising) Amendment Regulations 1999 (S.I. 1999/784)	The whole of the Regulations.
Medicines (Codification Amendments Etc.) Regulations 2002 (S.I. 2002/236)	The whole of the Regulations
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2003 (S.I. 2003/1618)	The whole of the Regulations.
Medicines (Child Safety) Regulations 2003 (S.I. 2003/2317)	The whole of the Regulations.
Medicines (Advertising) Amendment Regulations 2004 (S.I. 2004/1480)	The whole of the Regulations.
Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765)	The whole Order.
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/768)	The whole of the Regulations.
Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094)	The whole of the Regulations except paragraph 12(1), (4) and (5) of Schedule 1, and regulation 8 as it relates to those paragraphs.
Medicines (Sale or Supply) (Miscellaneous Amendments) Regulations 2005 (S.I. 2005/1520)	The whole of the Regulations.
Medicines (Provision of False or Misleading Information and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/1710)	The whole of the Regulations.
Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750)	The whole of the Regulations except paragraph 8(a)(i) and (b) of Schedule 7, and regulation 12 as it relates to those paragraphs.
Medicines (Advisory Bodies) (No 2) Regulations 2005 (S.I. 2005/2754)	The whole of the Regulations, except Schedule 3, and regulation 4 as it relates to that Schedule, and paragraphs 3 and 7(1) and (3) of Schedule 4, and regulation 5 as it relates to those paragraphs.
Medicines (Advertising Amendments) Regulations 2005 (S.I. 2005/2787)	The whole of the Regulations.
Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/2789)	The whole of the Regulations.

Medicines (Traditional Herbal Medicinal Products for Human Use) (Consequential Amendment) Regulations 2006 (S.I. 2006/395)	The whole of the Regulations.
Medicines for Human Use (National Rules for Homoeopathic Products) Regulations 2006 (S.I. 2006/1952)	The whole of the Regulations.
Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 (S.I. 2008/1692)	The whole of the Regulations.
Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2008 (S.I. 2008/3097)	The whole of the Regulations.
Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (S.I. 2009/1164)	The whole of the Regulations, except regulation 3.
Medicines (Exemptions and Miscellaneous Amendments) Order 2009 (S.I. 2009/3062)	The whole Order.
Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882)	The whole of the Regulations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations consolidate the law of the United Kingdom concerning medicinal products for human use ("products") in respect of the topics described below.

Parts 1 (general) and 2 (administration) consolidate, with only minor and drafting amendments, the administration provisions in Part 1 of the Medicines Act 1968 ("the 1968 Act"), including the definition of the licensing authority as the body responsible for regulating products. Part 1 also provides for interpretation, and for special provisions concerning the applicability of the Regulations to a number of activities by pharmacists and others. The latter provisions consolidate, with only minor and drafting amendments, provisions in Part 2 of the 1968 Act, except for the repeal of section 10(7) of the Act, which concerns wholesale dealing by pharmacists.

Part 3 (manufacturing and wholesale dealing) of the Regulations governs the manufacture and importation of, and wholesale dealing in, products. It consolidates, with only minor and drafting amendments, the provisions of Part 2 of the 1968 Act, and statutory instruments made under powers in that Part, on these topics. In doing so the Regulations continue to implement the obligations of the United Kingdom under Titles IV and VII of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use ("the 2001 Directive") (OJ No L 311, 28.11.2001, p.67, as amended most recently by Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use (OJ No L 348, 31.12.2010, p.74) ("the 2010 Directive")).

Part 4 (requirement for authorisation) of the Regulations establishes that products must not be sold, supplied, or offered for sale or supply in the United Kingdom unless authorised, either by the United Kingdom licensing authority under the Regulations, or by the European Commission under Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community Procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("Regulation (EC) No 726/2004") (OJ No L 136, 30.4.2004, p.1, as amended most recently by Regulation (EU) No 1235/2010, OJ No L 348, 31.12.2010, p.1).
Parts 5 to 8 (marketing authorisations, certification of homoeopathic medicinal products, traditional herbal registrations and Article 126a authorisations) provide for the procedures for authorisation by the United Kingdom licensing authority of medicinal products in various categories. Part 5 (marketing authorisations) also provides for offences in the case of breach of the corresponding requirements in the procedures under Regulation (EC) No 726/2004, and for the breach of certain obligations under Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ No L 378, 27.12.2006, p.1, as amended by Regulation (EC) No 1902/2006 (OJ No L 378, 27.12.2006, p.20).
In respect of United Kingdom authorisation, Parts 4 to 8 of the Regulations consolidate, with only minor and drafting amendments, the following principal statutory instruments: the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144, as amended, most recently by S.I. 2010/1882) ("the marketing authorisations regulations"), the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S.I. 1994/105, as amended, most recently by S.I. 2006/2407) ("the homoeopathic regulations"), except in respect of fees provisions that are not being revoked, and the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750, as amended, most recently by S.I. 2010/1621) ("the traditional herbal regulations"). In doing so, the Regulations continue to implement Titles III and VI of the 2001 Directive. At the same time the Regulations repeal the parallel national scheme for the licensing of the sale and supply of products, found in Part 2 of the 1968 Act, but now almost entirely superseded by EU provision in this field.
Part 9 (borderline products) of the Regulations consolidates, with only minor and drafting amendments, provision in the marketing authorisations regulations for the licensing authority to determine whether products that are supplied without authorisation are medicinal products and thus subject to the Regulations.
Part 10 (exceptions) consolidates, with only minor and drafting amendments, provisions in the marketing authorisations regulations, the homoeopathic regulations and the traditional herbal regulations concerning exemptions from the requirement for authorisation.
Part 11 (pharmacovigilance) consolidates provisions in the marketing authorisations regulations and the traditional herbal regulations concerning the monitoring of the safety of medicines in clinical use. This Part also implements the amendments to Title IX of the 2001 Directive made by the 2010 Directive. Part 11 also provides for offences in the case of breach of the corresponding requirements under Regulation (EC) No 726/2004.
Part 12 (dealings with medicinal products) governs the circumstances in which products may be sold, supplied and administered, and consolidates, with only minor and drafting amendments, the greater part of Part 3 of the 1968 Act, certain provisions of the latter which are outside the scope of the 2001 Directive being left unrepealed.
Parts 1, 3, 5, 10 and 12 contain provisions consolidating the effect of the Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882). In so doing, the Regulations continue to make provision necessary for the operation of Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ No L324, 10.12.2007, p.21).

Part 13 (packaging and leaflets) Chapter 1 consolidates, with only minor and drafting amendments, provisions in the marketing authorisations regulations, the homoeopathic regulations and the traditional herbal registrations in respect of the information to be supplied with products, continuing to implement Title V of the 2001 Directive. Chapter 2 consolidates certain United Kingdom provisions on child safety in the presentation of products. Part 5 of the 1968 Act, which made parallel provision, is repealed, and the instruments made under it revoked, except in respect of certain powers outside the scope of the 2001 Directive.
Part 14 (advertising) consolidates, with only minor and drafting amendments, the Medicines (Advertising) Regulations 1994 (S.I. 1994/1932, as amended, most recently by S.I. 2006/2407) and the Medicines (Monitoring of Advertising) Regulations 1994 (S.I. 1994/1933, as amended, most recently by S.I. 2006/2407). In doing so, it continues to implement Titles VIII and VIIIa of the 2001 Directive. Part 6 of the 1968 Act, which made parallel provision, is repealed, and the instruments made under it revoked.
Part 15 (British Pharmacopoeia) consolidates, with only minor and drafting amendments, Part 7 of the 1968 Act.
Parts 16 (enforcement) and Part 17 (miscellaneous and general) consolidate, with only minor and drafting amendments, Part 8 (miscellaneous and supplementary provisions) of the 1968 Act as it concerns the topics in the Regulations. That Part remains in force, in amended form, in relation primarily to Part 4 (pharmacies) of the 1968 Act, which remains in force, and to certain other matters outside the scope of the 2001 Directive.
Impact assessments for these Regulations have been prepared and are available from the Medicines and Healthcare Products Regulatory Agency (“MHRA”), 151 Buckingham Palace Road, London SW1W 9SZ, and published with the explanatory memorandum alongside the Regulations on www.legislation.gov.uk. A transposition note for the 2010 Directive has been prepared, and is also available from MHRA.

Status:
Point in time view as at 06/11/2023.

Changes to legislation:
The Human Medicines Regulations 2012 is up to date with all changes known to be in force on or before 25 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.