STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and come into force on exit day.

Commencement Information

I1 Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012 [M1] are amended in accordance with Parts 2 to 19.

Commencement Information

I2 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 S.I. 2012/1916.

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

3. Schedule 1 amends the Medicines (Products for Human Use) (Fees) Regulations 2016 [M2] and makes saving provision.

Commencement Information

I3 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 S.I. 2016/190.

PART 2

Amendment of Part 1 (General)

Definitions in relation to advanced therapy medicinal products

4. After regulation 2, insert—

"**Definition of advanced therapy medicinal product etc.**

2A.—(1) In these Regulations, **[**[F1]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, **[**[F1]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 Words in reg. 4 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 1**

Commencement Information

I4 Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 3 (scope of Regulations: special provisions)

5.—(1) Regulation 3 is amended as follows.

(2) In paragraph (12)(d)—

(a) in paragraph (i) insert " UK " before "marketing authorisation";

[[F2](b) after paragraph (i) insert—

"(ia) the EU marketing authorisation,".**]**

(3) In paragraph (15)—

(a) in sub-paragraph (a) insert " UK " before "marketing authorisation"; and

[F3](b) . . . . . .

Textual Amendments

F2 Reg. 5(2)(b) substituted for reg. 5(2)(b)(c) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 2(a)**

F3 Reg. 5(3)(b) omitted (3.8.2021) by virtue of The Human Medicines (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/834), regs. 1(2), **3**

Commencement Information

I5 Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 4 (special provision for pharmacies etc)

[[F4]**6.** In regulation 4—

(a) in paragraph (4)(d)—

(i) in paragraph (i) insert "UK" before "marketing authorisation";

(ii) after paragraph (i) insert—

"(ia) the EU marketing authorisation,";

(b) in paragraph (6) for "269 (offences relating to packaging and package leaflets: other persons)" substitute "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)".**]**

Textual Amendments

F4 Reg. 6 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 3**

Commencement Information

I6 Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 5 (classification of medicinal products)

7.—(1) Regulation 5 is amended as follows.

[F5(2) In paragraph (1)(b), before "a product that" insert "in the case of a medicinal product for sale or supply in Northern Ireland,".**]**

(3) In paragraph (2)—

F6(a) . . . . . .

[F7(b) in sub-paragraph (d), before "an Article 126a" insert "in the case of a medicinal product for sale or supply in Northern Ireland,".**]**

(4) In paragraph (3)—

[F8(a) in sub-paragraph (b), before "a medicinal product" insert "in the case of a medicinal product for sale or supply in Northern Ireland, ";**]**

F9(b) . . . . . .

(5) In paragraph (4), **[**F10in sub-paragraph (b), before "an Article" insert "in the case of a medicinal product for sale or supply in Northern Ireland,".**]**

(6) In paragraph (5)—

[F11(a) in sub-paragraph (b), before "a product that" insert "in the case of a medicinal product for sale or supply in Northern Ireland,"; and**]**

F12(b) . . . . . .

Textual Amendments

F5 Reg. 7(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(a)**

F6 Reg. 7(3)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(b)(i)**

F7 Reg. 7(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(b)(ii)**

F8 Reg. 7(4)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(c)(i)**

F9 Reg. 7(4)(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(c)(ii)**

F10 Words in reg. 7(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(d)**

F11 Reg. 7(6)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(e)(i)**

F12 Reg. 7(6)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 4(e)(ii)**

Commencement Information

I7 Reg. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 1 (further provisions for classification of medicinal products)

[[F13]**8.** In Schedule 1—

(a) in paragraph 1—

(i) in sub-paragraph (b), insert "UK" before "marketing authorisation";

(ii) in sub-paragraphs (e)(i), (f)(i) and (g)(i), for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence"; and

(b) in paragraph 4, for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation, Article 126a authorisation, parallel import licence".**]**

Textual Amendments

F13 Reg. 8 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 5**

PROSPECTIVE

Amendment of regulation 6 (the licensing authority and the Ministers)

[F14]**9.** . . . . . .

Textual Amendments

F14 Reg. 9 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 6**

Amendment of regulation 8 (general interpretation)

10.—(1) Regulation 8 [M3] is amended as follows.

(2) In paragraph (1), at the appropriate places, insert—

""active implantable medical device"—

(a) has the meaning given in regulation 2 of the Medical Devices Regulations 2002 [M4]; 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 [M5];";

““agreed paediatric investigation plan” means a paediatric investigation plan which the licensing authority has agreed in accordance with regulation 50B;”;

““Annex I to the 2001 Directive” means **[**F15, in relation to UKMA(GB),**]** Annex I to the 2001 Directive, as modified in accordance with Schedule 8B;”;

““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;”;

““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;”;

““the Committee for Medicinal Products for Human Use” means the committee established under Article 5(1) of Regulation (EC) No 726/2004;”;

““conditional marketing authorisation” means a **[**F16UKMA(GB)**]** granted under regulation 49(1)(a) in accordance with regulation 58F;”;

““country” means a country or territory;”;

““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 M6;”;

[F17““EU agreed paediatric investigation plan” means a paediatric investigation plan agreed in accordance with the Paediatric Regulation;”**]**;

““EU Exit Regulations” means the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019;”;

““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 M7;”;

[F17““nursing home” has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; ”; and**]**

““orphan criteria” means the criteria listed in regulation 50G(2);”;

““orphan marketing authorisation” means a UK marketing authorisation granted under regulation 49(1)(a) in accordance with regulation 58C;”;

““Orphan Regulation” means Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products M8 as it has effect in EU law;”;

““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 population” means that part of the population consisting of persons under the age of 18 years;”;

[F17““parallel import licence” has the meaning given in regulation 48(2);”**]**;

[F17““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;”**]**;

““supplementary protection certificate” has the meaning given in section 128B(2) of the Patents Act 1977 M9;”; and

[F17““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));”**]**.

““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;.”.

[F17““withdrawal agreement” has the meaning given in section 39 of the European Union (Withdrawal Agreement) Act 2020;”**]**;

(3) In paragraph (1), amend or substitute (as the case may be) the following definitions—

[F18(za) in the definition of “advanced therapy medicinal product”, after “means” insert “, in the case of a medicinal product for sale or supply by the holder of a UKMA(NI) or UKMA(UK),”;

(zb) in the definition of “certificate of registration”, after “these Regulations” insert—

“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;”;**]**

[F19(a) for the definition of “the Good Manufacturing Practice Directive” substitute—

““the Good Manufacturing Practice Directive” means—

(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;”;**]**

(b) in the definition of “homoeopathic medicinal product”, in paragraph (b), for “in any pharmacopoeia used officially in an EEA State” **[**F20substitute—

(i) 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;**]**

(c) in the definition of "import"[M10], insert at the end " and "imported" is to be construed accordingly ";

[F21](d) . . . . . .

(e) in the definition of "pharmacovigilance system", "pharmacovigilance system master file" and "post-authorisation safety study", **[**[F22]for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation"**]**

(f) in the definition of "post-authorisation efficacy study", insert " UK " before "marketing authorisation";

(g) at the end of the definition of "Regulation (EC) No 726/2004", insert " , as it has effect in EU law ";

(h) at the end of the definition of "Regulation (EC) No 1234/2008", insert " , as it has effect in EU law ";

(i) in the definition of "special medicinal product" for "an EEA State" substitute " a country ";

[[F23](j) in the definition of "traditional herbal registration", after "these Regulations" insert—

"and—

(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;";**]**

[[F24](k) for the definition of "UK marketing authorisation" substitute—

""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.";**]**

(4) In paragraph (1), omit the following definitions—

[F25](i) . . . . . .

[F26](ii) . . . . . .

(iii) "care home" [M11],

[F27](iv) . . . . . .

(v) "Directive 2002/98/EC",

(vi) "Directive 2004/23/EC",

[F28](vii) . . . . . .

[F29](viii) . . . . . .

[F30](ix) . . . . . .

F31(x) . . . . . .

F32(xi) . . . . . .

F33(xii) . . . . . .

(xiii) "third country".

(5) In paragraph (5)(a) insert " UK " before "marketing authorisation".

(6) In paragraph (6)(a)—

(a) insert " UK " before "marketing authorisation"; and

(b) for "or 60(1)" substitute " , 60(1) or 60A ".

(7) In paragraph (8) M12, for "References" substitute " Subject to regulation C17(6), references ".

[F34(8) After paragraph (8) insert—

"(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

F15 Words in reg. 10(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(i)(aa)**

F16 Word in reg. 10(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(i)(bb)**

F17 Words in reg. 10(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(ii)**

F18 Reg. 10(3)(za)(zb) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(i)**

F19 Reg. 10(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(ii)**

F20 Words in reg. 10(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(iii)**

F21 Reg. 10(3)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(iv)**

F22 Words in reg. 10(3)(e) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(v)**

F23 Reg. 10(3)(j) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(vi)**

F24 Reg. 10(3)(k) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(vii)**

F25 Reg. 10(4)(i) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

F26 Reg. 10(4)(ii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F27 Reg. 10(4)(iv) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F28 Reg. 10(4)(vii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F29 Reg. 10(4)(viii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F30 Reg. 10(4)(ix) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F31 Reg. 10(4)(x) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F32 Reg. 10(4)(xi) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F33 Reg. 10(4)(xii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**
F34 Reg. 10(8) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(d)**

Commencement Information

I8 Reg. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 Regulation 8 was amended by S.I. 2013/1855 and 2593, 2015/1503, 2016/186, 190 and 696, 2017/715, 2018/199 and 2019/62.
M4 S.I. 2002/618. It was amended by S.I. 2008/2936.
M5 Regulation 137 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
M6 OJ No. L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350.
M7 Regulation 69 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
M8 OJ No. L 018, 22.01.2000, p. 1.
M9 1977 c. 37. Section 128B was inserted by S.I. 2007/3293 and subsection (2) was amended by S.I.2014/2411.
M10 The definition of "import" was inserted by S.I. 2013/1855.
M11 The definition of "care home" was inserted by S.I. 2019/62.
M12 Paragraph (8) was inserted by S.I. 2013/1855.

Insertion of Schedule 8B (modifications of Annex I to the 2001 Directive)

11. Schedule 2 inserts a new Schedule 8B after Schedule 8A.

Commencement Information

I9 Reg. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of Schedule 2A (modifications of Commission Directive 2003/94/EC)

12. Schedule 3 inserts a new Schedule 2A after Schedule 2.

Commencement Information

I10 Reg. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 3

Amendment of Part 3 (manufacture and distribution of medicinal products and active substances)

New regulation B17 and C17 (good manufacturing practice and good distribution practice)

13. After regulation A17 [M13] insert—

"Chapter 1A

Good manufacturing practice and good distribution practice

Regulations on good manufacturing practice

B17.—(1) The **[**[F35]Secretary of State**]** may by regulations **[**[F36]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 **[**[F37]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 **[**[F38]in Great Britain**]** on and after **[**[F39]IP completion day**]** as they had effect immediately before **[**[F39]IP completion day**]**, but subject to the modifications specified in Schedule 2A.

(4) The **[**[F40]Secretary of State**]** may by regulations **[**[F41]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 **[**F42in 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 **[**F43IP completion day**]**M14, continue to apply on and after **[**F43IP 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).”.

Textual Amendments

F35 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(i)(aa)**

F36 Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(i)(bb)**

F37 Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(ii)**

F38 Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(iii)(aa)**

F39 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(iii)(bb)**

F40 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(iv)(aa)**

F41 Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(a)(iv)(bb)**

F42 Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(b)(i)**

F43 Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 8(b)(ii)**

Commencement Information

I11 Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M13 Regulation A17 was inserted by S.I. 2013/1855.

M14 The principles and guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

Amendment of regulation 17 (manufacturing of medicinal products)

14.—(1) Regulation 17 is amended as follows.

[[F44](2) For paragraph (1) substitute—

"(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).".**]**

[F45](3) . . . . . .

[[F46](4) In paragraph (4), after sub-paragraph (a) insert—

"(aa) a UK marketing authorisation; or".**]**

[[F47](5) In paragraph (5) omit "from a state other than an EEA State".**]**

[[F48](6) After paragraph (6) insert—

"(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.".**]**

Textual Amendments

F44 Reg. 14(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(a)**

F45 Reg. 14(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(b)**

F46 Reg. 14(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(c)**

F47 Reg. 14(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(d)**

F48 Reg. 14(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 9(e)**

Commencement Information

I12 Reg. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 18 (wholesale dealing in medicinal products)

15.—(1) Regulation 18 [M15] is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), omit "or";

(b) in sub-paragraph (b) for "distribution." substitute " distribution; or ";

(c) insert at the end—

"(c) import a medicinal product **[**[F49]into Great Britain**]** from an approved country for import [F50]....".

[[F51](2A) After paragraph (2) insert—

"(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.".**]**

[[F52](3) For paragraph (6) substitute—

"(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, or

(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,

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

[[F53](4) In paragraph (7) for "paragraph (6)" substitute "paragraph (6)(b)".**]**

Textual Amendments

F49 Words in reg. 15(2)(c) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 10(a)(i)**

F50 Words in reg. 15(2)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 10(a)(ii)**

F51 Reg. 15(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 10(b)**

F52 Reg. 15(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 10(c)**

F53 Reg. 15(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 10(d)**

Commencement Information

I13 Reg. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M15 Regulation 18 was substituted by S.I. 2013/1855 and further amended by S.I. 2016/186.

Insertion of new regulation 18A (approved country for import)

16. After regulation 18, insert—

"**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.".

Commencement Information

I14 Reg. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 19 (exemptions from requirement for wholesale dealer's licence)

17.—(1) Regulation 19 [M16] is amended as follows.

[[F54](2) For paragraph (1)(a) substitute—

"(a) the holder of—

(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") 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".**]**

(3) In paragraph (1)(b), after "or assembled the product" insert " in the United Kingdom ".

[[F55](4) At the end insert—

"(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

F54 Reg. 17(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(a)**

F55 Reg. 17(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 11(b)**

Commencement Information

I15 Reg. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M16 Regulation 19 was amended by S.I. 2013/1855.

Amendment of Schedule 3 (applications for licences under Part 3)

18.—(1) Schedule 3 is amended as follows.

[F56(2) For paragraph 1(2)(g) substitute—

"(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);".**]**

[F57(3) For paragraph 2(1) substitute—

"**2.**—(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.".**]**

(4) In paragraph 3—

(a) in sub-paragraph (2)(d) at the end insert " or the responsible person (import) ".

(b) in sub-paragraph (3)(b)—

[F58(i) for paragraph (i) substitute—

"(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,",**]**

[F59(ii) in paragraph (iv) before "an Article" insert "in the case of a product for sale or supply in Northern Ireland,", and**]**

(iii) after paragraph (iii) insert—

"(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) in sub-paragraph (3)(d)—

(i) in paragraph (i) omit "or",

(ii) in paragraph (ii) for "etc);" substitute " etc), or ",

(iii) at the end insert—

"(iii) to be distributed by means of export **[**[F60]from Great Britain**]** to an approved country for import;"; and

(d) for sub-paragraph (4) substitute—

"(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

F56 Reg. 18(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(a)**

F57 Reg. 18(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(b)**

F58 Reg. 18(4)(b)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(i)**

F59 Reg. 18(4)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(ii)**

F60 Words in reg. 18(4)(c)(iii) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(d)**

Commencement Information

I16 Reg. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 23 (grant or refusal of licence)

19. In regulation 23(1)(b), omit "and any European Union obligation".

Commencement Information

I17 Reg. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F61]Amendment of regulation 24 (standard provisions of licences)

19A. In regulation 24, after paragraph (2) insert—

"(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

F61 Reg. 19A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 13**

Commencement Information

I18 Reg. 19A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 4 (standard provisions of licences under Part 3)

20.—(1) Schedule 4 is amended as follows.

[F62(2) For paragraph 13(b) substitute—

"(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,".**]**

[F63(2A) After paragraph 14 insert—

"**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.".**]**

[F64(3) In the heading of Part 2, after "State Other Than an EEA State" insert "/ Country other than an Approved Country for Import".**]**

[F65(4) In paragraph 15, for "from a state other than an EEA State" substitute—

"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".

(4A) In paragraphs 22(1) and 23, for "a state other than an EEA State" substitute ", 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".

(4B) After paragraph 23, insert—

"**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."**]**.

(5) In paragraph 25(m), for the words "referred to in Article 8(2) of Directive 2004/23/EC", substitute—

"assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 [M17], 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 [M18], as regards other human tissues and cells.".

[[F66](6) In paragraph 33, for "another EEA State" substitute ", 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".**]**

[[F67](7) After paragraph 41 insert—

"**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

F62 Reg. 20(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(a)**

F63 Reg. 20(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(b)**

F64 Reg. 20(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(c)**

F65 Reg. 20(4)-(4B) substituted for reg. 20(4) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(d)**

F66 Reg. 20(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(e)**

F67 Reg. 20(7) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 14(f)**

Commencement Information

I19 Reg. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M17 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.

M18 S.I. 2007/1523.

Amendment of regulation 26 (general power to suspend, revoke or vary licences)

[[F68]**21.** For regulation 26(5)(a) substitute—

"(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"), 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) or a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation"),

and has habitually failed to comply with the provisions of that authorisation; or".**]**

Textual Amendments

F68 Reg. 21 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 15**

Commencement Information

I20 Reg. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 5 (review upon oral representations)

22.—(1) Schedule 5 [M19] is amended as follows.

(2) In paragraph 1(2)(e), 3(11)(b) and 5(2)(d) after—

(a) "UK marketing authorisation," in each place it appears, insert " parallel import licence, "; and

(b) "an authorisation," or "the authorisation," in each place it appears, insert " licence, ".

(3) In paragraph 3 omit sub-paragraph (11)(b)(iii).

(4) In paragraph 5 omit sub-paragraph (2)(c).

Commencement Information

I21 Reg. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M19 Schedule 5 was amended by S.I. 2013/1855.

Amendment of regulation 29 (variation of licence on the application of the holder)

23. In regulation 29(5)—

(a) in sub-paragraph (b) omit "or";

(b) in sub-paragraph (c) for "granted." substitute " granted; or "; and

(c) at the end insert—

"(d) the responsible person (import) under regulation 45AA.".

Commencement Information

I22 Reg. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 31 (certification of manufacturer's licence)

24.—(1) Regulation 31 is amended as follows.

(2) In paragraph (1)(c), for "an EEA State" substitute " the United Kingdom ".

[F69(3) In paragraphs (3)(b), (5)(a) and (5)(b) for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation, Article 126a authorisation".**]**

Textual Amendments

F69 Reg. 24(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 16**

Commencement Information

I23 Reg. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 33 (offence concerning data for advanced therapy medicinal products)

25.—(1) Regulation 33 is amended as follows.

(2) In paragraph (1)(a)—

(a) for "Article 15(1) of Regulation 1394/2007" substitute " paragraph 8 of Schedule 6 "; and

(b) for "Article 15(4) of that Regulation" substitute " paragraph 9 of that Schedule ".

(3) In paragraph (1)(b), for "Article 15(1)" substitute " paragraph 8 ".

(4) In paragraph (2) for "Article 15(4)" substitute " paragraph 9 ".

Commencement Information

I24 Reg. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 6 (manufacturer's and wholesale dealer's licences for exempt advanced therapy medicinal products)

26.—(1) Schedule 6 is amended as follows.

(2) In paragraph 3, for "Directive 2004/23/EC", substitute—

"requirements 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.".

(3) In paragraph 4, for the words "laid down in" to the end, substitute—

"imposed 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.".

(4) In paragraph 5, for the words from "Commission" to the end substitute " the Blood Quality and Safety Regulations 2005 [M20] ".

(5) In paragraph 11, for the words from "laid down in" to the end, substitute—

"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 [M21];

(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;".

Commencement Information

I25 Reg. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M20 S.I. 2005/50. It was amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.

M21 Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.

Amendment of regulation 36 (conditions for manufacturer's licence)

27. In regulation 36 **[**[F70]—

(a) in paragraph (4)—.

(i) for "The requirements" substitute "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";

(ii) for "provisions of a manufacturer's" substitute "provisions of that";

(b) in paragraph (6), after "by way of wholesale dealing" insert "in Northern Ireland".**]**

Textual Amendments

F70 Reg. 27(a)(b) substituted for words (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 17**

Commencement Information

I26 Reg. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 37 (manufacturing and assembly)

28.—(1) Regulation 37 [M22] is amended as follows.

[[F71](1A) In paragraph (2), after "Good Manufacturing Practice Directive" insert "which apply under or by virtue of regulation B17".**]**

[[F72](2) For paragraph (4)(b) substitute—

"(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".**]**

[[F73](3) In paragraph (5)(b), after "as described" insert "in the case of a product for sale or supply in Great Britain, 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,**]**

[[F74](4) For paragraph (6)(b) substitute—

"(b) in the case of a product for sale or supply—

(i) in Great Britain, 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.".**]**

(5) In paragraph (9)(a), from "Commission" to the end substitute " the Blood Quality and Safety Regulations 2005 [M23]; or ".

(6) In paragraph (11)—

(a) for "competent authority of a member State" substitute " licensing authority "; and

(b) insert " UK " before "marketing authorisation".

Textual Amendments

F71 Reg. 28(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(a)**

F72 Reg. 28(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(b)**

F73 Reg. 28(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(c)**

F74 Reg. 28(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 18(d)**

Commencement Information

I27 Reg. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M22 Regulation 37 was substituted by S.I. 2013/1855.

M23 S.I. 2005/50. It has been amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.

Amendment of regulation 38 (imports)

29.—(1) Regulation 38 [M24] is amended as follows.

[[F75](2) In the heading, after "states other than EEA states" insert "/ countries other than approved countries for import".**]**

[[F76](3) In paragraph (2) for "from a state other than an EEA State" substitute—

"from—

(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".**]**

[[F77](4) In paragraph (3)(b) for "a state other than an EEA State" substitute ", 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".**]**

Textual Amendments

F75 Reg. 29(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 19(a)**

F76 Reg. 29(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 19(b)**

F77 Reg. 29(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 19(c)**

Commencement Information

I28 Reg. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M24 Regulation 38 was amended by S.I. 2015/1503.

Amendment of regulation 39 (further requirements for manufacturer's licence)

30.—**[**[F78](a)**]** In regulation 39(8) [M25], omit ", 43A" **[**[F79]and

(b) after "and (6)" insert " and, where the product is being distributed in Northern Ireland, regulation 43A, ".**]**

Textual Amendments

F78 Words in reg. 30 renumbered as reg. 30(a) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 20(a)**

F79 Reg. 30(b) and word inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 20(b)**

Commencement Information

I29 Reg. 30 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M25 Regulation 39 was amended by S.I. 2013/1855, 2015/354 and 2019/62.

Amendment of regulation 42 (conditions for wholesale dealer's licence)

31.—(1) Regulation 42 [M26] is amended as follows.

[[F80](2) In paragraph (1), after "45" insert "(in the case of a wholesale dealer's licence held in Northern Ireland) or regulations 43 to 45AA (in the case of a wholesale dealer's licence held in Great Britain)".**]**

[[F81](3) In paragraph (4)—

(a) for "The requirements" substitute "Where a wholesale dealer's licence relates to wholesale dealings in Northern Ireland, the requirements"; and

(b) for "provisions of a wholesale dealer's" substitute "provisions of that".**]**

Textual Amendments

F80 Reg. 31(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 21(a)**

F81 Reg. 31(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 21(b)**

Commencement Information

I30 Reg. 31 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M26 Regulation 42 was amended by S.I. 2013/1855 and 2019/62.

Amendment of Schedule 7 (qualified persons)

32.—(1) Schedule 7 [M27] is amended as follows.

(2) In Part 1—

(a) in paragraph 3, for "the member State in which it is studied" substitute " the licensing authority ";

(b) in paragraph 6, for "the member State in which the courses take place" substitute " the licensing authority ".

(3) In Part 3 (obligations of qualified person)—

(a) in paragraph 12—

(i) the existing text becomes sub-paragraph (1),

[[F82](ia) for "The qualified person" substitute "In Great Britain, the qualified person";**]**

(ii) in paragraph (a) of that sub-paragraph—

[[F83](zaa) for "the United Kingdom" substitute "Great Britain";**]**

(aa) for "marketing authorisation, Article 126a authorisation" substitute " UK marketing authorisation ",

(bb) after "herbal registration" insert " , or an equivalent authorisation, ", and

(cc) insert " and " at the end,

(iii) in paragraph (b) of that sub-paragraph—

(aa) for "medicinal products imported from **[**F84a country other than Northern Ireland or**]** a non-EEA State, irrespective of whether the products have been manufactured in an EEA State" substitute " medicinal 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 ", and

(bb) in paragraph (iii), for "marketing authorisation, Article 126a authorisation" substitute " UK marketing authorisation ", and

(cc) after "herbal registration" insert " , or an equivalent authorisation, ",

(iv) omit paragraph (c) of that sub-paragraph, and

(v) after that sub-paragraph insert—

"(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.".

[F85(aa) after paragraph 12 insert—

"**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.".**]**

[F86(b) in paragraph 13—

(i) in sub-paragraph (1) after "This paragraph applies" insert "in Northern Ireland";

(ii) in sub-paragraph (1)(a) for "paragraph 12 in another member State is imported to the United Kingdom" substitute "paragraph 12A in a member State is imported to Northern Ireland";

(iii) in sub-paragraph (2) for "12" substitute "12A";**]**

(c) in paragraph 14—

[F87(i) in sub-paragraph (1)(a) after "are imported" insert "into Great Britain from a country other than an approved country for import or into Northern Ireland;**]**

[F88(ii) for sub-paragraph (1)(b) substitute—

"(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.".**]**

[F89(iia) in paragraph (2) after "paragraph 12" insert "or 12A".**]**

(iii) at the end insert—

"(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

F82 Reg. 32(3)(ia) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(a)**

F83 Reg. 32(3)(a)(ii)(zaa) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(b)**

F84 Words in reg. 32(3)(a)(iii)(aa) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(c)**

F85 Reg. 32(3)(aa) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(d)**

F86 Reg. 32(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**

F87 Reg. 32(3)(c)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(i)**

F88 Reg. 32(3)(c)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(ii)**

F89 Reg. 32(3)(c)(iia) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(iii)**

Commencement Information

I31 Reg. 32 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M27 Schedule 7 was amended by S.I. 2019/62.

Amendment of regulation 43 (obligations of licence holder)

33.—(1) Regulation 43 [M28] is amended as follows.

[F90](2) For paragraph (1), substitute—

"**43.**—(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.".**]**

[F91(3) For paragraph (5)(a) substitute—

"(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".**]**

(4) In paragraph (6)—

(a) in sub-paragraph (a), insert at the end " in the United Kingdom "; and

[F92(aa) in sub-paragraph (b), after "the export" insert "from Northern Ireland";**]**

(b) **[**F93after sub-paragraph (b), insert**]**—

[F94"(ba)**]** the export **[**F95from 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.".

[F96(c) for sub-paragraph (d) substitute—

"(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.".**]**

(5) In paragraph (7)—

(a) in sub-paragraph (b)—

[F97(i) for sub-paragraph (i) substitute—

"(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";**]**

[F98(ii) for sub-paragraph (ii) substitute—

"(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";**]**

[F99(b) in sub-paragraph (c)(vii), before "the batch number" insert "where the receipt, dispatch or brokering of medicinal products takes places in Northern Ireland,";**]**

[F100(5A) In paragraph (8)—

(a) after "A licence holder" insert "in Northern Ireland";

(b) for "third country" substitute ""country other than an EEA State".**]**

(6) **[**F101After paragraph (8) insert**]** —

[F102"(8A)**]** **[**F103Paragraph (8B)**]** applies to a person ("P") who—

(a) imports **[**F104into 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.

[F102(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.".

[F105(7) In paragraph (10), after "The holder" insert "of a licence relating to wholesale dealings in Northern Ireland".**]**

[F106(8) In paragraph (13), for "marketing authorisation holder" substitute "UK marketing authorisation holder or EU marketing authorisation holder".**]**

[F107(9) For paragraph (14) substitute—

"(14) 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.".

(10) In paragraph (15), after "In this regulation" insert "as it applies in the case of a product for sale or supply in Northern Ireland".**]**

Textual Amendments

F90 Reg. 33(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(a)**

F91 Reg. 33(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(b)**

F92 Reg. 33(4)(aa) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(c)**

F93 Words in reg. 33(4)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(d)(i)**

F94 Words in reg. 33(4)(b) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(d)(ii)(aa)**

F95 Words in reg. 33(4)(b) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(d)(ii)(bb)**

F96 Reg. 33(4)(c) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(e)**

F97 Reg. 33(5)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(i)**

F98 Reg. 33(5)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(f)(ii)**

F99 Reg. 33(5)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(g)**

F100 Reg. 33(5A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(h)**

F101 Words in reg. 33(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(i)(i)**

F102 Words in reg. 33(6) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, Sch. 2 para. 23(i)**(ii)**

F103 Words in reg. 33(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(i)(iii)(aa)**

F104 Words in reg. 33(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(i)(iii)(bb)**

F105 Reg. 33(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(j)**

F106 Reg. 33(8) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(k)**

F107 Reg. 33(9)(10) substituted for reg. 33(9) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 23(l)**

Commencement Information

I32 Reg. 33 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M28 Regulation 43 was amended by S.I. 2013/1855 and 2016/186.

[F108Amendment of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)

34. In regulation 43A—

(a) in paragraph (2) for "in the United Kingdom" substitute "in Northern Ireland"; and

(b) in paragraph (3)—

(i) in sub-paragraph (g) omit "a police force in England, Wales or Scotland or"; and

(ii) in sub-paragraph (l) for "care" substitute "nursing".**]**

Textual Amendments

F108 Reg. 34 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 24**

Commencement Information

I33 Reg. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons)

35.—(1) Regulation 44 [M29] is amended as follows.

(2) In paragraph (2)—

[F109(a) in sub-paragraph (b), for "another EEA State" substitute "an 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)"; and**]**

[F110(b) for sub-paragraph (c) substitute—

"(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.".**]**

[F111(3) For paragraph (5)(b) substitute—

"(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;".**]**

[[F112](4) For paragraph (5)(e) substitute—

"(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.".**]**

(5) In paragraph (6)—

(a) insert " and " at the end of sub-paragraph (c); and

[[F113](b) in sub-paragraph (e) after "of the 2001 Directive" insert ", in the case of a licence holder in Northern Ireland.".**]**

[[F114](6) After paragraph (7) insert—

"(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

F109 Reg. 35(2)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(a)(i)**

F110 Reg. 35(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(a)(ii)**

F111 Reg. 35(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(b)**

F112 Reg. 35(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(c)**

F113 Reg. 35(5)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(d)**

F114 Reg. 35(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(e)**

Commencement Information

I34 Reg. 35 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M29 Regulation 44 was amended by S.I. 2013/1855, 2015/1503 and 2016/186.

Amendment of regulation 45 (requirement as to responsible persons)

36.—(1) Regulation 45 is amended as follows.

[F115(2) After paragraph (1) insert—

"(1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.".**]**

[F116(3) For paragraph (2)(b) substitute—

"(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, Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.".**]**

Textual Amendments

F115 Reg. 36(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 26(a)**

F116 Reg. 36(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 26(b)**

Commencement Information

I35 Reg. 36 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulations 45AA and 45AB (responsible persons: import)

37. After regulation 45, insert—

"**Requirement as to responsible persons where licence holder imports from an approved country for import**

45AA.—(1) Subject to paragraph (2), this regulation applies **[**F117to 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; [F118]...

(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 **[**[F119]; 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.

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

F117 Words in reg. 37 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 27(a)**

F118 Word in reg. 37 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 27(b)**

F119 Words in reg. 37 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 27(c)**

Commencement Information

I36 Reg. 37 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 45A (brokering in medicinal products)

38.—(1) Regulation 45A [M30] is amended as follows.

[[F120](2) For paragraph (1) substitute—

"(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.".**]**

[[F121](3) In paragraph (2)—

(a) after "paragraph (1)(b)" insert "or (1A)(b)";

(b) in sub-paragraphs (a) and (c), after "competent authority of a member State" insert "or the licensing authority (as appropriate)".**]**

(4) Omit paragraph (3).

Textual Amendments

F120 Reg. 38(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 28(a)**

F121 Reg. 38(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 28(b)**

Commencement Information

I37 Reg. 38 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M30 Regulation 45A was inserted by S.I. 2013/1855.

Amendment of regulation 45D (grant or refusal of a broker's registration)

39. In regulation 45D(1)(b) [M31] omit sub-paragraph (ii) (and "and" immediately preceding it).

Commencement Information

I38 Reg. 39 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M31 Regulation 45D was inserted by S.I. 2013/1855.

Amendment of regulation 45E (criteria of broker's registration)

40. [M32]In regulation 45E(3) —

[[F122](a) for sub-paragraph (b)(i) substitute—

"(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";**]**

[[F123](b) in sub-paragraph (d)(iii), before "the batch number" insert "where the sale or supply of the medicinal product is in Northern Ireland,".**]**

Textual Amendments

F122 Reg. 40(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 29(a)**

F123 Reg. 40(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 29(b)**

Commencement Information

I39 Reg. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M32 Regulation 45E was inserted by S.I. 2013/1855.

Amendment of regulation 45F (provision of information)

41. In regulation 45F(1) [M33] for sub-paragraph (b) substitute—

[[F124]"(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,"**]**.

Textual Amendments

F124 Words in reg. 41 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 30**

Commencement Information

I40 Reg. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M33 Regulation 45F was inserted by S.I. 2013/1855.

Amendment of regulation 45M (criteria for importation, manufacture or distribution of an active substance)

42.—(1) Regulation 45M [M34] is amended as follows.

[[F125](2) For paragraph (2)(a) substitute—

"(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";**]**

(3) In paragraph (3), omit "from a state other than an EEA State".

Textual Amendments

F125 Reg. 42(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 31**

Commencement Information

I41 Reg. 42 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M34 Regulation 45M was inserted by S.I. 2013/1855.

Amendment of Schedule 7A (information to be provided for registration as an importer, manufacturer or distributor of active substances)

43.—(1) Schedule 7A [M35] is amended as follows.

(2) In paragraph 13(b), omit "from third countries".

(3) In paragraph 15(c), omit "to a third country".

Commencement Information

I42 Reg. 43 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M35 Schedule 7A was inserted by S.I. 2013/1855.

Amendment of regulation 45O (requirements for registration as an importer, manufacturer or distributor of an active substance)

44.—(1) Regulation 45O [M36] is amended as follows.

[[F126](2) For paragraph (1) substitute—

"(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.".**]**

[[F127](3) For paragraph (2) substitute—

"(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.".**]**

[[F128](4) In paragraph (3)—

(a) for "the UK" substitute "Northern Ireland";

(b) for "from a third country" substitute "into Northern Ireland from a country other than an EEA State";

(c) for "exporting third country" in both places it occurs substitute "exporting country";

(d) in sub-paragraph (c)(ii), for "the Union" substitute "Northern Ireland".**]**

[F129(4A) After paragraph (3) insert—

"(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.".**]**

[F130(5) In paragraph (4)—

(a) for "(3)(c) does" substitute "(3)(c) and (3A)(c) do";

(b) in sub-paragraph (a), after "Article 111b of the 2001 Directive" insert "(in the case of an import into Northern Ireland) or paragraph (6) (in the case of an import into Great Britain)";

(c) in sub-paragraph (b)(i), after "competent authority of a member State" insert "or 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)".**]**

(6) At the end insert—

"(6) The licensing authority may publish a list of countries which it is satisfied have a regulatory framework applicable to active substances exported to **[**F131Great Britain**]** that is equivalent to the regulatory framework in **[**F131Great 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

F126 Reg. 44(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(a)**

F127 Reg. 44(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(b)**

F128 Reg. 44(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(c)**

F129 Reg. 44(4A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(d)**

F130 Reg. 44(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(e)**

F131 Words in reg. 44(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 32(f)**

Commencement Information

I43 Reg. 44 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M36 Regulation 45O was inserted by S.I. 2013/1855.

PART 4

Amendment of Part 4 (requirement for authorisation)

Amendment of regulation 46 (requirement for authorisation)

45.—(1) Regulation 46 is amended as follows.

(2) In paragraph (2)—

(a) in sub-paragraph (a), before "marketing authorisation", insert " UK ";

[F132(b) after sub-paragraph (a) insert—

"(aa) an EU marketing authorisation;".**]**

(3) In paragraph (3), before "European Economic Area" insert " United Kingdom or the ".

(4) In paragraph (6)—

[F133(a) after "in force for the product" insert "in the country in which the product is intended to be sold or supplied, or offered for sale or supply";

(b) in sub-paragraph (a), before "marketing authorisation", insert "UK"; and

(c) after sub-paragraph (a) insert—

"(aa) an EU marketing authorisation;".**]**

F134(5) . . . . . .

(6) In paragraph (9), before "European Economic Area" insert " United Kingdom or the ".

(7) In paragraph (11)(a), before "European Economic Area" insert " United Kingdom or the ".

Textual Amendments

F132 Reg. 45(2)(b) substituted for reg. 45(2)(b)(c) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 33(a)**

F133 Reg. 45(4)(a)-(c) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 33(b)**

F134 Reg. 45(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 33(c)**

Commencement Information

I44 Reg. 45 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 47 (breach of requirement)

46.—(1) Regulation 47 is amended as follows.

(2) In paragraphs (3) and (4), before "European Economic Area", insert " United Kingdom or the ".

F135(3) . . . . . .

Textual Amendments

F135 Reg. 46(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 34**

Commencement Information

I45 Reg. 46 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 48 (application of Part 5)

47.—(1) Regulation 48 [M37] is amended as follows.

(2) In paragraph (2)—

(a) at the appropriate place insert—

[[F136]““EU reference medicinal product” means a medicinal product which falls within paragraph (b)(ii) or (iii) of the definition of “reference medicinal product”;”**]**

[[F137]““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);”**]**;

(b) for the definition of “generic medicinal product”, substitute—

[[F138]““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;”**]**;

(c) for the definition of “parallel import licence” substitute—

““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;”; and

(d) for the definition of “reference medicinal product”, substitute—

[[F139]““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;"**]**.

(3) After paragraph (2) insert—

"(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 **[**F140regulations 51 to 53B**]**.

(7) Where this paragraph applies, the medicinal product is treated for the purposes of the application of **[**F141regulation 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 **[**F142regulations 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 **[**F143regulation 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

F136 Words in reg. 47(2)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(a)(i)**

F137 Words in reg. 47(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(a)(ii)**

F138 Words in reg. 47(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(b)**

F139 Words in reg. 47(2)(d) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(c)**

F140 Words in reg. 47(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(d)(i)**

F141 Words in reg. 47(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(d)(ii)**

F142 Words in reg. 47(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(d)(iii)**

F143 Words in reg. 47(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 35(d)(iv)**

Commencement Information

I46 Reg. 47 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M37 Regulation 48 was amended by S.I. 2014/1878.

Amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence)

48.—(1) Regulation 49 [M38] is amended as follows.

(2) In paragraph (1), after "regulation 58," insert " 58C, 58E, 58F and 58G, ".

(3) After paragraph (1) insert—

[[F144]"(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.**]**

[[F145](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.

[[F146](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."**]**.

[[F147](4) For paragraph (3) substitute—

"(3) The applicant, where it is applying for—

(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.".**]**

(5) After paragraph (3) insert—

"(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.".

(6) At the end insert—

[[F148]"(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.**]**

[[F149](10)**]** In this regulation "group" has the same meaning as in Part 15 of the Companies Act 2006 [M39] (see section 474(1) of that Act).".

Textual Amendments

F144 Words in reg. 48(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(a)(ii)**

F145 Words in reg. 48(3) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(a)(i)**

F146 Words in reg. 48(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(a)(iii)**

F147 Reg. 48(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(b)**

F148 Words in reg. 48(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(c)(ii)**

F149 Words in reg. 48(6) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 36(c)(i)**

Commencement Information

I47 Reg. 48 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M38 Regulation 49 was amended by S.I. 2014/1878.

M39 2006 c.46.

Amendment of regulation 50 (accompanying material)

49.—(1) Regulation 50 [M40] is amended as follows.

[[F150](1A) After paragraph (1) insert—

"(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.";

(1B) After paragraph (3) insert—

"(3A) Paragraph (4) does not apply in respect of an application under the unfettered access route."**]**.

[[F151](2) For paragraph (4) substitute—

"(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.".**]**

(3) After paragraph (5) insert—

[[F152]"(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 **[**[F153]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 [M41];

(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 [M42]; 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 [M43].".

(4) In paragraph (6), before sub-paragraph (a), insert—

"(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);".

[[F154](4A) In paragraph (6)—

(a) for sub-paragraph (a), substitute—

"(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);";

(b) for sub-paragraph (b), substitute—

"(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);";

(c) for sub-paragraph (c), substitute—

"(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);".**]**

(5) After paragraph (6), insert—

"(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

F150 Reg. 49(1A)(1B) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(a)**

F151 Reg. 49(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(b)**

F152 Words in reg. 49(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(c)(i)**

F153 Words in reg. 49(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(c)(ii)**

F154 Reg. 49(4A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 37(d)**

Commencement Information

I48 Reg. 49 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M40 Regulation 50 was amended by S.I. 2014/1878.

M41 The guidance is available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

M42 The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

M43 The guidance is available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)

50.—(1) Schedule 8 [M44] is amended as follows.

(2) In paragraph 12—

(a) in sub-paragraph (a), after "pharmacovigilance" insert " who is ordinarily resident, and operates, in the United Kingdom **[**[F155]or a member State**]**";

[[F156](b) for sub-paragraph (b) substitute—

"(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;";**]**

[[F157](c) for paragraph (e) substitute—

"(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.".**]**

(3) For paragraph 18 substitute—

[[F158]"**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."**]**.

[F159(4) In paragraph 19, for "a member State or by a third country" substitute ", 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".**]**

[F160(5) In paragraph 20, after "Where" insert ", in the case of a medicinal product for sale or supply in Northern Ireland,".**]**

[F161(6) For paragraph 21 substitute—

"**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.".**]**

[F162(7) In paragraph 22 for "A copy of any" substitute "In the case of a medicinal product for sale or supply in Northern Ireland, a copy of any".**]**

[F163(8) For paragraph 23 substitute—

"**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".".**]**

(9) After paragraph 25, insert—

"**25A.** In the case of an advanced therapy medicinal product **[**F164for 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.".

(10) After paragraph 35, insert—

"**36.** In the case of an advanced therapy medicinal product **[**F165for 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

F155 Words in reg. 50(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(a)(i)**

F156 Reg. 50(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(a)(ii)**

F157 Reg. 50(2)(c) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(a)(iii)**

F158 Words in reg. 50(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(b)**

F159 Reg. 50(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(c)**

F160 Reg. 50(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(d)**

F161 Reg. 50(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(e)**

F162 Reg. 50(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(f)**

F163 Reg. 50(8) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(g)**

F164 Words in reg. 50(9) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(h)**

F165 Words in reg. 50(10) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 38(i)**

Commencement Information

I49 Reg. 50 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M44 Schedule 8 was amended by S.I. 2013/1855.

Amendment of Schedule 8A (material to accompany an application for a parallel import licence)

51. Paragraph 6 of Schedule 8A [M45] is amended as follows—

(a) in sub-paragraph (a), after "pharmacovigilance" insert " who resides and operates in the United Kingdom ";

(b) omit sub-paragraph (b); and

(c) in paragraph (e) at the end inset "or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom".

Commencement Information

I50 Reg. 51 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M45 Schedule 8A was inserted by S.I. 2014/1878.

[F166Insertion of new Schedule 8C in relation to material to accompany unfettered access applications

51A. Schedule 2A inserts a new Schedule 8C after Schedule 8B.]

Textual Amendments

F166 Reg. 51A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 39**

Commencement Information

I51 Reg. 51A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 9 (undertakings by non-United Kingdom manufacturers)

52.—(1) Schedule 9 is amended as follows.

(2) In the heading, for "EEA" substitute " United Kingdom ".

(3) In each place where it occurs, insert " UK " before "marketing authorisation".

Commencement Information

I52 Reg. 52 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

New regulation 50A to 50J (applications in relation to particular medicinal products)

53. After regulation 50, insert—

"**Requirement 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 **[**F167UKMA(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 **[**F167UKMA(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.

[[F168](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.**]**

Agreement and modification of paediatric investigation plan

50B.—(1) Any person may prepare a paediatric investigation plan **[**[F169]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).

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).

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 pharmacokinetic 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).

Application for paediatric use marketing authorisation

50E.—(1) This regulation applies in relation to an application for a **[**[F170]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.

[F171(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.**]**

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 **[**F172UKMA(GB)**]** for a relevant medicinal product which includes a paediatric indication; or

(b) an application to include a paediatric indication in an existing **[**F172UKMA(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.

Applications relating to orphan medicinal products

50G.—[F173(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 **[**F174Great 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 **[**F174Great 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.

Applications relating to advanced therapy medicinal products

50H.—(1) This regulation applies in relation to an application for a **[**F175UKMA(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 **[**F175UKMA(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 M46, including, where available, the results of the assessment of a notified body in accordance with those Regulations.

Applications relating to conditional marketing authorisations [F176**for sale or supply in Great Britain only]**

50I.—(1) This regulation applies in relation to an application for a **[**F177UKMA(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.

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 [M47],

(ii) regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 [M48],

(iii) regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 [M49], or

(iv) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003 [M50];

(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

F167 Words in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(a)(i)**

F168 Words in reg. 53 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(a)(ii)**

F169 Words in reg. 53 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(b)**

F170 Words in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(c)(i)**

F171 Words in reg. 53 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(c)(ii)**

F172 Word in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(d)**

F173 Words in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(e)(i)**

F174 Words in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(e)(ii)**

F175 Word in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(f)**

F176 Words in reg. 53 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(g)(i)**

F177 Word in reg. 53 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 40(g)(ii)**

Commencement Information

I53 Reg. 53 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M46 S.I. 2002/618, as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

M47 S.I. 2002/2443, as amended by S.I. 2004/2411.

M48 S.I. 2002/3188, as amended by S.I. 2005/1913.

M49 S.S.I. 2002/541, as amended by S.S.I. 2004/439.

M50 S.R. 2003/167, as amended by S.R. 2005/272.

Insertion of new Schedule in relation to orphan provisions

54. Schedule 4 inserts a new Schedule 9A after Schedule 9.

Commencement Information

I54 Reg. 54 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 10 (national homoeopathic products)

55. In paragraph 4(4)(a) of Schedule 10 (exceptions to requirement to submit safety data) insert " UK " before "marketing authorisation".

Commencement Information

I55 Reg. 55 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F178Substitution of regulation 51 (applications relating to generic medicinal products)

56. For regulation 51 substitute—

"**Application 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.

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.

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

F178 Reg. 56 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 41**

Commencement Information

I56 Reg. 56 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F179Substitution of regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc)

57. For regulation 52 substitute—

"**Application 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.

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.

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

F179 Reg. 57 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 42**

Commencement Information

I57 Reg. 57 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F180Substitution of regulation 53 (applications relating to similar biological medicinal products)

58. For regulation 53 substitute—

“**Application 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.

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.

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

F180 Reg. 58 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**

Commencement Information

I58 Reg. 58 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 54 (applications relating to products in well-established medicinal use)

59.—(1) Regulation 54 is amended as follows.

(2) In paragraph (1) before “European Union”, insert “ United Kingdom or the ”.

(3) For paragraph (2), substitute—

“(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.”.

Commencement Information

I59 Reg. 59 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F181Substitution of regulation 55 (applications relating to new combinations of active substances)

60. For regulation 55 substitute—

"**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

F181 Reg. 60 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 44**

Commencement Information

I60 Reg. 60 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 56 (applications containing information supplied in relation to another product with consent)

61. In regulation 56(2), omit "in accordance with Article 10c of the 2001 Directive".

Commencement Information

I61 Reg. 61 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 58 (consideration of application)

62.—(1) Regulation 58 is amended as follows.

(2) After paragraph (4), insert—

[[F182]"(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."**]**.

(3) Omit paragraphs (6) and (7).

[[F183](4) After paragraph (7) insert—

"(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

F182 Words in reg. 62(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 45(a)**

F183 Reg. 62(4) substituted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 45(b)**

Commencement Information

I62 Reg. 62 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 11 (advice and representations)

63.—(1) Schedule 11 is amended as follows.

(2) In paragraph 1 (application of Part 1)—

(a) in sub-paragraph (1)—

(i) in sub-paragraph (b) omit "and", and

[[F184](ii) at the end insert—

"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.";**]**

(b) after sub-paragraph (1) insert—

"(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."; and

[[F185](c) for sub-paragraph (2) substitute—

"(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.";**]**

[[F186](2A) In paragraph 2 (requirement to consult the appropriate committee), after sub-paragraph (2), insert—

"(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.".

(2B) In paragraph 3 (exceptions to requirement to consult)—

(a) in sub-paragraph (1), after "traditional herbal registration" insert " , 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, "; and

(b) in sub-paragraph (1)(a), after "determined", insert " or the decision to be made ".

(2C) In paragraph 5 (provisional opinion against authorisation)—

(a) after sub-paragraph (2), insert—

"(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."; and

(b) in sub-paragraph (3), after "grant or renewal", insert " , the applicant intending to demonstrate that the orphan criteria are met in relation to a medicinal product, ".

(2D) In paragraph 10 (decision of licensing authority)—

(a) omit the "or" at the end of sub-paragraph (1)(b); and

(b) at the end of sub-paragraph (1)(c) insert—

"; 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,"**]**.

[F187(3) In paragraph 12 (licensing authority decisions in other cases)—

(a) in sub-paragraph (1), insert " , parallel import licence " after " UK marketing authorisation " in each place it appears;

(b) in sub-paragraph (5), insert " , licence " after " the authorisation "; and

(c) after sub-paragraph (4), insert—

"(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.".**]**

[F188(3A) After Part 1 insert—

"PART 1A

Paediatric Decisions

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.".**]**

[F189(4) In paragraph 14(a) (application of Part 2), after "veterinary medicinal products" insert "or paragraph 1 of Schedule 10A".**]**

(5) In paragraph 15(2) and (3)(b), insert " UK " before "marketing authorisation".

(6) In paragraph 16—

(a) in sub-paragraph (2)(b), insert " UK " before "marketing authorisation"; and

(b) in sub-paragraph (5), omit the words from "or in any Directive" to the end.

[F190(7) For paragraph 17 substitute—

"**17.** In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.".**]**

(8) In Part 3 (referral to the Committee for Herbal Medicinal Products)—

(a) in the heading to Part 3, for "Committee for Herbal Medicinal Products" substitute " appropriate committee for traditional herbal registrations ";

(b) in paragraph 24—

(i) in sub-paragraph (1), for the words from "Committee" to the end substitute " appropriate committee in accordance with regulation 130A(1) "; and

[[F191](ii) for sub-paragraph (2) substitute—

"(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule."; and**]**

(c) in paragraph 29(1), for "proceed with its proposal" substitute " grant or refuse the application ".

[[F192](9) In Part 4 (exceptions to Schedule) omit paragraphs 31, 34, 35, 37 and 38.**]**

Textual Amendments

F184 Reg. 63(2)(a)(ii) substituted (31.12.2020 immediately before IP completion day) 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)

F185 Reg. 63(2)(c) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(a)**

F186 Reg. 63(2A)-(2D) inserted (31.12.2020 immediately before IP completion day) 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)

F187 Reg. 63(3) substituted (31.12.2020 immediately before IP completion day) 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)

F188 Reg. 63(3A) inserted (31.12.2020 immediately before IP completion day) 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)

F189 Reg. 63(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(b)**

F190 Reg. 63(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(c)**

F191 Reg. 63(8)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(d)**

F192 Reg. 63(9) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(e)**

Commencement Information

I63 Reg. 63 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of provisions concerning consideration of certain applications for UK marketing authorisations

64. After regulation 58, insert—

"**Paediatric rewards**

58A.—[[F193](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.

[F194(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

[F195(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).**]**

[F196(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 **[**[F197]regulation 51A(1) and (6)**]** in relation to the material supplied pursuant to regulation 50E(2).

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 **[**[F198]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.

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 **[**F199(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.

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.

F200(2) . . . . . .

F200(3) . . . . . .

(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.

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 [M51] 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.

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 **[**[F201]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.

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

F193 Words in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(a)(i)**

F194 Words in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(a)(ii)**

F195 Words in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(a)(iii)**

F196 Words in reg. 64 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(a)(iv)**

F197 Words in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(a)(v)**

F198 Words in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(b)**

F199 Words in reg. 64 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(c)**

F200 Words in reg. 64 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(d)**

F201 Word in reg. 64 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 47(e)**

Commencement Information

I64 Reg. 64 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M51 S.I. 2002/618, as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

Amendment of regulation 59 (conditions of UK marketing authorisation or parallel import licence: general)

65.—(1) Regulation 59 [M52] is amended as follows.

[[F202](1A) In paragraph (3) for "An obligation" substitute "In relation to a UKMA(NI) or UKMA(UK), an obligation".**]**

[F203](2) . . . . . .

[[F204](3) After paragraph (3), insert—

"(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) In paragraph (4), insert " UK " before "marketing authorisation".

(5) After paragraph (4), insert—

"(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).".

[[F205](6) In paragraph (5) for "marketing authorisation" substitute "UKMA(NI) or UKMA(UK).**]**

Textual Amendments

F202 Reg. 65(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 48(a)**

F203 Reg. 65(2) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 48(b)**

F204 Reg. 65(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 48(c)**

F205 Reg. 65(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 48(d)**

Commencement Information

I65 Reg. 65 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M52 Regulation 59 was amended by S.I. 2014/1878.

Amendment of regulation 60 (conditions of UK marketing authorisation: exceptional circumstances)

[[F206]**66.** In regulation 60—

(a) after "UK marketing authorisation" in each place it occurs (including the heading to the regulation) insert "or parallel import licence";

(b) after "the authorisation" in each place it occurs insert "or licence";

(c) in paragraph (3), after "an authorisation" insert "or licence";

(d) for paragraph (9) substitute—

"(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.";

(e) in paragraph (10), after "a marketing authorisation" insert "or licence".**]**

Textual Amendments

F206 Reg. 66 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 49**

Commencement Information

I66 Reg. 66 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority) [F207and 60B (submitting of samples and other information: EU marketing authorisations)]

67. After regulation 60, insert—

"**Condition 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 [M53];

"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

[[F208]"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 [F209]... 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) **[**[F210]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 **[**[F211]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 **[**[F211]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).

[[F212](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.**]**

[F213Submitting 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

F207 Words in reg. 67 heading inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(a)**

F208 Words in reg. 67 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(b)(i)**

F209 Word in reg. 67 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(b)(ii)**

F210 Words in reg. 67 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(b)(iii)**

F211 Words in reg. 67 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(b)(iv)**

F212 Words in reg. 67 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(b)(v)**

F213 Words in reg. 67 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 50(c)**

Commencement Information

I67 Reg. 67 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M53 2012 c.7.

Amendment of regulation 61 (conditions of UK marketing authorisation)

68.—(1) Regulation 61 is amended as follows.

(2) For paragraph (4), substitute—

"(4) The obligation in this paragraph is—

(a) to conduct a post-authorisation safety study; or

(b) **[**F214in 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.".

[[F215](2A) In paragraph (6), after "one medicinal product" insert "authorised by a UKMA(NI) or UKMA(UK)".**]**

[[F216](3) After paragraph (6) insert—

"(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.".**]**

[[F217](3A) In paragraph (7) for "The obligation under paragraph (5) shall" substitute "In relation to a UKMA(NI) or UKMA(UK), the obligation under paragraph (5) must".**]**

[[F218](4) After paragraph (7) insert—

"(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).".**]**

[[F219](5) In paragraph (13), after "notify the EMA" insert ", in relation to a UKMA(NI) or UKMA(UK),".**]**

Textual Amendments

F214 Words in reg. 68(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(a)**

F215 Reg. 68(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(b)**

F216 Reg. 68(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(c)**

F217 Reg. 68(3A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(d)**

F218 Reg. 68(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(e)**

F219 Reg. 68(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 51(f)**

Commencement Information

I68 Reg. 68 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 64 (duties of licensing authority in connection with determination)

[[F220]**69.** For regulation 64(4)(d) substitute—

"(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".**]**

Textual Amendments

F220 Reg. 69 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 52**

Commencement Information

I69 Reg. 69 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Obligation of licensing authority in case of change of classification

70. After regulation 64, insert—

"**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—

[[F221](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

F221 Words in reg. 70 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 53**

Commencement Information

I70 Reg. 70 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 65 (validity of UK marketing authorisation)

71. In regulation 65(5) before sub-paragraph (a) insert—

"(za) regulation 65B;".

Commencement Information

I71 Reg. 71 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Validity of conditional marketing authorisation and variation of a UK marketing authorisation

72. After regulation 65A [M54], insert—

"**Validity 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.

Variation of a [F222UKMA(GB)]

65C.—(1) A **[**F223UKMA(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 **[**F223UKMA(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[M55] which applied immediately before **[**F224IP 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 **[**F224IP completion day**]**; or

(b) applications made before **[**F224IP 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

F222 Word in reg. 72 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 54(a)**

F223 Word in reg. 72 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 54(b)**

F224 Words in reg. 72 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 54(c)**

Commencement Information

I72 Reg. 72 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M54 Regulation 65A was inserted by S.I. 2014/1878.

M55 The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

Insertion of new Schedule 10A (variations to a UK marketing authorisation)

73. Schedule 5 inserts a new Schedule 10A after Schedule 10.

Commencement Information

I73 Reg. 73 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 66 (application for renewal of authorisation)

74. In regulation **[**[F225]66, for paragraph (2) substitute—

"(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."**]**

Textual Amendments

F225 Words in reg. 74 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 55**

Commencement Information

I74 Reg. 74 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 66A (application for renewal of a parallel import licence)

75. In regulation 66A(2) [M56], for "European Union" substitute " United Kingdom ".

Commencement Information

I75 Reg. 75 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M56 Regulation 66A was inserted by S.I. 2014/1878.

Renewal of conditional marketing authorisation

76. After regulation 66A, insert—

"**Renewal 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.".

Commencement Information

I76 Reg. 76 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F226Amendment of regulation 67 (failure to place on the market etc.)

76A.—(1) Regulation 67 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after "in the United Kingdom" insert "(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)".

(3) In paragraph (2) after "in the United Kingdom" insert "(or, in the case of a UKMA(GB) granted after an application under the unfettered access route, in Great Britain)".**]**

Textual Amendments

F226 Reg. 76A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 56**

Commencement Information

I77 Reg. 76A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 68 (revocation, variation and suspension of UK marketing authorisation or parallel import licence)

77.—(1) Regulation 68 [M57] is amended as follows.

(2) In paragraph (5), after "exceptional circumstances)", insert " , regulation 60A (conditions as to testing of samples by the appropriate authority) ".

(3) In paragraph (7)—

(a) after "authorisation" insert " or licence "; and

[[F227](b) for "established in the European Union" substitute—

"established 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.".**]**

(4) In paragraph (8)(b), for "states other than EEA states" substitute " countries other than approved countries for import ".

[[F228](5) In paragraph (9)(a) omit "other than the United Kingdom".**]**

(6) In paragraph (10)—

(a) in sub-paragraph (a) for "authorisation; or" substitute " authorisation or licence. "; and

(b) omit sub-paragraph (b).

(7) In paragraph (11)(a), after authorisation insert " or licence ".

(8) After paragraph (11A), insert—

"(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 **[**[F229]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 **[**[F229]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).

[[F230](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."**]**.

(9) In paragraph (12)—

(a) after "UK marketing authorisation", insert " or parallel import licence "; and

(b) after "an authorisation" insert " or licence ".

(10) Omit paragraph (13).

Textual Amendments

F227 Reg. 77(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(a)**

F228 Reg. 77(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(b)**

F229 Words in reg. 77(8) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(c)(i)**

F230 Words in reg. 77(8) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 57(c)(ii)**

Commencement Information

I78 Reg. 77 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M57 Regulation 68 was amended by S.I. 2013/1855 and 2014/1878.

Amendment of regulation 69 (suspension of use etc of relevant medicinal product)

78. In regulation 69 [M58], omit paragraph (10).

Commencement Information

I79 Reg. 78 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M58 Regulation 69 was amended by S.I. 2014/1878.

Omission of regulation 70 (authorisations granted under Chapter 4 of Title III of the 2001 Directive

79. Omit regulation 70.

Commencement Information

I80 Reg. 79 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 71 (withdrawal of medicinal product from the market)

80.—(1) Regulation 71 [M59] is amended as follows.

(2) In paragraph (1)—

(a) for sub-paragraph (a) substitute—

"(a) under regulation 68 the licensing authority revokes or suspends a UK marketing authorisation or parallel import licence; or"; and

[[F231](b) for sub-paragraph (b) substitute—

"(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.".**]**

Textual Amendments

F231 Reg. 80(2)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 58**

Commencement Information

I81 Reg. 80 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M59 Regulation 71 was amended by S.I. 2014/1878.

Amendment of regulation 72 (sale etc of suspended medicinal product)

[[F232]**81.** In regulation 72(1), for "regulation 69 or 70(2) or Article 20(4) of Regulation (EC) No 726/2004" substitute—

"—

(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.".**]**

Textual Amendments

F232 Reg. 81 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 59**

Commencement Information

I82 Reg. 81 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 73 (obligation to notify placing on the market etc)

82.—(1) Regulation 73 [M60] is amended as follows.

(2) In paragraph (5A)(c), for "third country" substitute " country other than the United Kingdom ".

[[F233](3) In paragraph (5C), for "UK marketing authorisation" insert "UKMA(NI) or UKMA(UK)".**]**

Textual Amendments

F233 Reg. 82(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 60**

Commencement Information

I83 Reg. 82 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M60 Regulation 73 was amended by S.I. 2013/2593: regulation 3 inserted sub-paragraphs (5A) to (5C).

Amendment of regulation 75 (obligation to provide information relating to safety etc)

83. In regulation 75(5) [M61]—

(a) for sub-paragraph (a) substitute—

"(a) in a country other than the United Kingdom;" and

(b) in sub-paragraph (b), insert " UK " before "marketing authorisation".

Commencement Information

I84 Reg. 83 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M61 Regulation 75 was amended by S.I. 2014/1878.

Amendment of regulation 76 (obligation in relation to product information)

[[F234]**84.** For regulation 76(2), substitute—

"(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

F234 Reg. 84 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 61**

Commencement Information

I85 Reg. 84 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 77 (record-keeping obligations)

F235 85. . . . . . .

Textual Amendments

F235 Reg. 85 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 62**

PROSPECTIVE

Amendment of regulation 78 (obligation to ensure appropriate and continued supplies)

F236 86. . . . . . .

Textual Amendments

F236 Reg. 86 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 63**

Post authorisation requirements in relation to UK marketing authorisations with paediatric aspects and advanced therapy medicinal products

87. After regulation 78, insert—

"**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.

Post authorisation requirements in relation to [F237UKMA(GB)] for advanced therapy medicinal products

78B.—(1) The holder of a **[**F238UKMA(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 M62,

(ii) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005 [M63], 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 [M64];

(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 **[**[F238]UKMA(GB)**]**; and

(d) in the event of the **[**[F238]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 **[**[F238]UKMA(GB)**]** who is subject to the obligations in paragraph (1) remains subject to them even if the **[**[F238]UKMA(GB)**]** is suspended or revoked.".

Textual Amendments

F237 Word in reg. 87 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 64(a)**

F238 Word in reg. 87 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 64(b)**

Commencement Information

I86 Reg. 87 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M62 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.

M63 S.I. 2005/50. It was amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.

M64 S.I. 2007/1523.

[[F239]**Amendment of regulation 79 (failure to provide information on marketing authorisations to EMA)**

88. In regulation 79 (failure to provide information on marketing authorisations to EMA)—

(a) in paragraph (1), for the first reference to "a marketing authorisation" substitute "a UKMA(NI) or UKMA(UK)";

(b) in paragraph (2), for the first reference to "a marketing authorisation" substitute "UKMA(NI) or UKMA(UK)".**]**

Textual Amendments

F239 Reg. 88 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 65**

Commencement Information

I87 Reg. 88 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 80 (urgent safety restrictions)

89.—(1) Regulation 80 is amended as follows.

(2) In the introductory words, insert " UK " before "marketing authorisation".

[[F240](3) For paragraph (a) substitute—

"(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;".**]**

[[F241](4) For paragraph (b) substitute—

"(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".**]**

[[F242](4A) In paragraph (c) after "fails" insert "in respect of a UKMA(NI)".**]**

(5) **[**[F243]After paragraph (c) insert**]** —

[[F244]"(d)**]** fails **[**[F245]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

F240 Reg. 89(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(a)**

F241 Reg. 89(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(b)**

F242 Reg. 89(4A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(c)**

F243 Words in reg. 89(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(d)(i)**

F244 Reg. 89(5): inserted para. (c) renumbered as para. (d) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(d)(ii)**

F245 Words in reg. 89(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 66(d)(iii)**

Commencement Information

I88 Reg. 89 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F246Application of regulations 81 to 94 (offences relating to EU marketing authorisations)

90. Before regulation 81 (obligation to update information supplied in connection with EU application), insert—

"**Application of regulations 81 to 94**

A81. Regulations 81 to 94 apply in relation to medicinal products for sale or supply in Northern Ireland.".

Textual Amendments

F246 Regs. 90-90B substituted for reg. 90 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**

Commencement Information

I89 Reg. 90 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 89 (offences in connection with withdrawal of product from market)

90A. In regulation 89(1)(b) (offences in connection with withdrawal of product from market) for "any of Articles 36, 37 and 38" substitute "Article 37 or 38".

Textual Amendments

F246 Regs. 90-90B substituted for reg. 90 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**

Commencement Information

I90 Reg. 90A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Omission of regulation 91 (failure to notify results of third country clinical trials)

90B. Omit regulation 91.]

Textual Amendments

F246 Regs. 90-90B substituted for reg. 90 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**

Commencement Information

I91 Reg. 90B in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F247Amendment of regulation 94A (offences relating to Commission Regulation 2016/161)

91. In regulation 94A—

(a) for paragraph (1) substitute—

"(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).";

(b) for paragraph (3) substitute—

"(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

F247 Reg. 91 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 68**

Commencement Information

I92 Reg. 91 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F248Amendment of regulation 95 (offences in connection with application)

92. In regulation 95—

(a) in sub-paragraph (c), before "fails" insert ", in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,";

(b) in sub-paragraph (d), before "provides" insert ", in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,".**]**

Textual Amendments

F248 Reg. 92 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 69**

Commencement Information

I93 Reg. 92 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 96 (provision of misleading information)

F249**93.** . . . . . .

Textual Amendments

F249 Reg. 93 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 70**

Amendment of regulation 97 (breach of pharmacovigilance condition)

94.—(1) Regulation 97 M65, is amended as follows.

F250(2) . . . . . .

(3) In paragraph (2), after "exceptional circumstances)" insert " , regulation 60A (condition as to the testing of samples by the appropriate authority) ".

Textual Amendments

F250 Reg. 94(2) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 71**

Commencement Information

I94 Reg. 94 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M65 Regulation 97 was substituted by S.I. 2014/1878.

PROSPECTIVE

Amendment of regulation 98 (general offence of breach of Part 5)

F251**95.** . . . . . .

Textual Amendments

F251 Reg. 95 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 72**

PROSPECTIVE

Amendment of regulation 99 (penalties)

[F252]96. . . . . . .

Textual Amendments

F252 Reg. 96 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 73**

PROSPECTIVE

Amendment of regulation 101 (defences)

[F253]97. . . . . . .

Textual Amendments

F253 Reg. 97 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 74**

PART 6

Amendment of Part 6 (certification of homoeopathic products)

Amendment of regulation 102 (regulation-making power to amend regulation 102(4) to (6))

98. In regulation 102 (application of Part 6), at the end insert—

[[F254]"(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

F254 Words in reg. 98 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 75**

Commencement Information

I95 Reg. 98 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 103 (application for certificate of registration)

99.—(1) Regulation 103 is amended as follows.

[[F255](1A) After paragraph (1) insert—

"(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) In paragraph (4), **[**[F256]for "must be established in the European Union" substitute—

, 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.**]**

[[F257](2A) After paragraph (5) insert—

"(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.".**]**

(3) In paragraph (8)—

(a) in sub-paragraph (e)—

(i) omit "or another EEA State", and

(ii) for "that EEA State" substitute " a country other than the United Kingdom "; and

(b) in sub-paragraph (f), for "another member state" substitute " a country other than the United Kingdom ".

Textual Amendments

F255 Reg. 99(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(a)**

F256 Words in reg. 99(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(b)**

F257 Reg. 99(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 76(c)**

Commencement Information

I96 Reg. 99 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 104 (consideration of application)

[F258100.—(1) Regulation 104 (consideration of application) is amended as follows.

(2) After paragraph (6) insert—

"(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

F258 Reg. 100 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 77**

Commencement Information

I97 Reg. 100 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 108 (application for renewal of certificate)

101. In regulation 108(2), **[F259**for "must be established in the European Union" substitute—

", 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."**]**

Textual Amendments

F259 Words in reg. 101 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 78**

Commencement Information

I98 Reg. 101 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F260Amendment of regulation 109 (failure to place on the market etc.)

101A.—(1) Regulation 109 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after "in the United Kingdom" insert "(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)".

(3) In paragraph (2) after "in the United Kingdom" insert "(or, in the case of a COR(GB) granted after an application under the unfettered access route, in Great Britain)".**]**

Textual Amendments

F260 Reg. 101A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 79**

Commencement Information

I99 Reg. 101A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 110 (revocation, variation and suspension of certificate of registration)

102.—(1) Regulation 110 [M66] is amended as follows.

[[F261](2) In paragraph (7) for "established in the European Union" substitute—

"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.".**]**

[[F262](2A) After paragraph (8A) insert—

"(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.".**]**

(3) Omit paragraph (10).

Textual Amendments

F261 Reg. 102(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(a)**

F262 Reg. 102(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 80(b)**

Commencement Information

I100 Reg. 102 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M66 Regulation 110 was amended by S.I.2013/1855.

Omission of regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive)

103. Omit regulation 111.

Commencement Information

I101 Reg. 103 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 112 (withdrawal of homoeopathic medicinal product from the market)

104. In regulation 112(1), omit "or regulation 111(2)".

Commencement Information

I102 Reg. 104 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 113 (obligation to notify placing on the market etc)

105. In regulation 113(3A) [M67], omit "in accordance with article 123(2) of the 2001 Directive".

Commencement Information

I103 Reg. 105 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M67 Paragraph (3A) was inserted by S.I. 2013/2593.

Amendment of regulation 115 (obligation to provide information relating to safety etc)

106. In regulation 115(5)(a) for "which is not an EEA State" substitute " other than the United Kingdom ".

Commencement Information

I104 Reg. 106 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F263Amendment of regulation 116 (obligation in relation to product information)

107. For regulation 116(2), substitute—

"(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

F263 Reg. 107 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 81**

Commencement Information

I105 Reg. 107 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

Amendment of italic heading above regulation 125 (traditional herbal medicinal products)

108. For the italic heading "Application of Part", substitute " Interpretation and application of Part ".

Commencement Information

I106 Reg. 108 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 124A (interpretation)

109. Before regulation 125 (traditional herbal medicinal products), insert—

"**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.".

Commencement Information

I107 Reg. 109 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 125 (traditional herbal medicinal products)

110. In regulation **[**[F264]125(5) for sub-paragraph (b) substitute—

(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.**]**

Textual Amendments

F264 Words in reg. 110 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 82**

Commencement Information

I108 Reg. 110 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 125A (list of approved countries for herbal medicinal products)

111. After regulation 125 insert—

"**List 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.".

Commencement Information

I109 Reg. 111 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new italic heading and regulation 126A (list of herbal substances, preparations and combinations for use in traditional herbal medicinal products)

112. After regulation 126 (addition of vitamins or minerals) insert—

"List of herbal substances, preparations and combinations for use in traditional herbal medicinal products

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 **[**[F265]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.".

Textual Amendments

F265 Words in reg. 112 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 83**

Commencement Information

I110 Reg. 112 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 127 (application for grant of traditional herbal registration)

[[F266]**113.**—(1) Regulation 127 (application for grant of traditional herbal registration) is amended as follows.

(2) After paragraph (1) insert—

"(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.".

(3) In paragraph (3) for "must be established in the European Union" substitute—

", 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) After paragraph (4) insert—

"(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.".**]**

Textual Amendments

F266 Reg. 113 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 84**

Commencement Information

I111 Reg. 113 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 128 (accompanying material)

[[F267]**114.**—(1) Regulation 128 (accompanying material) is amended as follows.

(2) For paragraph (1) substitute—

"**128.**—(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.".

(3) In paragraph (3), after "of the 2001 Directive" insert "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)".**]**

Textual Amendments

F267 Reg. 114 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 85**

Commencement Information

I112 Reg. 114 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 12 (material to accompany an application for a traditional herbal registration)

115.—(1) Schedule 12 is amended as follows.

(2) In paragraphs 16 and 17, for "another member State or a third country" substitute " a country other than the United Kingdom ".

(3) In paragraph 21—

[[F268](a) after "Article 23 of Regulation (EC) No 726/2004" insert "or regulation 202A, as the case may be";**]**

(b) before "statement", insert " symbol and "; and

(c) before "This", insert " ▼ ".

Textual Amendments

F268 Reg. 115(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 86**

Commencement Information

I113 Reg. 115 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 130 (consideration of application)

116.—(1) Regulation 130 is amended as follows.

(2) In paragraph (6), insert " UK " before "marketing authorisation".

(3) In paragraph (7), **[**F269for "is subject to" to the end substitute—

"(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."**]**

(4) In paragraph (8), **[**F270after "of the 2001 Directive" insert "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)**]**

[F271(5) In paragraph (9), after "Where" insert ", in relation to an application for a THR(NI) or THR(UK),".**]**

(6) In paragraph (10)(a) **[**F272for "in Article 16h(3)" to the end substitute—

—

(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**]**

[F273(7) In paragraph (12), after "This regulation does not apply where" insert ", in relation to an application for a THR(NI) or THR(UK),".**]**

[F274(8) After paragraph (13) insert—

"(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

F269 Words in reg. 116(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(a)**

F270 Words in reg. 116(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(b)**

F271 Reg. 116(5) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(c)**

F272 Words in reg. 116(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(d)**

F273 Reg. 116(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(e)**

F274 Reg. 116(8) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 87(f)**

Commencement Information

I114 Reg. 116 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 130A (procedure where less than 15 years use of traditional herbal medicinal product)

117. After regulation 130 (consideration of application) insert—

"**Procedure where less than 15 years use of traditional herbal medicinal product**

130A.—(1) Where an application for a **[**[F275]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

F275 Words in reg. 117 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 88**

Commencement Information

I115 Reg. 117 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 133 (application for renewal of registration)

118. In regulation 133(2), **[**[F276]for "must be established in the European Union" substitute—

""", 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."**]**."

Textual Amendments

F276 Words in reg. 118 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 89**

Commencement Information

I116 Reg. 118 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F277]Amendment of regulation 134 (failure to place on the market etc.)

118A.—(1) Regulation 134 (failure to place on the market etc.) is amended as follows.

(2) In paragraph (1) after "in the United Kingdom" insert "(or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)".

(3) In paragraph (2) after "in the United Kingdom" insert "(or, in the case of a THR(GB) granted after an application under the unfettered access route, in Great Britain)".**]**

Textual Amendments

F277 Reg. 118A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 90**

Commencement Information

I117 Reg. 118A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration)

119.—(1) Regulation 135 [M68] is amended as follows.

[[F278](1A) For paragraph (6) substitute—

"(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.".**]**

(2) In paragraph (7)(b), **[**[F279]after "states other than EEA states" insert "/ countries other than approved countries for import".**]**

[[F280](3) In paragraph (8)(a) omit "other than the United Kingdom".**]**

(4) In paragraph (9), **[**[F281]in sub-paragraph (b), at the beginning insert "in the case of a THR(NI) or THR(UK),".**]**

[[F282](4A) After paragraph (10A) insert—

"(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.".**]**

(5) Omit paragraph (11).

Textual Amendments

F278 Reg. 119(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(a)**

F279 Words in reg. 119(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(b)**

F280 Reg. 119(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(c)**

F281 Words in reg. 119(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(d)**

F282 Reg. 119(4A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 91(e)**

Commencement Information

I118 Reg. 119 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M68 Regulation 135 was amended by S.I. 2013/1855.

Amendment of regulation 136 (revocation by licensing authority: further provisions)

120.—(1) Regulation 136 is amended as follows.

(2) In paragraph (1)(a), **[**[F283]for "the list referred to in" to the end substitute—

"(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"**]**

(3) Omit paragraph (3).

Textual Amendments

F283 Words in reg. 120(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 92**

Commencement Information

I119 Reg. 120 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 138 (suspension of use etc of traditional herbal medicinal product)

121. Omit regulation 138(10).

Commencement Information

I120 Reg. 121 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Omission of regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive)

122. Omit regulation 139.

Commencement Information

I121 Reg. 122 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market)

123. In regulation **[**F284140(1) for sub-paragraph (a) substitute—

"(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"**]**

Textual Amendments

F284 Words in reg. 123 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 93**

Commencement Information

I122 Reg. 123 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 141 (sale etc of suspended traditional herbal medicinal product)

124. In regulation 141(1), omit "or 139(2)".

Commencement Information

I123 Reg. 124 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 142 (obligation to notify placing on the market etc)

125. **[**[F285]In regulation 142(5C), for "traditional herbal registration" substitute "THR(NI) or THR(UK)**]**[M69].

Textual Amendments

F285 Words in reg. 125 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 94**

Commencement Information

I124 Reg. 125 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M69 Regulation 142 was amended by S.I. 2013/2593.

Insertion of new regulation 143A (establishment of herbal monographs)

126. After regulation 143 (obligation to take account of scientific or technical progress) insert—

"**Establishment of herbal monographs**

143A.—(1) The licensing authority may establish herbal monographs for herbal medicinal products and traditional herbal medicinal products **[**[F286]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

F286 Words in reg. 126 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 95**

Commencement Information

I125 Reg. 126 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F287Substitution of regulation 144 (obligation following new herbal monograph)

127. For regulation 144 substitute—

"**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

F287 Reg. 127 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 96**

Commencement Information

I126 Reg. 127 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 145 (obligation to provide information relating to safety etc)

128. In regulation 145(5)(a), for "which is not an EEA State" substitute " other than the United Kingdom ".

Commencement Information

I127 Reg. 128 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 146 (obligation in relation to product information)

[[F288]**129.** For regulation 146(2), substitute—

"(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

F288 Reg. 129 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 97**

Commencement Information

I128 Reg. 129 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 148A (urgent safety restrictions)

130. After regulation 148 (obligation to ensure appropriate and continued supplies) insert—

"**Urgent 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.".

Commencement Information

I129 Reg. 130 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F289]Substitution of regulation 149 (urgent safety restrictions)

131. For regulation 149 substitute—

"**149.**—(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

F289 Reg. 131 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 98**

Commencement Information

I130 Reg. 131 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 8

Omission of Part 8 (Article 126a authorisations)

[F290Amendment of regulation 156 (article 126a authorisations)

132. In regulation 156—

(a) in paragraph (1)—

(i) after "126a authorisation for" insert "sale or supply of";

(ii) after "medicinal product" insert "in Northern Ireland only,";

(b) in paragraph (2), after "is in force" insert "in Northern Ireland";

(c) in paragraph (3), after "traditional herbal registration" insert "to be in force in Northern Ireland";

(d) in paragraph (4) for "the United Kingdom" substitute "Northern Ireland"; and

(e) in paragraph (5) for "another member State" substitute "an EU member State".

Textual Amendments

F290 Regs. 132, 132A substituted for reg. 132 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**

Commencement Information

I131 Reg. 132 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 157 (requests from other member States)

132A. In regulation 157(1)—

(a) in the heading for "other member States" substitute "EU member States"; and

(b) in paragraph (1)—

(i) after "where the licensing authority" insert ", in relation to a UKMA(NI),"; and

(ii) for "another member State" substitute "a member State".**]**

Textual Amendments

F290 Regs. 132, 132A substituted for reg. 132 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 99**

Commencement Information

I132 Reg. 132A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 9

Amendment of Part 9 (borderline products)

Amendment of regulation 159 (provisional determination)

133. In regulation 159(1)—

(a) insert " UK " before "marketing authorisation"; and

[[F291](b) for "Article 126a authorisation" insert ", only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,".**]**

Textual Amendments

F291 Reg. 133(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 100**

Commencement Information

I133 Reg. 133 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 164 (effect of determination)

134. In regulation 164(2)(a) and (b)—

(a) insert " UK " before "marketing authorisation"; and

[[F292](b) for "Article 126a authorisation" insert ", only in relation to a product for sale or supply in Northern Ireland, an Article 126a authorisation or an EU marketing authorisation,".**]**

Textual Amendments

F292 Reg. 134(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 101**

Commencement Information

I134 Reg. 134 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 10

Amendment of Part 10 (exceptions to requirement for marketing authorisations etc)

[F293New regulation 135ZA (amendment of regulation 167 (supply to fulfil special patient needs))

135ZA. In regulation 167 (supply to fulfil special patient needs)—

(a) in paragraph (6), for "or imported into the United Kingdom from a country other than an EEA State" substitute ", 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";

(b) in paragraph (7)—

(i) for "imported from an EEA State" substitute "imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import";

(ii) for sub-paragraph (a) substitute—

"(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";

(iii) for sub-paragraph (b) substitute—

"(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,".**]**

Textual Amendments

F293 Reg. 135ZA inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**

Commencement Information

I135 Reg. 135ZA in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F294Amendment of regulation 168 (use of non-prescription medicines in the course of a business)

135. In regulation 168 (use of non-prescription medicines in the course of a business), for paragraph (8) substitute—

"(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.".**]**

Textual Amendments

F294 Reg. 135 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 103**

Commencement Information

I136 Reg. 135 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 169 (mixing of general sale medicinal products)

136. In regulation 169(9)(a), **[**[F295]for "marketing authorisation" substitute "UK marketing authorisation or EU marketing authorisation"**]** .

Textual Amendments

F295 Words in reg. 136 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 104**

Commencement Information

I137 Reg. 136 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 171 (exempt advanced therapy medicinal products)

137. In regulation 171(2)(c) for "Regulation (EC) No 726/2004**[**[F296]substitute—

"—

(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)."**]**

Textual Amendments

F296 Words in reg. 137 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 105**

Commencement Information

I138 Reg. 137 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 173 (exemption for certain radiopharmaceuticals)

138. In regulation 173(c), **[**[F297]for "marketing authorisation" substitute "UK marketing authorisation or EU marketing authorisation"**]** .

Textual Amendments

F297 Words in reg. 138 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 106**

Commencement Information

I139 Reg. 138 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 177 (application of Part and interpretation)

139.—(1) Regulation 177 [M70] is amended as follows.

[[F298](2) After paragraph (1) insert—

"(1A) Schedule 12A applies in relation to medicinal products that are the subject of a UKMA(GB) ora THR(GB).".**]**

(3) In paragraph (2)—

(a) after "this Part" insert " and Schedule 12A ";

[F299](b) . . . . . .

[F300](c) . . . . . .

(4) In paragraph (3)—

(a) for "Schedule 33" substitute " Schedules 12A and 33 ";

[F301](b) . . . . . .

[F302](c) . . . . . .

[F303](5) . . . . . .

[[F304](6) In paragraph (5)—

(a) for "Schedule 33" substitute "Schedules 33 and 33A";

(b) in paragraph (c) of the definition of "relevant post-authorisation safety study", omit "and"; and

(c) after that definition, insert—

""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".**]**

Textual Amendments

F298 Reg. 139(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(a)**

F299 Reg. 139(3)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(b)**

F300 Reg. 139(3)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(b)**

F301 Reg. 139(4)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(c)**

F302 Reg. 139(4)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(c)**

F303 Reg. 139(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(d)**

F304 Reg. 139(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(e)**

Commencement Information

I140 Reg. 139 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M70 Regulation 177 was amended by S.I. 2013/1855 and 2014/1878.

[F305Amendment of regulation 179 (obligation on licensing authority to operate pharmacovigilance system)

139A. In regulation 179—

(a) in paragraph (1), after "pharmacovigilance system" insert "in relation to medicinal products for sale or supply in Great Britain";

(b) after paragraph (1) insert—

"(1A) The licensing authority must operate a pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland.";

(c) in paragraph (2) for "The pharmacovigilance system" substitute "Each pharmacovigilance system"; and

(d) in paragraph (3)(a) for "the pharmacovigilance system" substitute "each pharmacovigilance system".**]**

Textual Amendments

F305 Reg. 139A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**

Commencement Information

I141 Reg. 139A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system)

140.—(1) Regulation 180 is amended as follows.

(2) In paragraph (1),

[F306(a) after "its pharmacovigilance system" insert "relating to medicinal products for sale or supply in Great Britain" and**]**

[F307(b)**]** omit "and report the results of that audit to the European Commission".

[F308(2A) After paragraph (1) insert—

"(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.".**]**

(3) In paragraph (2)—

(a) omit "results of the"; and

(b) for "reported to the European Commission" substitute " performed ".

[F309(4) After paragraph (2) insert—

"(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

F306 Reg. 140(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(a)(i)**

F307 Words in reg. 140(2) renumbered as reg. 140(2)(b) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(a)(ii)**

F308 Reg. 140(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(b)**

F309 Reg. 140(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(c)**

Commencement Information

I142 Reg. 140 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F310**Amendment of regulation 181 (delegation of obligations under Part 11)**

141. In regulation 181(1), for "to another EEA State" substitute "in connection with its pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland to an EEA State".**]**

Textual Amendments

F310 Reg. 141 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 110**

Commencement Information

I143 Reg. 141 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system)

142.—(1) Regulation 182 [M71] is amended as follows.

(2) In paragraph (2)(a), **[**[F311]after "in the EU" insert "or United Kingdom"**]** .

[[F312](2A) In paragraph (2)(b), after "pharmacovigilance system master file" insert "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".

(2B) After paragraph (2) insert—

"(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.".**]**

[[F313](3) For paragraph (3) substitute—

"(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) Omit paragraph (6).

Textual Amendments

F311 Words in reg. 142(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(a)**

F312 Reg. 142(2A)(2B) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**

F313 Reg. 142(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(c)**

Commencement Information

I144 Reg. 142 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M71 Regulation 182 was amended by S.I. 2013/1855.

Amendment of regulation 184 (obligation on holder to audit pharmacovigilance system)

143. In regulation 184, after paragraph (2) insert—

"(3) The holder **[**[F314]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

F314 Words in reg. 143 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 112**

Commencement Information

I145 Reg. 143 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 185 (recording obligations on the licensing authority)

144. In regulation 185(b), after "by" insert " a holder, ".

Commencement Information

I146 Reg. 144 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 186 (reporting obligations on the licensing authority)

[[F315]**145.** In regulation 186—

(a) in paragraph (1), for sub-paragraphs (d) and (e) substitute—

"(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.";

(b) omit paragraph (4).**]**

Textual Amendments

F315 Reg. 145 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 113**

Commencement Information

I147 Reg. 145 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulation 187A (collaboration with the World Health Organisation)

146. After regulation 186 insert—

"**186A.** 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.".

Commencement Information

I148 Reg. 146 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 187 (recording obligations on holders)

147.—(1) Regulation 187 is amended as follows.

[[F316](2) In paragraph (1) for "in the EEA or in third countries" substitute "in the United Kingdom or another country".**]**

(3) In paragraph (4), for "EEA" substitute " United Kingdom ".

Textual Amendments

F316 Reg. 147(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 114**

Commencement Information

I149 Reg. 147 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 188 (reporting obligations on holders)

148.—(1) Regulation 188 is amended as follows.

(2) In each place where it occurs, for "Eudravigilance database" substitute " licensing authority ".

(3) In paragraph (1)—

[[F317](za) for "Subject to paragraph (2), the holder" substitute "The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation";**]**

(a) in sub-paragraph (a)—

(i) for "EEA" substitute " United Kingdom ", and

(ii) for "third countries" substitute " countries other than the United Kingdom ";

(b) in sub-paragraph (b), for "EEA" substitute " United Kingdom ";

(c) in sub-paragraph (e), for "EMA and the competent authorities of the EEA States" substitute " licensing authority ".

[[F318](3A) After paragraph (1) insert—

"(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.".**]**

[[F319](4) In paragraph (2)—

(a) after "holder" insert "of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation";

(b) for "paragraph (1)(a) or (b)" substitute "paragraph (1A)(a) or (b)"; and

(c) for "paragraph (1)(d)" substitute "paragraph (1A)(c)".

(4A) In paragraph (3) for "paragraph (4)" substitute "paragraph (4A)".**]**

(5) In paragraph (4)(a), omit "other than monitored publications".

[[F320](5A) After paragraph (4) insert—

"(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).".**]**

(6) In paragraph (5), omit the definitions of "monitored active substance" and "monitored publication".

(7) Omit paragraph (6).

Textual Amendments

F317 Reg. 148(3)(za) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(a)**

F318 Reg. 148(3A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(b)**

F319 Reg. 148(4)(4A) substituted for reg. 148(4) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**

F320 Reg. 148(5A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(d)**

Commencement Information

I150 Reg. 148 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 189 (signal detection: licensing authority obligations)

149.—(1) Regulation 189 is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "in the Eudravigilance database" substitute " that it collects by virtue of operating its pharmacovigilance system under this Part "; and

(b) in sub-paragraph (d), for "regulations 59 to 61" substitute " regulations 59, 60 and 61 ".

[[F321](3) In paragraphs (2) and (3), for "The licensing" insert "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".**]**

Textual Amendments

F321 Reg. 149(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 116**

Commencement Information

I151 Reg. 149 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 190 (signal detection: holder obligation)

[[F322]**150.** For regulation 190(1) substitute—

"(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.".**]**

Textual Amendments

F322 Reg. 150 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 117**

Commencement Information

I152 Reg. 150 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements)

151.—(1) Regulation 191 is amended as follows.

(2) In paragraphs (1) and (7), **[**F323after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,"**]**.

(3) In paragraph (2), insert " UK " before "marketing authorisation".

F324(4) . . . . . .

(5) After paragraph (4) insert—

"(4A) A PSUR **[**F325in 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.".

(6) After paragraph (8), insert—

"(8A) In the case of a conditional marketing authorisation **[**F326in 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.".

[F327(7) In paragraph (10)—

(a) for sub-paragraph (b) substitute—

"(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";

(b) for sub-paragraph (c) substitute—

"(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.".**]**

(8) Omit paragraph (11).

Textual Amendments

F323 Words in reg. 151(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(a)**

F324 Reg. 151(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(b)**

F325 Words in reg. 151(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(c)**

F326 Words in reg. 151(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(d)**

F327 Reg. 151(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(e)**

Commencement Information

I153 Reg. 151 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 192 (obligation to submit periodic safety reports: derogation from general requirements)

152.—(1) Regulation 192 is amended as follows.

(2) In paragraph (1)(a), insert " UK " before "marketing authorisation".

(3) In paragraph (3), **[**F328after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]**

[F329(4) In paragraph (9), after "paragraph (3)(a)" insert "from the holder of a UKMA(UK), UKMA(NI), THR(UK), THR(NI) or Article 126a authorisation".**]**

Textual Amendments

F328 Words in reg. 152(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(a)**

F329 Reg. 152(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(b)**

Commencement Information

I154 Reg. 152 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)

153.—(1) Regulation 193 is amended as follows.

[F330(2) In paragraph (1) substitute—

"(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.";**]**

[F331(2A) In paragraph (2), after "holder" insert "of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

(3) **[**F332After paragraph (2) insert—**]**

[F333"(2A)**]** Where one or more of the grounds in paragraph (3) is met, the holder **[**F334of 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.".

(4) **[**F335After paragraph (4) insert—**]**

[F336"(4A)**]** Where the licensing authority makes a decision under paragraph (2) following a written request from a holder **[**F337of a UKMA(GB) or THR(GB)**]**, it must notify that holder in writing of its decision to approve or refuse the request.".

(5) In paragraph (5)—

[F338(a) after "of the 2001 Directive" insert "or paragraph (2A) (as the case may be)"**]**

[F339(b) after "EMA" insert "or licensing authority (as the case may be)"**]**

(6) **[**F340After paragraph (6) insert**]**—

[F341"(6A)**]** Subject to paragraph **[**F342(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.

[F341(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.".

(7) After paragraph **[**F343(6B)**]** insert—

"(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

F330 Reg. 153(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(a)**

F331 Reg. 153(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(b)**

F332 Words in reg. 153(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(i)**

F333 Words in reg. 153(3) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(ii)**

F334 Words in reg. 153(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(iii)**

F335 Words in reg. 153(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(i)**

F336 Words in reg. 153(4) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(ii)**

F337 Words in reg. 153(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(iii)**

F338 Reg. 153(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(i)**

F339 Reg. 153(5)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(ii)**

F340 Words in reg. 153(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(i)**

F341 Words in reg. 153(6) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(ii)**

F342 Word in reg. 153(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(iii)**

F343 Word in reg. 153(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(g)**

Commencement Information

I155 Reg. 153 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F344Amendment] of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive)

[F345154. In regulation 194(1) after "medicinal product" insert "authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

Textual Amendments

F344 Word in reg. 154 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 121(a)**

F345 Words in reg. 154 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 121(b)**

Commencement Information

I156 Reg. 154 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 195 (obligation on licensing authority to assess PSURs)

155.—(1) Regulation 195 [M72] is amended as follows.

(2) In the heading, omit "where EU single assessment procedure does not apply".

[[F346](2A) Before paragraph (1) insert—

"(A1) This regulation applies in the circumstances specified in paragraphs (1) and (1A).".

(2B) In paragraph (1)—

(a) after "relating to a medicinal product" insert "authorised for sale or supply authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation"; and

(b) in sub-paragraph (a)(i) omit "other than the United Kingdom".**]**

(3) **[**[F347]After**]** paragraph (1) **[**[F348]insert**]**—

[[F349]"(1A)**]** This regulation applies where PSURs relating to a medicinal product **[**[F350]authorised for sale or supply under a UKMA(GB) or THR(GB)**]** have been submitted to the licensing authority under regulations 191 to 192.".

(4) After paragraph (3) insert—

"(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.".

[F351](5) . . . . . .

Textual Amendments

F346 Reg. 155(2A)-(2B) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(a)**

F347 Word in reg. 155(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(i)**

F348 Word in reg. 155(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(ii)**

F349 Words in reg. 155(3) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(iii)**

F350 Words in reg. 155(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(iv)**

F351 Reg. 155(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(c)**

Commencement Information

I157 Reg. 155 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M72 Regulation 195 was amended by S.I. 2014/1878.

[F352Amendment of regulation 196 (urgent action)

156ZA. In regulation 196—

(a) in the italic heading immediately preceding it, after "Urgent action" insert "and major safety review";

(b) in paragraph (1), for "The licensing authority must initiate the Section 4 procedure by informing" substitute "In 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";

(c) omit sub-paragraph (2B);

(d) omit paragraphs (4) to (7);

(e) in paragraph (8), omit the definition of "EU urgent action procedure" and "Section 4 procedure".**]**

Textual Amendments

F352 Reg. 156ZA inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**

Commencement Information

I158 Reg. 156ZA in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F353Insertion of new regulation 196A (major safety review by the licensing authority)]

156. **[**F354After regulation 196 insert**]** substitute—

F355 "…

Major safety review by the licensing authority

[F356 **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

F353 Reg. 156 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(a)**

F354 Words in reg. 156 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(b)**

F355 Words in reg. 156 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(c)(i)**

F356 Words in reg. 156 renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(c)(ii)**

Commencement Information

I159 Reg. 156 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F357Amendment] of regulation 197 (EU urgent action procedure)

157. [F358In] regulation 197 [F359, in paragraph (1), after "class of medicinal products" insert "authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation"] .

Textual Amendments

F357 Word in reg. 157 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(a)**

F358 Word in reg. 157 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(b)**

F359 Words in reg. 157 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(c)**

Commencement Information

I160 Reg. 157 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 198 (post-authorisation safety studies: general provisions)

158.—(1) Regulation 198 is amended as follows.

(2) In paragraph (2),

[[F360](a) "the competent authorities" to the end becomes sub-paragraph (a);

(b) in sub-paragraph (a), at the end insert "and 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;"

(c) after sub-paragraph (a) insert—

"(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) In paragraph (3)—

(a) in sub-paragraph (c),

[[F361](i) "for "the relevant competent authorities" substitute—

"(i) "for "the relevant competent authorities" substitute—

"(i) the relevant competent authorities and the licensing authority, where paragraph (2)(a) applies;

(ii) the licensing authority where paragraph (2)(b) applies,"

(ii) "any new information" to the end becomes full-out words;"**]**

(b) in sub-paragraph (d),

[[F362](i) "the competent authorities of the EEA States in which the study was conducted" becomes paragraph (i);

(ii) in paragraph (i), after "the study was conducted" insert "and the licensing authority, where paragraph (2)(a) applies;"

(iii) after paragraph (i) insert—

"(ii) the licensing authority, where paragraph (2)(b) applies,";

(iv) "before the end of the period" to the end becomes full-out words.**]**

Textual Amendments

F360 Words in reg. 158(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(a)**

F361 Words in reg. 158(3)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(i)**

F362 Words in reg. 158(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**

Commencement Information

I161 Reg. 158 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 199 (submission of draft study protocols for required studies)

159.—(1) Regulation 199 is amended as follows.

[[F363](2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"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.".**]**

[[F364](3) In paragraph (4)—

(a) after "protocol is submitted" insert "only";

(b) after "paragraphs (2) and (3)(a)" insert "(and is not submitted to the Pharmacovigilance Risk Assessment Committee)".**]**

[F365](4) . . . . . .

[F365](5) . . . . . .

[F365](6) . . . . . .

Textual Amendments

F363 Reg. 159(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(a)**

F364 Reg. 159(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(b)**

F365 Reg. 159(4)-(6) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(c)**

Commencement Information

I162 Reg. 159 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 200 (amendment to study protocols for required studies)

160.—(1) Regulation 200 is amended as follows.

[[F366](2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"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.".**]**

[[F367](3) In paragraph (4)—

(a) after "protocol is submitted" insert "only";

(b) after "paragraphs (2) and (3)(a)" insert "(and is not submitted to the Pharmacovigilance Risk Assessment Committee)".**]**

[F368](4) . . . . . .

F369(5) . . . . . .

Textual Amendments

F366 Reg. 160(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(a)**

F367 Reg. 160(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(b)**

F368 Reg. 160(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(c)**

F369 Reg. 160(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(c)**

Commencement Information

I163 Reg. 160 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 201 (submission and evaluation of final study reports for required studies)

161.—(1) Regulation 201 is amended as follows.

[F370(2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"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),

a final study report and an abstract of the study results.".**]**

F371(3) . . . . . .

(4) In paragraph (4), **[**F372omit "for reports falling under paragraph (3)(a)" and "for reports falling under paragraph (3)(b)**]**

Textual Amendments

F370 Reg. 161(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(a)**

F371 Reg. 161(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(b)**

F372 Words in reg. 161(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(c)**

Commencement Information

I164 Reg. 161 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F373Amendment of regulation 202 (follow up of final study reports)

162. In regulation 202(1), after "This regulation applies" insert "in respect of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

Textual Amendments

F373 Reg. 162 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 130**

Commencement Information

I165 Reg. 162 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulation 202A (medicinal products subject to additional monitoring)

163. After regulation 202 insert—
"Medicinal products subject to additional monitoring

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.".

Commencement Information

I166 Reg. 163 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 203 (obligations on licensing authority in relation to national medicines web-portal)

164.—(1) Regulation 203 is amended as follows.

(2) In paragraph (1), omit from "linked" to the end.

[[F374](3) In paragraph (2), after sub-paragraph (d) insert—

"(da) the list published by the licensing authority under, or which applies by virtue of, regulation 202A;".**]**

Textual Amendments

F374 Reg. 164(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 131**

Commencement Information

I167 Reg. 164 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F375]Amendment] of regulation 204 (obligation on licensing authority in relation to public announcements)

165. [[F376]In**]** regulation 204 **[**[F377], in paragraph (1), after "pharmacovigilance concerns" insert "which relate to products authorised under a UKMA(NI) or UKMA(UK)**]**.

Textual Amendments

F375 Word in reg. 165 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(a)**

F376 Word in reg. 165 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(b)**

F377 Words in reg. 165 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(c)**

Commencement Information

I168 Reg. 165 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 205 (obligations on holders in relation to public announcements)

166.—(1) Regulation 205 is amended as follows.

(2) In paragraph (2), **[**F378after "bodies listed in paragraph (3)" insert "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),"**]**

F379(3) . . . . . .

Textual Amendments

F378 Words in reg. 166(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 133(a)**

F379 Reg. 166(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 133(b)**

Commencement Information

I169 Reg. 166 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 205A (further obligations in respect of pharmacovigilance activities)

167. After regulation 205 insert—

"Further obligations in respect of pharmacovigilance activities

Further obligations in respect of pharmacovigilance activities

205A.—(1) Schedule 12A **[**F380applies 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) **[**F381The Secretary of State**]** may by regulations **[**F382in 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.".

Textual Amendments

F380 Words in reg. 167 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(a)**

F381 Words in reg. 167 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(b)(i)**

F382 Words in reg. 167 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(b)(ii)**

Commencement Information

I170 Reg. 167 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new Schedule 12A (further provision as to performance of pharmacovigilance activities)

168. Schedule 6 inserts a new Schedule 12A after Schedule 12 to the 2012 Regulations.

Commencement Information

I171 Reg. 168 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 205B (guidance in respect of good pharmacovigilance practice and post authorisation efficacy studies)

169. After new regulation 205A insert—
"Guidance in respect of pharmacovigilance

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.".

Commencement Information

I172 Reg. 169 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 206 (infringement notices)

170.—(1) Regulation 206 [M73] is amended as follows.

[[F383](2) In paragraph (3), after "paragraph (1)" insert "in relation to a product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI) or THR(UK)".

(3) In paragraph (4) after sub-paragraph (a) insert—

"(aa) Schedule 12A;".**]**

Textual Amendments

F383 Reg. 170(2)(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 135**

Commencement Information

I173 Reg. 170 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M73 Regulation 206 was amended by S.I. 2013/1855.

Amendment of regulation 207 (offences)

171. In regulation 207(1), after "other than" insert " Schedule 12A (further requirements in respect of pharmacovigilance activities) and ".

Commencement Information

I174 Reg. 171 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 208 (false and misleading information)

[F384]**172.** . . . . . .

Textual Amendments

F384 Reg. 172 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

PROSPECTIVE

Amendment of regulation 209 (penalties)

[F385]**173.** . . . . . .

Textual Amendments

F385 Reg. 173 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

PROSPECTIVE

Omission of regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004)

[F386]**174.** . . . . . .

Textual Amendments

F386 Reg. 174 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

Amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation)

175.—(1) Regulation 210A [M74] is amended as follows.

(2) In the heading, **[**[F387]after**]** "the Implementing Regulation **[**[F388]insert "and Schedule 12A"**]**.

(3) In paragraph (1)—

[[F389](a) in sub-paragraph (a), at the beginning insert "in relation to a UKMA(NI), UKMA(UK), THR(NI) THR(UK) or Article 126a authorisation,";

(b) after sub-paragraph (a) insert—

"(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".**]**

(4) **[**[F390]After paragraph (2) insert**]**—

[[F391]"(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).

F392(3) . . . . . .

F392(4) . . . . . .".

[F393(5) In paragraph (4), after "Implementing Regulation" insert ", or of paragraph 26(8) or 29(1) of Schedule 12A,".**]**

Textual Amendments

F387 Word in reg. 175(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(a)(i)**

F388 Words in reg. 175(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(a)(ii)**

F389 Reg. 175(3)(a)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(b)**

F390 Words in reg. 175(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(i)**

F391 Words in reg. 175(4) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(ii)**

F392 Words in reg. 175(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(iii)**

F393 Reg. 175(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(d)**

Commencement Information

I175 Reg. 175 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M74 Regulation 210A was inserted by S.I. 2013/1855.

PROSPECTIVE

Amendment of regulation 211 (persons liable)

F394**176.** . . . . . .

Textual Amendments

F394 Reg. 176 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 138**

Amendment of regulation 212 (transitional arrangements)

[F395177. In regulation 212, omit "182, 186, 188, 191, 192".**]**

Textual Amendments

F395 Reg. 177 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 139**

Commencement Information

I176 Reg. 177 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 33 (transitional arrangements: pharmacovigilance)

178. In Schedule 33, omit paragraphs 1, 2 and **[F3965]** to 10.

Textual Amendments

F396 Word in reg. 178 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 140**

Commencement Information

I177 Reg. 178 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 12

Amendment of Part 12 (dealings with medicinal products)

Amendment of regulation 213 (interpretation of Part 12)

179. In regulation 213(1) [M75]—

(a) insert at the appropriate place—

""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;";

(b) omit the definition of "EEA health professional"[M76]; and

(c) in the definition of "relevant prescriber", for "EEA health professional" substitute " approved country health professional ".

Commencement Information

I178 Reg. 179 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M75 Regulation 213 was amended by S.I. 2013/235 and 2014/490 and 1878.

M76 The definition was substituted by S.I. 2014/1878.

Amendment of regulation 214 (sale or supply of prescription only medicines)

180.—(1) Regulation 214 [M77] is amended as follows.

(2) In paragraph (2)(a), for "EEA health professional" substitute " approved country health professional ".

(3) In paragraph (6), for "EEA health professional" substitute " approved country health professional ".

(4) After paragraph (6) insert—

"(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.".

Commencement Information

I179 Reg. 180 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M77 Regulation 214 was amended S.I. 2013/1855, 2014/490, 2016/186 and 2018/199.

Amendment of regulation 216 (exceptions to regulation 215)

181. In regulation 216(2), for "EEA health professional" substitute " approved country health professional ".

Commencement Information

I180 Reg. 181 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 217 (requirements for prescriptions: general)

182. In regulation 217(8)(a) [M78], for "EEA health professional" substitute " approved country health professional ".

Commencement Information

I181 Reg. 182 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M78 Regulation 217 was amended by S.I. 2014/490.

Amendment of regulation 217A (requirements for prescriptions to be dispensed in an EEA State)

183.—(1) Regulation 217A [M79] is amended as follows.

(2) In the heading, omit "other than the UK".

(3) In paragraph (2)(a), omit "other than the UK".

Commencement Information

I182 Reg. 183 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M79 Regulation 217A was inserted by S.I. 2014/490.

Amendment of regulation 218 (requirements for prescriptions: EEA health professionals)

184.—(1) Regulation 218 [M80] is amended as follows.

(2) In the heading, and each place where it subsequently occurs, for "EEA health professional" substitute " approved country health professional ".

(3) In paragraph (5)(c) and (d)(ii)(bb), for "EEA health professional's" substitute "approved country health professional's".

(4) In paragraph (2)(a), for "relevant European State except the United Kingdom" substitute " country included in the list published under regulation 214(6A) ".

Commencement Information

I183 Reg. 184 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M80 Regulation 218 was amended by S.I. 2014/490 and 1878 and 2015/903.

Amendment of regulation 219 (electronic prescriptions)

185. In regulation 219(2) [M81], for "EEA health professional" substitute " approved country health professional ".

Commencement Information

I184 Reg. 185 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M81 Regulation 219 was amended by S.I. 2015/903 and 2016/696.

Amendment of regulation 219A (electronic prescriptions: EEA health professionals)

186.—(1) Regulation 219A [M82] is amended as follows.

(2) In the heading, for "EEA health professionals" substitute " approved country health professionals ".

(3) In paragraph (2), for "EEA health professional" substitute " approved country health professional ".

Commencement Information

I185 Reg. 186 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M82 Regulation 219A was amended by S.I. 2015/903.

Amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)

[[F397]**187.** In regulation 229(3), for sub-paragraph (f) substitute—

"(f) when the product is supplied—

(i) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), 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.".**]**

Textual Amendments

F397 Reg. 187 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 141**

Commencement Information

I186 Reg. 187 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

[F398188. For regulation 230(8) substitute—

"(8) Condition G is that when the product is supplied or (as the case may be) administered —

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), 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

F398 Reg. 188 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 142**

Commencement Information

I187 Reg. 188 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc.)

[F399189. For regulation 231(8) substitute—

"(8) Condition G is that when the product is supplied—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), 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

F399 Reg. 189 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 143**

Commencement Information

I188 Reg. 189 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)

[[F400]**190.** For regulation 232(8) substitute—

"(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.".**]**

Textual Amendments

F400 Reg. 190 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 144**

Commencement Information

I189 Reg. 190 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)

[[F401]**191.** For regulation 233(7) substitute—

"(7) Condition F is that when the prescription only medicine is supplied or (as the case may be) administered—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), 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

F401 Reg. 191 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 145**

Commencement Information

I190 Reg. 191 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)

[[F402]**192.** For regulation 234(9) substitute—

"(9) Condition H is that when the product is supplied—

(a) in Northern Ireland, a UKMA(NI), UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration, THR(NI) or THR(UK), 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

F402 Reg. 192 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 146**

Commencement Information

I191 Reg. 192 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)

193.—(1) Schedule 17 [M83] is amended as follows.

(2) In the table in Part 1, in column 1 in entry 10, **[**[F403]for "marketing authorisations" substitute "UK marketing authorisations, EU marketing authorisations**]**.

(3) In the table in Part 4, in columns 1 and 2 in entry 9, **[**[F404]for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation**]**.

Textual Amendments

F403 Words in reg. 193(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 147(a)**

F404 Words in reg. 193(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 147(b)**

Commencement Information

I192 Reg. 193 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M83 Schedule 17 was amended by S.I. 2014/1878, 2015/1503, 2016/186 and 2017/715,

Amendment of regulation 249 (restrictions on persons to be supplied with medicinal products)

194. In regulation 249(2)—

(a) in sub-paragraph (a), insert " UK " before "marketing authorisation";

[[F405](b) after sub-paragraph (a) insert—

"(aa) an EU marketing authorisation;".**]**

Textual Amendments

F405 Reg. 194(b) substituted for reg. 194(b)(c) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 148**

Commencement Information

I193 Reg. 194 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F406Amendment of regulation 251 (compliance with standards specified in certain publications)

194A. In regulation 251 (compliance with standards specified in certain publications), after paragraph (5) insert—

"(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

F406 Reg. 194A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 149**

Commencement Information

I194 Reg. 194A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products)

195. In regulation 254(2)(a), for the words from "laid down in" to the end, substitute—

"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 M84;

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005 M85; 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 M86;".

Commencement Information

I195 Reg. 195 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M84 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.

M85 S.I. 2005/50. It has been amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/604, 2017/1320 and 2018/231.

M86 S.I. 2007/1523.

[F407Amendment of regulation 255B (exception to Article 25 of Commission Regulation 2016/161: health care institutions)

196. In regulation 255A(1), after "purpose of sale or supply," insert "in Northern Ireland,".

Textual Amendments

F407 Regs. 196, 196A substituted for reg. 196 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**

Commencement Information

I196 Reg. 196 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 255B (exception to Article 25 of Commission Regulation 2016/161: health care institutions)

196A. In regulation 255B, after "medicinal products to the public" in the first place it occurs insert "in Northern Ireland".**]**

Textual Amendments

F407 Regs. 196, 196A substituted for reg. 196 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 150**

Commencement Information

I197 Reg. 196A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 13

Omission of Part 12A (sale of medicines to the public at a distance)

[F408Amendment of Part 12A

197.—(1) Before regulation 256A (interpretation) insert—

"**Application of Part**

256ZA. This part applies to Northern Ireland only.".

(2) In regulation 256A(1) (interpretation)—

(a) in the definition of "the list", for "competent authority of a member State in which the person named on the list is established" substitute "licensing authority";

(b) omit the definition of "relevant website of the member State";

(c) at the appropriate place in the alphabetical order insert—

""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;";

(d) in the definition of "website of the EMA"—

(i) in paragraph (a)—

(aa) for "relevant website of the member State" substitute "website of the licensing authority";

(bb) for "that member State" substitute "Northern Ireland";

(ii) in paragraph (e), for "hyperlinks to the relevant website of the member State" substitute "a hyperlink to the website of the licensing authority".

(3) In regulation 256B (person who may sell medicinal products by information society services)—

(a) before paragraph (1) insert—

"(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.";

(b) in paragraph (2), omit "of persons selling medicinal products at a distance that is published on the relevant website of the member State";

(c) for paragraph (3) substitute—

"(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.";

(d) in paragraph (4), omit "in the member State in which that person is established";

(e) in paragraphs (6), for "the competent authority in a member State in which the person is established" substitute "the licensing authority";

(f) in each of paragraphs (8)(b) and (c), for "the competent authority of a member State" substitute "the licensing authority".

(4) In regulations 256C (notification requirements for sellers of medicinal products at a distance) to 256M (offences: breach of regulations and false information), for "competent authority of a member State" in each place it occurs (including in the headings to regulations 256F and 256J) substitute "licensing authority".

(5) In regulation 256C (notification requirements for sellers of medicinal products at a distance), in paragraph (2)(b)(iv), for "informantion" substitute "information".

(6) In regulation 256D(3) (procedure for listing persons who may supply medicinal products at a distance), for "that competent authority" in both places substitute "the licensing authority".

(7) In regulation 256G (grant or refusal to list a person)—

(a) in paragraph (2), for "that competent authority" substitute "the licensing authority";

(b) in paragraph (3)—

(i) for "that competent authority" substitute "the licensing authority";

(ii) for "relevant website of the member State" substitute "website of the licensing authority".

(8) In regulation 256H(3) (conditions to be met by a person entered on the list)—

(a) in sub-paragraph (a), omit "which is responsible for maintaining the list on which the person selling products at a distance is included";

(b) in sub-paragraph (b), for "relevant website of the Member State" substitute "website of the licensing authority".

(9) In regulation 256J (procedure where the licensing authority proposes to suspend, vary or remove a person's entry on the list), omit sub-paragraph (6)(b) (and the "and" at the end of sub-paragraph (a)).

(10) In regulation 256K(1) (suspension of a person's entry on the list in cases of urgency), for "that competent authority" substitute "the licensing authority".

(11) In regulation 256L (variation of a person's entry on the list on the application of that person) —

(a) in paragraph (3), for "that competent authority" substitute "the licensing authority";

(b) in paragraph (6)(b), for "that competent authority's" substitute "the licensing authority's".**]**

Textual Amendments

F408 Reg. 197 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 151**

Commencement Information

I198 Reg. 197 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 14

Amendment of Part 13 (packaging and leaflets)

Amendment of regulation 257 (packaging requirements: general)

198.—(1) Regulation 257 is amended as follows.

(2) In paragraph (6), after "this regulation," insert " regulation 257C **[**[F409]where the product is for sale or supply in Great Britain only**]**,".

(3) After paragraph (7) insert—

"(8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product **[**[F410]for sale or supply in Great Britain only**]**.".

Textual Amendments

F409 Words in reg. 198(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 152(a)**

F410 Words in reg. 198(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 152(b)**

Commencement Information

I199 Reg. 198 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F411]Amendment of regulation 257A (packaging requirements: medicinal products required to bear safety features)

199. In regulation 257A, after "either fully or partially," insert "from a product to which Article 54a of the 2001 Directive applies".

Textual Amendments

F411 Regs. 199, 199A substituted for reg. 199 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**

Commencement Information

I200 Reg. 199 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 257B (transitional arrangements)

199A. In regulation 257B, after "unless the product" insert "is one to which Article 54a of the 2001 Directive applies and".**]**

Textual Amendments

F411 Regs. 199, 199A substituted for reg. 199 (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**

Commencement Information

I201 Reg. 199A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling)

200. After regulation 257, insert—

"**Packaging 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 **[**F412for sale or supply in Great Britain only**]** (other than an exempt advanced therapy medicinal product); and

(b) on the immediate packaging **[**F413of 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.

Guidance as to packaging and package leaflets

[[F414]**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).**]**

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

F412 Words in reg. 200 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 154(a)(i)**

F413 Words in reg. 200 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 154(a)(ii)**

F414 Words in reg. 200 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 154(b)**

Commencement Information

I202 Reg. 200 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 24 (packaging information requirements)

201.—(1) Schedule 24 is amended as follows.

(2) In paragraph 7(b), for "published pursuant to Article 65 of the 2001 Directive" substitute " published under regulation 257D **[**F415in 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.**]**".

(3) In paragraphs 15, 16 and 23, **[**F416for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".**]**.

F417(4) . . . . . .

(5) After Part 3 insert—

"PART 4

Outer and immediate packaging: advanced therapy medicinal products **[**F418for sale or supply in Great Britain only**]**

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 [M87], 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 [M88], 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 **[**[F419]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"."

Textual Amendments

F415 Words in reg. 201(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 155(a)**

F416 Words in reg. 201(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 155(b)**

F417 Reg. 201(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 155(c)**

F418 Words in reg. 201(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 155(d)(i)**

F419 Words in reg. 201(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 155(d)(ii)**

Commencement Information

I203 Reg. 201 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M87 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.

M88 S.I. 2007/1523.

Amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)

202. In regulation 259(2), **[**F420for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".**]**

Textual Amendments

F420 Words in reg. 202 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 156**

Commencement Information

I204 Reg. 202 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 260 (package leaflets)

203.—(1) Regulation 260 is amended as follows.

(2) After paragraph (1) insert—

"(1A) If the medicinal product is an advanced therapy medicinal product **[**F421for 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.".

(3) In paragraph (2), after "Part 2 of that Schedule)" insert " , or where the product is an advanced therapy medicinal product **[**F422for sale or supply in Great Britain only**]**, the information specified in Part 3 of that Schedule, ".

(4) In paragraph (3), for "marketing authorisation**F423**..." substitute " UK marketing authorisation **[**F424, EU marketing authorisation,**]** ".

Textual Amendments

F421 Words in reg. 203(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 157(a)**

F422 Words in reg. 203(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 157(b)**

F423 Words in reg. 203(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 157(c)(i)**

F424 Words in reg. 203(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 157(c)(ii)**

Commencement Information

I205 Reg. 203 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 27 (package leaflets)

204.—(1) Schedule 27 [M89] is amended as follows.

(2) In paragraph 8(c)(ii), for "Article 65 of the 2001 Directive", substitute " published under regulation 257D **[**[F425]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.**]** ".

(3) In paragraph 11(f), **[**[F426]for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".**]**

(4) **[**[F427]In**]** paragraph 12 **[**[F428] after " Where the product " insert "is authorised for sale or supply in Northern Ireland and".**]** .

(5) In paragraph 13—

(a) **[**[F429]after**]** "Article 23 of Regulation (EC) No 726/2004"**[**[F430]insert "in 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,";**]** ;

(b) before "statement", insert " symbol and "; and

(c) before "This", insert " ▼ ".

(6) At the end insert—

"Part 3

Advanced therapy medicinal products **[**[F431]for sale or supply in Great Britain only**]**

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.".

Textual Amendments

F425 Words in reg. 204(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(a)**

F426 Words in reg. 204(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(b)**

F427 Word in reg. 204(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(c)(i)**

F428 Words in reg. 204(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(c)(ii)**

F429 Word in reg. 204(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(d)(i)**

F430 Words in reg. 204(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(d)(ii)**

F431 Words in reg. 204(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 158(e)**

Commencement Information

I206 Reg. 204 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M89 Schedule 27 was amended by S.I. 2014/1878.

PROSPECTIVE

Amendment of regulation 266 (language requirements etc)

[F432205. . . . . . .

Textual Amendments

F432 Reg. 205 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 159**

Amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)

206. In regulation 267 **[**[F433]before "marketing authorisation", in each place where it occurs, insert "UK".**]**

Textual Amendments

F433 Words in reg. 206 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 160**

Commencement Information

I207 Reg. 206 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 268 (offence relating to packaging and package leaflets)

207.—(1) Regulation 268 [M90] is amended as follows.

[[F434](1A) In the heading to the regulation, after "packaging and package leaflets" insert "in Great Britain".**]**

[[F435](2) In paragraph (1)—

(a) for "marketing authorisation, Article 126a authorisation" substitute "UKMA(UK), UKMA(GB)";

(b) after "the purpose of sale or supply" insert ", in Northern Ireland".**]**

(3) In paragraph (2)(a)—

(a) for "Article 28 or 32 of the Paediatric Regulation" substitute " regulation 50C(4), 50D(8) or 58A(2)(b) "; and

(b) omit ", Article 9 of Commission Regulation 2016/161".

Textual Amendments

F434 Reg. 207(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 161(a)**

F435 Reg. 207(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 161(b)**

Commencement Information

I208 Reg. 207 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M90 Regulation 268 was amended by S.I. 2019/62.

[F436Insertion of new regulation 268A (offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc)

207A. After regulation 268 insert—

"**Offence 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

F436 Reg. 207A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 162**

Commencement Information

I209 Reg. 207A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)

208.—(1) Regulation 269 M91 is amended as follows.

[F437(1A) In the heading to the regulation, after "packaging and package leaflets" insert "in Great Britain".**]**

[F438(2) In paragraph (1)—

(a) for "marketing authorisation, Article 126a authorisation" substitute "UKMA(UK), UKMA(GB)";

(b) after "the purpose of sale or supply" insert ", in Great Britain".**]**

[F439(2A) In paragraph (2), after "for the purpose of sale or supply," insert "in Great Britain".**]**

(3) In paragraph (2)(a)—

(a) for "Article 28 or 32 of the Paediatric Regulation" substitute " regulation 50C(4), 50D(8) or 58A(2)(b) "; and

(b) omit ", Article 9 of Commission Regulation 2016/161".

Textual Amendments

F437 Reg. 208(1A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 163(a)**

F438 Reg. 208(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 163(b)**

F439 Reg. 208(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 163(c)**

Commencement Information

I210 Reg. 208 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M91 Regulation 269 was amended by S.I. 2015/903 and 2019/62.

[F440Insertion of new regulation 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)

208A. After regulation 269 insert—

"**Offences 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

F440 Reg. 208A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 164**

Commencement Information

I211 Reg. 208A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 270 (non-compliance with requirements of this Part)

209. In regulation 270(1) and (2), **[**[F441]for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation,**]**.

Textual Amendments

F441 Words in reg. 209 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 165**

Commencement Information

I212 Reg. 209 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F442]Amendment of regulation 271 (offences: penalties)

209A. In regulation 271 for "268, 269" substitute "268, 268A, 269, 269A".**]**

Textual Amendments

F442 Reg. 209A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 166**

Commencement Information

I213 Reg. 209A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 273 (child resistant containers for regulated medicinal products)

210.—(1) Regulation 273 is amended as follows.

(2) In paragraph (2), for sub-paragraph (b) substitute—

"(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) In paragraph (3), for sub-paragraph (b) substitute—

"(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).".

Commencement Information

I214 Reg. 210 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 15

Amendment of Part 14 (advertising)

Amendment of regulation 279 (products without a marketing authorisation)

[[F443]**211.** For regulation 279 substitute—

"**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);

(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);

(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

F443 Reg. 211 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 167**

Commencement Information

I215 Reg. 211 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 280 (general principles)

212. In regulation **[**[F444]280**]** —

(a) **[**[F445]in paragraph (1)**]** for "marketing authorisation," substitute " **[**[F446]UK marketing authorisation, EU marketing authorisation,**]** "; and

[[F447](b) after paragraph (1) insert—

"(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).".**]**

Textual Amendments

F444 Word in reg. 212 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(a)**

F445 Words in reg. 212(a) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(b)(i)**

F446 Words in reg. 212(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(b)(ii)**

F447 Reg. 212(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 168(c)**

Commencement Information

I216 Reg. 212 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 281 (duties of authorisation holders and registration holders)

213. In regulation 281(1)—

(a) in sub-paragraph (a), insert " UK " before "marketing authorisation";

[F448(b) omit "or" at the end of sub-paragraph (c); and

(c) in sub-paragraph (d), after "for a medicinal product" insert—

"; or

(e) an EU marketing authorisation for a medicinal product.".]

Textual Amendments

F448 Reg. 213(b)(c) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 169**

Commencement Information

I217 Reg. 213 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F449Insertion of new regulation 284A (Medicines with differing classification status in Great Britain and Northern Ireland)

213A. After regulation 284, insert—

"**Medicines 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

F449 Reg. 213A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 170**

Commencement Information

I218 Reg. 213A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 293 (prohibition of supply to the public for promotional purposes)

[[F450]**214.** For regulation 293(1) substitute—

"(1) The holder of—

(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.".**]**

Textual Amendments

F450 Reg. 214 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 171**

Commencement Information

I219 Reg. 214 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F451Amendment of regulation 294 (general requirements)

214A. In regulation 294, after paragraph (4) insert—

"(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

F451 Reg. 214A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 172**

Commencement Information

I220 Reg. 214A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 295 (abbreviated advertisements)

[F452215. In regulation 295—

(a) for paragraph (2)(d) substitute—

"(d) the name and address of the holder—

(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.";

(b) after paragraph (4) insert—

"(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.".**]**

Textual Amendments

F452 Reg. 215 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 173**

Commencement Information

I221 Reg. 215 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F453Amendment of regulation 298 (free samples for persons qualified to prescribe or supply medicinal products)

215A. In regulation 298, for paragraph (5)(a) substitute—

"(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;".**]**

Textual Amendments

F453 Reg. 215A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 174**

Commencement Information

I222 Reg. 215A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply)

[[F454]**216.** In Schedule 30—

(a) in paragraphs 1, 2 and 6, for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation";

(b) after paragraph 2 insert—

"**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

F454 Reg. 216 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 175**

Commencement Information

I223 Reg. 216 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 299 (medical sales representatives)

217. In regulation 299(3), **[**[F455]for "marketing authorisation," substitute "UK marketing authorisation, EU marketing authorisation".**]**

Textual Amendments

F455 Words in reg. 217 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 176**

Commencement Information

I224 Reg. 217 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F456 Amendment of regulation 305 (invitation to make representations about compatibility)

217A. In regulation 305—

(a) for paragraph (3)(a) substitute—

"(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) in paragraph (4), after "the advertisement" insert—

"—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland".

Textual Amendments

F456 Regs. 217A-217D inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**

Commencement Information

I225 Reg. 217A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 306 (decision about compatibility)

217B. In regulation 306—

(a) in paragraph (2), after "Chapter 2" insert—

"and 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";

(b) in paragraph (4)—

(i) in sub-paragraph (a), after "Chapter 2" insert—

"insofar as the advertisement is for publication—

(i) in Great Britain;

(ii) in Northern Ireland; or

(iii) in both Great Britain and Northern Ireland";

(ii) after "no longer applies" insert "in Great Britain, Northern Ireland, or both Great Britain and Northern Ireland (as appropriate)";

(c) in paragraph (5), after "Chapter 2" insert—

"insofar as the advertisement is for publication—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland";

(d) in paragraph (7)(b), after "no longer applies" insert—

",

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";

(e) in paragraph (8), after "the advertisement" insert—

"—

(a) in Great Britain;

(b) in Northern Ireland; or

(c) in both Great Britain and Northern Ireland".

Textual Amendments

F456 Regs. 217A-217D inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**

Commencement Information

I226 Reg. 217B in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 307 (corrective statement)

217C. In regulation 307—

(a) in paragraph (1)(a), after "subject of the notice" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland";

(b) in paragraph (1)(b), after "that advertisement" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland";

(c) in paragraph (2)(a), for ", either in full or in part; and" substitute—

"in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

either in full or in part; and".

Textual Amendments

F456 Regs. 217A-217D inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**

Commencement Information

I227 Reg. 217C in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 311 (application for injunction)

217D. In regulation 311—

(a) in paragraph (1)(a), for "Chapter 2; and" substitute—

"Chapter 2 in respect of—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland; and";

(b) in paragraph (3), after " the advertisement" insert—

"in—

(i) Great Britain;

(ii) Northern Ireland; or

(iii) both Great Britain and Northern Ireland,

as the case may be.".]

Textual Amendments

F456 Regs. 217A-217D inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 177**

Commencement Information

I228 Reg. 217D in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 16

Amendment of Part 15 (British Pharmacopoeia)

Amendment of regulation 321 (specified publications)

218. In regulation 321(5)—

(a) in sub-paragraph (c), insert " UK " before "marketing authorisation";

[[F457](b) after sub-paragraph (c) insert—

"(ca) an EU marketing authorisation;".**]**

Textual Amendments

F457 Reg. 218(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 178**

Commencement Information

I229 Reg. 218 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PART 17

Amendment of Part 16 (enforcement)

PROSPECTIVE

Amendment of regulation 322 (validity of proceedings)

[F458]**219.** . . . . . .

Textual Amendments

F458 Reg. 219 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 179**

Amendment of regulation 323 (enforcement in England, Wales and Scotland)

220.—(1) Regulation 323 [M92] is amended as follows.

(2) In paragraph (1) omit "and the relevant EU provisions".

(3) In paragraph (3)—

(a) at the end of sub-paragraph (b) insert " and "; and

(b) omit sub-paragraph (d).

(4) Omit paragraph (4A).

Commencement Information

I230 Reg. 220 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M92 Regulation 323 was amended S.I. 2019/62.

Amendment of regulation 327 (powers of inspection, sampling and seizure)

221.—(1) Regulation 327 [M93] is amended as follows.

(2) In paragraph (1)(c)—

(a) in paragraph (v), insert " UK " before "marketing authorisation";

[[F459](b) after paragraph (v), insert—

"(va) an EU marketing authorisation;".**]**

[[F460](3) In paragraph (2)(g), after paragraph (iv) insert—

"(iva) the requirements of Schedule 12A (further provision as to the performance of pharmacovigilance activities);".**]**

[F461](4) . . . . . .

[F462](5) . . . . . .

Textual Amendments

F459 Reg. 221(2)(b) substituted for reg. 221(2)(b)(c) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(a)**

F460 Reg. 221(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(b)**

F461 Reg. 221(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(c)**

F462 Reg. 221(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 180(c)**

Commencement Information

I231 Reg. 221 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M93 Regulation 327 was amended by S.I. 2013/1855 and 2019/62.

Amendment of regulation 331 (findings and reports of inspections)

222.—(1) Regulation 331 is amended as follows.

[[F463](2) In paragraph (1)—

(a) for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation";

(b) in sub-paragraph (c), at the beginning, insert "in the case of a product authorised under a UKMA(NI) or UKMA(UK),".**]**

[[F464](3) In paragraph (4)—

(a) for sub-paragraph (b) substitute—

"(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;";

(b) after sub-paragraph (c) insert—

"(d) Schedule 12A; and

(e) the Implementing Regulation (as defined in regulation 177(5)).".**]**

Textual Amendments

F463 Reg. 222(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(a)**

F464 Reg. 222(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 181(b)**

Commencement Information

I232 Reg. 222 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 331A (guidelines on inspections)

223. After regulation 331 (finding and reports of inspections) insert—

"**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 **[**[F465]IP completion day**]**[M94], are to continue to apply.".

Textual Amendments

F465 Words in reg. 223 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 182**

Commencement Information

I233 Reg. 223 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M94 The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

PART 18

Amendment of Part 17 (miscellaneous and general)

[F466Amendment of regulation 335 (contravention due to fault of another person)

224ZA. In regulation 335(6)(b) for "268 and 269" substitute "268, 268A, 269 and 269A".

Textual Amendments

F466 Regs. 224ZA-224ZD inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**

Commencement Information

I234 Reg. 224ZA in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 336 (warranty as defence)

224ZB. In regulation 336(3)(b) for "268 and 269" substitute "268, 268A, 269 and 269A".

Textual Amendments

F466 Regs. 224ZA-224ZD inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**

Commencement Information

I235 Reg. 224ZB in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 340 (presumptions)

224ZC. In regulation 340(5) for "268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)" substitute "268 (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)".

Textual Amendments

F466 Regs. 224ZA-224ZD inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**

Commencement Information

I236 Reg. 224ZC in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 32 (transitional provisions and savings)

224ZD. In paragraph 3(10) of Schedule 32 for "268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)" substitute "268 (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)".**]**

Textual Amendments

F466 Regs. 224ZA-224ZD inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**

Commencement Information

I237 Reg. 224ZD in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)

[[F467]**224.** In regulation 341(4)—

(a) in paragraph (a), insert "UK" before "marketing authorisation";

(b) after paragraph (a), insert—

"(aa) a decision to grant or revoke an EU marketing authorisation;".**]**

Textual Amendments

F467 Reg. 224 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 184**

Commencement Information

I238 Reg. 224 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 344A (modifications to deal with serious shortages) and 344B (regulation making powers)

225. After regulation 344 insert—

"**Modifications 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 **[**F468IP completion day**]**.

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

F468 Words in reg. 225 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 185**

Commencement Information

I239 Reg. 225 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 345 (immunity from civil liability)

[F469**226.** In regulation 345(5), for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation".**]**

Textual Amendments

F469 Reg. 226 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 186**

Commencement Information

I240 Reg. 226 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

227. In regulation 346 [M95]—

(a) in sub-paragraph (c), omit **[**[F470]paragraph (xixa)**]**; and

(b) in sub-paragraph (d), omit **[**[F471]paragraph (ia)**]**.

Textual Amendments

F470 Words in reg. 227(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 187(a)**

F471 Words in reg. 227(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 187(b)**

Commencement Information

I241 Reg. 227 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M95 Regulation 346 was substituted by S.I. 2013/1855 and then amended by S.I. 2013/2593, 2014/490 and 1878, 2015/323, 903 and 1503, 2016/186, 2017/715, 2018/199 and 2019/62.

PART 19

Transitional and consequential provision and revocations

Transitional provision in relation to EU exit

228.—(1) After regulation 347 insert—

"**Transitional provision in relation to EU exit**

347A. Schedule 33A contains transitional provision in relation to the EU Exit Regulations.".

(2) Schedule 7 inserts a new Schedule 33A after Schedule 33.

Commencement Information

I242 Reg. 228 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Consequential amendments

229. Schedule 8 contains consequential amendments.

Commencement Information

I243 Reg. 229 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Revocations of retained direct EU law

230. Schedule 9 contains revocations of retained direct EU law.

Commencement Information

I244 Reg. 230 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Signed by authority of the Secretary of State for Health and Social Care.

Jackie Doyle-Price
Mike Freer
Jeremy Quin
Parliamentary Under-Secretary of State, Two of the Lords Commissioners of Her Majesty's Treasury

Department of Health and Social Care
Her Majesty's Treasury

Status:
This version of this Instrument contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.