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.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**1**) are amended in accordance with Parts 2 to 19.

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

3. Schedule 1 amends the Medicines (Products for Human Use) (Fees) Regulations 2016(**2**) and makes saving provision.

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, "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—

(**1**) S.I. 2012/1916.
(**2**) S.I. 2016/190.

(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, "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.".

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";

(b) at the end of paragraph (ii) insert "or"; and

(c) omit paragraph (iv) (and "or" immediately preceding it).

(3) In paragraph (15)—

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

(b) at the end of sub-paragraph (b) insert "or"; and

(c) omit sub-paragraph (d) (and "or" immediately preceding it).

Amendment of regulation 4 (special provision for pharmacies etc)

6. In regulation 4(4)(d)—

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

(b) at the end of paragraph (ii) insert "or"; and

(c) omit paragraph (iv) (and "or" immediately preceding it).

Amendment of regulation 5 (classification of medicinal products)

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

(2) Omit paragraph (1)(b) (and "or" immediately preceding it).

(3) In paragraph (2)—

(a) at the end of sub-paragraph (b), insert "or"; and

(b) omit sub-paragraph (d) (and "or" immediately preceding it).

(4) In paragraph (3)—

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

(b) in paragraph (d), omit "or (b)".

(5) In paragraph (4), omit sub-paragraph (b) (and "or" immediately preceding it).

(6) In paragraph (5)—

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

(b) in paragraph (d), omit "or (b)".

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

8. In Schedule 1(**3**), in each place where it occurs, insert "UK" before "marketing authorisation".

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

9. In regulation 6—

(a) in paragraph (3) omit sub-paragraph (b) (and "or" immediately preceding it); and

(b) omit paragraphs (4) and (5).

Amendment of regulation 8 (general interpretation)

10.—(1) Regulation 8(**4**) 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(**5**); 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(**6**);";

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

(**3**) Schedule 1 was amended by S.I. 2014/490.
(**4**) 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.
(**5**) S.I. 2002/618. It was amended by S.I. 2008/2936.
(**6**) Regulation 137 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

""Annex I to the 2001 Directive" means 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 UK marketing authorisation 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(**7**);";

""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(**8**);";

""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(**9**) 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;";

""supplementary protection certificate" has the meaning given in section 128B(2) of the Patents Act 1977(**10**);"; and

""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,

(**7**) OJ No. L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350.
(**8**) Regulation 69 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
(**9**) OJ No. L 018, 22.01.2000, p. 1.
(**10**) 1977 c. 37. Section 128B was inserted by S.I. 2007/3293 and subsection (2) was amended by S.I.2014/2411.

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

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

(a) in the definition of "the Good Manufacturing Practice Directive" insert at the end "as modified in accordance with Schedule 2A";

(b) in the definition of "homoeopathic medicinal product", in paragraph (b), for "in any pharmacopoeia used officially in an EEA State" substitute "the British Pharmacopoeia, or in any pharmacopoeia used officially in a country that is included in a list published by the licensing authority for this purpose";

(c) in the definition of "import"(**11**), insert at the end "and "imported" is to be construed accordingly";

(d) in the definition of "name", omit paragraphs (b) and (c);

(e) in the definition of "pharmacovigilance system", "pharmacovigilance system master file" and "post-authorisation safety study", for "marketing authorisation, traditional herbal registration or Article 126a authorisation" substitute "UK marketing authorisation or traditional herbal registration";

(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";

(j) in the definition of "the summary of the product characteristics", omit paragraph (b) (and "or" immediately preceding it); and

(k) in the definition of "UK marketing authorisation", omit paragraph (b) (and "or" immediately preceding it).

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

(i) "advanced therapy medicinal product",

(ii) "Article 126a authorisation",

(iii) "care home"(**12**),

(iv) "Commission Regulation 2016/161"(**13**),

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

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

(vii) "healthcare institution"(**14**),

(viii) "hospice"(**15**),

(ix) "marketing authorisation",

(x) "Paediatric Regulation",

(xi) "the Pharmacovigilance Risk Assessment Committee",

(**11**) The definition of "import" was inserted by S.I. 2013/1855.
(**12**) The definition of "care home" was inserted by S.I. 2019/62.
(**13**) The definition of "Commission Regulation 2016/161" was inserted by S.I. 2019/62.
(**14**) The definition of "healthcare institution" was inserted by S.I. 2019/62.
(**15**) The definition of "hospice" was inserted by S.I. 2019/62.

(xii) "Regulation (EC) No 1394/2007", and

(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)(**16**), for "References" substitute "Subject to regulation C17(6), references".

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

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

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

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

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(**17**) insert—

"Chapter 1A

Good manufacturing practice and good distribution practice

Regulations on good manufacturing practice

B17.—(1) The Ministers may by regulations 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;

(c) quality assurance systems;

(d) personnel;

(e) premises and equipment;

(f) documentation;

(g) production;

(h) quality control;

(i) the contracting out of work;

(**16**) Paragraph (8) was inserted by S.I. 2013/1855.
(**17**) Regulation A17 was inserted by S.I. 2013/1855.

(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 on and after exit day as they had effect immediately before exit day, but subject to the modifications specified in Schedule 2A.

(4) The Ministers may by regulations amend or revoke Schedule 2A.

Guidelines on good manufacturing practice and good distribution practice

C17.—(1) The licensing authority may publish—

(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 exit day(**18**), continue to apply on and after exit 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).".

Amendment of regulation 17 (manufacturing of medicinal products)

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

(2) In paragraph (1)(a), for "state other than an EEA State" substitute "country other than an approved country for import".

(**18**) 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.

(3) In paragraph (3)(a), for "a marketing authorisation, Article 126a authorisation" substitute "a UK marketing authorisation".

(4) Omit paragraph (4).

(5) In paragraph (5), for "state other than EEA State" substitute "country other than an approved country for import".

Amendment of regulation 18 (wholesale dealing in medicinal products)

15.—(1) Regulation 18(**19**) 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 from an approved country for import for either purpose.".

(3) In paragraph (6), for "a marketing authorisation, Article 126a authorisation" substitute "a UK marketing authorisation".

(4) Omit paragraph (7).

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.

(**19**) Regulation 18 was substituted by S.I. 2013/1855 and further amended by S.I. 2016/186.

(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.".

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

17.—(1) Regulation 19(**20**) is amended as follows.

(2) In paragraph (1)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

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

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

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

(2) In paragraph 1(2)(g), for "marketing authorisation, Article 126a authorisation," substitute "UK marketing authorisation".

(3) In paragraph 2(1), for "state other than an EEA state" substitute "country other than an approved country for import".

(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)—

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

(ii) omit paragraph (iv), 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 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).".

(**20**) Regulation 19 was amended by S.I. 2013/1855.

Amendment of regulation 23 (grant or refusal of licence)

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

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

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

(2) In paragraph 13(b), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In the heading of Part 2, for "State Other Than an EEA State" substitute "Country other than an Approved Country for Import".

(4) In paragraphs 15, 22(1) and 23, for "state other than an EEA State" substitute "country other than an approved country for import".

(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(**21**), 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(**22**), as regards other human tissues and cells.".

(6) In paragraph 33, for "another EEA State" substitute "an approved country for import".

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

21. In regulation 26(5)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 5 (review upon oral representations)

22.—(1) Schedule 5(**23**) 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).

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.".

(**21**) 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.
(**22**) S.I. 2007/1523.
(**23**) Schedule 5 was amended by S.I. 2013/1855.

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".

(3) In paragraphs (3)(b), (5)(a) and (5)(b) insert "UK" before "marketing authorisation".

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".

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(**24**)".

(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(**25**);

(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;".

(**24**) 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.

(**25**) 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(**26**), omit paragraphs (4) to (7).

Amendment of regulation 37 (manufacturing and assembly)

28.—(1) Regulation 37(**27**) is amended as follows.

(2) In paragraph (4)(b)—

(a) for "third country" substitute "country other than an approved country for import"; and

(b) for "competent authority of a member State" substitute "appropriate authority for the registration of such persons in the approved country for import".

(3) In paragraph (5)(b), for "paragraph 5 of Article 47 of the 2001 Directive" substitute "the guidelines which apply under or by virtue of regulation C17".

(4) In paragraph (6)(b), for "marketing authorisations, Article 126a authorisations" substitute "UK marketing authorisations".

(5) In paragraph (9)(a), from "Commission" to the end substitute "the Blood Quality and Safety Regulations 2005(**28**); or".

(6) In paragraph (11)—

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

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

Amendment of regulation 38 (imports)

29.—(1) Regulation 38(**29**) is amended as follows.

(2) In the heading, for "states other than EEA states" substitute "countries other than approved countries for import".

(3) In paragraphs (2) and (3)(b), for "state other than an EEA State" substitute "country other than an approved country for import".

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

30. In regulation 39(8)(**30**), omit ", 43A".

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

31.—(1) Regulation 42(**31**) is amended as follows.

(2) In paragraph (1), for "45" substitute "45AA".

(3) Omit paragraphs (4) and (5).

Amendment of Schedule 7 (qualified persons)

32.—(1) Schedule 7(**32**) is amended as follows.

(**26**) Regulation 36 was amended by S.I. 2013/1855 and 2019/62.
(**27**) Regulation 37 was substituted by S.I. 2013/1855.
(**28**) 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.
(**29**) Regulation 38 was amended by S.I. 2015/1503.
(**30**) Regulation 39 was amended by S.I. 2013/1855, 2015/354 and 2019/62.
(**31**) Regulation 42 was amended by S.I. 2013/1855 and 2019/62.
(**32**) Schedule 7 was amended by S.I. 2019/62.

(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),

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

(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 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.".

(b) omit paragraph 13;

(c) in paragraph 14—

(i) in sub-paragraph (1)(a) for "country other than an EEA State" substitute "country other than approved country for import",

(ii) in sub-paragraph (1)(b)—

(aa) for "European Union" substitute "licensing authority",

(bb) for "that country" substitute "the country from which those products are imported", and

(cc) in sub-paragraph (i), for "laid down by the European Union" substitute "in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17",

(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.".

Amendment of regulation 43 (obligations of licence holder)

33.—(1) Regulation 43(**33**) is amended as follows.

(2) In paragraph (1), for "by the European Commission in accordance with Article 84 of the 2001 Directive" substitute "under, or that apply by virtue of, regulation C17".

(3) In paragraph (5)(a) and 7(b)(ii), for "marketing authorisation, Article 126a authorisation", substitute "UK marketing authorisation".

(4) In paragraph (6)—

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

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

"(b) the export 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—

(**33**) Regulation 43 was amended by S.I. 2013/1855 and 2016/186.

(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.".

(5) In paragraph (7)—

(a) in sub-paragraph (b)—

(i) in sub-paragraph (i), for "the competent authority of any EEA State" substitute "an appropriate authority for the licensing of medicinal products in an approved country for import", and

(ii) in sub-paragraph (ii), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation"; and

(b) omit sub-paragraph (c)(vii).

(6) For paragraph (8) substitute—

"(8) Paragraph (8A) applies to a person ("P") who—

(a) imports 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.

(8A) 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.".

(7) Omit paragraphs (10) and (11).

(8) In paragraph (13), insert "UK" before "marketing authorisation holder".

(9) Omit paragraph (15).

Omission of regulation 43A (requirement for wholesale dealer to decommission the unique identifier)

34. Omit regulation 43A(**34**).

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

35.—(1) Regulation 44(**35**) is amended as follows.

(**34**) Regulation 43A was inserted by S.I. 2019/62.
(**35**) Regulation 44 was amended by S.I. 2013/1855, 2015/1503 and 2016/186.

(2) In paragraph (2)—

(a) in sub-paragraph (b), for "another EEA State" substitute "an approved country for import"; and

(b) in sub-paragraph (c), for "from a third country ("A") for export to a third country ("B")", substitute "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")".

(3) In paragraph (5)(b), for "competent authority of another EEA State" substitute "appropriate authority of an approved country for import that is responsible for".

(4) In paragraph (5)(e)—

(a) for "third countries" substitute "countries other than approved countries for import"; and

(b) for "third country concerned" substitute "country to which the product is supplied".

(5) In paragraph (6)—

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

(b) omit sub-paragraph (e) (and "and" immediately preceding it).

Amendment of regulation 45 (requirement as to responsible persons)

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

(2) In paragraph (1), for "The licence holder" insert substitute "Subject to regulation 45AA, the licence holder".

(3) In paragraph (2)(b) for "marketing authorisations, Article 126a authorisations" substitute "UK marketing authorisations".

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 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; and

(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.

(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).".

Amendment of regulation 45A (brokering in medicinal products)

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

(2) In paragraph (1)—

(a) in sub-paragraph (a) for paragraphs (i) and (ii) substitute—

"(i) by the licensing authority, or

(ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import,";

(b) in sub-paragraph (b)—

(i) in paragraph (i), for "a competent authority of a member State" substitute "the licensing authority",

(ii) in paragraph (ii), omit "except where the person is validly registered with the competent authority of another EEA State", and

(iii) in paragraph (iii), for "published by the European Commission in accordance with Article 84 of the 2001 Directive" substitute "which apply under, or by virtue of, regulation C17".

(3) In paragraph (2)—

(a) in sub-paragraph (a), for "a competent authority of a member State" substitute "the licensing authority";

(b) in sub-paragraph (c), for "competent authority of a member State" substitute "licensing authority".

(4) Omit paragraph (3).

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

39. In regulation 45D(1)(b)(**37**) omit sub-paragraph (ii) (and "and" immediately preceding it).

(**36**) Regulation 45A was inserted by S.I. 2013/1855.
(**37**) Regulation 45D was inserted by S.I. 2013/1855.

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

40. In regulation 45E(3)(**38**)—

(a) in sub-paragraph (b)(i), for "the competent authority of any EEA State" substitute "an appropriate authority responsible for the licensing of medicinal products in an approved country for import"; and

(b) omit sub-paragraph (d)(iii).

Amendment of regulation 45F (provision of information)

41. In regulation 45F(1)(**39**) for sub-paragraph (b) substitute—

"(b) either—

(i) the UK marketing authorisation holder; or

(ii) 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;".

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

42.—(1) Regulation 45M(**40**) is amended as follows.

(2) In paragraph (2)(a), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

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

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

43.—(1) Schedule 7A(**41**) is amended as follows.

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

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

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

44.—(1) Regulation 45O(**42**) is amended as follows.

(2) In paragraph (1), for "the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply".

(3) In paragraph (2), for "the Commission has adopted principles and guidelines of good distribution practice under the fourth paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good distribution practice have been published under, or apply by virtue of, regulation C17, which apply".

(4) In paragraph (3)—

(**38**) Regulation 45E was inserted by S.I. 2013/1855.
(**39**) Regulation 45F was inserted by S.I. 2013/1855.
(**40**) Regulation 45M was inserted by S.I. 2013/1855.
(**41**) Schedule 7A was inserted by S.I. 2013/1855.
(**42**) Regulation 45O was inserted by S.I. 2013/1855.

(a) for "the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies" substitute "principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply";

(b) for "imported from a third country" substitute "so imported";

(c) in sub-paragraph (c)—

(i) omit "third" in both places it appears,

(ii) in paragraph (ii), for "Union" substitute "United Kingdom", and

(iii) in paragraph (iii), for "Union" substitute "licensing authority".

(5) In paragraph (4)—

(a) in sub-paragraph (a), for "Article 111b of the 2001 Directive" substitute "paragraph (6)"; and

(b) in sub-paragraph (b)(i), for "competent authority of a member State" substitute "licensing authority or an appropriate authority responsible for the licensing of medicinal products in a country included in a list under paragraph (6)".

(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 the United Kingdom that is equivalent to the regulatory framework in the United Kingdom, 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 .".

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";

(b) at the end of sub-paragraph (b), insert "or"; and

(c) omit sub-paragraph (d) (and "or" immediately preceding it).

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

(4) In paragraph (6)—

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

(b) at the end of sub-paragraph (b), insert "or"; and

(c) omit sub-paragraph (d) (and "or" immediately preceding it).

(5) In paragraph (7), omit sub-paragraph (b) (and "and" immediately preceding it).

(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".

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".

(3) In paragraph (6), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation", substitute "UK marketing authorisation, certificate of registration or traditional herbal registration".

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 48 (application of Part 5)

47.—(1) Regulation 48(**43**) is amended as follows.

(2) In paragraph (2)—

(a) at the appropriate place insert—

""EU reference medicinal product" means a medicinal product which falls within paragraph (b) of the definition of "reference medicinal product";";

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

""generic medicinal product", in relation to a reference medicinal product, means a medicinal product—

(**43**) Regulation 48 was amended by S.I. 2014/1878.

(a) that has the same qualitative and quantitative composition in active substances as the reference medicinal product;

(b) that has the same pharmaceutical form as the reference medicinal product; and

(c) 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—

""reference medicinal product" means a medicinal product—

(a) authorised under regulation 49(1)(a), in accordance with the provisions of regulation 50; or

(b) in relation to which an EU marketing authorisation was in force on exit 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.".

(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 regulations 51 to 53.

(7) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) as if it had been authorised on the date of authorisation of the medicinal product to which the initial marketing authorisation relates.

(8) Paragraph (9) applies in relation to a medicinal product if—

(a) it is an EU reference medicinal product;

(b) it is used as a reference medicinal product in accordance with regulations 51 to 53; and

(c) it belongs to a global marketing authorisation, as described in the second paragraph of Article 6(1) of the 2001 Directive; but

(d) it is not the initial marketing authorisation for the purposes of that global marketing authorisation.

(9) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) 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.".

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

48.—(1) Regulation 49(**44**) is amended as follows.

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

(3) After paragraph (1) insert—

"(1A) 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.".

(4) In paragraph (3), for "European Union" substitute "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—

"(9) In this regulation "group" has the same meaning as in Part 15 of the Companies Act 2006(**45**) (see section 474(1) of that Act).".

(**44**) Regulation 49 was amended by S.I. 2014/1878.
(**45**) 2006 c.46.

Amendment of regulation 50 (accompanying material)

49.—(1) Regulation 50(**46**) is amended as follows.

(2) In paragraph (4), omit "from a country other than an EEA State".

(3) After paragraph (5) insert—

"(5A) The Ministers may by regulations amend Schedule 8B (modifications of Annex I) 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 exit 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(**47**);

(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(**48**); 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(**49**).".

(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);

(**46**) Regulation 50 was amended by S.I. 2014/1878.

(**47**) 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.

(**48**) 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.

(**49**) 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.

(zg) regulation 50J (applications relating to medicinal products containing or consisting of genetically modified organisms);".

(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.".

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

50.—(1) Schedule 8(**50**) 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";

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

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

(3) For paragraph 18 substitute—

"**18.** Where 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.".

(4) In paragraph 19, for "a member state or by a third country", substitute "a country other than the United Kingdom or by the European Commission".

(5) Omit paragraph 20.

(6) In paragraph 21, for "a member state or by a third country", substitute "a country other than the United Kingdom".

(7) Omit paragraph 22.

(8) In paragraph 23—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

(9) After paragraph 25, insert—

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

(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

(**50**) Schedule 8 was amended by S.I. 2013/1855.

(b) descriptions, instructions and warnings must include explanatory drawings and pictures where necessary.".

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

51. Paragraph 6 of Schedule 8A(**51**) 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".

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".

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 UK marketing authorisation 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 UK marketing authorisation.

(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—

(**51**) Schedule 8A was inserted by S.I. 2014/1878.

(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.

Agreement and modification of paediatric investigation plan

50B.—(1) Any person may prepare a paediatric investigation plan 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 UK marketing authorisation—

(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.

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 UK marketing authorisation for a relevant medicinal product which includes a paediatric indication; or

(b) an application to include a paediatric indication in an existing UK marketing authorisation.

(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.—(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product in relation to which the applicant intends to demonstrate that the orphan criteria are met.

(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 the United Kingdom; 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 the United Kingdom, 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 UK marketing authorisation 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 UK marketing authorisation 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(**52**), including, where available, the results of the assessment of a notified body in accordance with those Regulations.

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

Applications relating to conditional marketing authorisations

50I.—(1) This regulation applies in relation to an application for a UK marketing authorisation 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(**53**),

(ii) regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(**54**),

(**53**) S.I. 2002/2443, as amended by S.I. 2004/2411.
(**54**) S.I. 2002/3188, as amended by S.I. 2005/1913.

(iii) regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**55**), or

(iv) regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(**56**);

(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.".

Insertion of new Schedule in relation to orphan provisions

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

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".

Substitution of regulation 51 (applications relating to generic medicinal products)

56. For regulation 51 substitute—

"(1) An applicant for a UK marketing authorisation 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 which is or has been authorised for not less than eight years—

(a) under regulation 49(1)(a) (subject to paragraphs (2) and (3)); or

(b) if the product is an EU reference medicinal product, under Regulation (EC) No 726/2004.

(2) If, after exit day but before the date of grant of the UK marketing authorisation in relation to the reference medicinal product, an EU marketing authorisation took effect in relation to that product, the period of not less than eight years referred to in paragraph (1) is treated as having started on the date on which the EU marketing authorisation took effect.

(3) If, after exit day but before the date of grant of the UK marketing authorisation in relation to the reference medicinal product, the competent authority of an EEA state granted a marketing authorisation in relation to that product, the period of not less than eight years referred to in paragraph (1) is treated as having started on the date on which the marketing authorisation in the first EEA state in which the product was authorised took effect.

(4) 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

(**55**) S.S.I. 2002/541, as amended by S.S.I. 2004/439.
(**56**) S.R. 2003/167, as amended by S.R. 2005/272.

providing proof of the safety or efficacy of the salt, ester, ether, isomer, mixture of isomers, complex or derivative.

(5) 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 (6).

(6) 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 (5).

(7) Until replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(2)(b) of the 2001 Directive(**57**) continue to apply on and after exit day as they applied immediately before exit day (subject to any amendments or variations published under paragraph (6)).

(8) If the licensing authority grants a UK marketing authorisation 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 the United Kingdom before the expiry of ten years beginning with—

(a) the date on which the reference medicinal product was granted a UK marketing authorisation;

(b) the date referred to in paragraph (2) or (3), if earlier than the date in sub-paragraph (a); or

(c) if the reference medicinal product is an EU reference medicinal product, the date on which the EU marketing authorisation for the reference medicinal product took effect.

(9) Paragraph (10) applies where an EU reference medicinal product is used as a reference medicinal product for the purposes of this regulation.

(10) 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 exit day.

(11) Paragraph (12) applies if—

(a) during the first eight of the ten years referred to in paragraph (8) the marketing authorisation holder for the reference medicinal product obtained a UK marketing authorisation 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.

(12) Where this paragraph applies, the period of ten years referred to in paragraph (8) is extended to eleven years, subject to the provisions of paragraphs (13) and (14).

(13) Where the European Commission, or an EEA state, has granted or varied a marketing authorisation in relation to the new therapeutic indication before the licensing authority does so, the one year extension of the period of ten years referred to in paragraph (8) is reduced by the period of time—

(a) beginning on the date on which the EU or EEA state marketing authorisation took effect or was varied; and

(**57**) 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.

(b) ending immediately before the date on which the licensing authority granted or varied the UK marketing authorisation.

(14) If the period of time by which the one year extension is to be reduced in accordance with paragraph (13) is one year or longer, paragraph (12) does not apply.

(15) Paragraph (16) applies where—

(a) an application 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.

(16) Where this paragraph applies, the applicant for a UK marketing authorisation under paragraph (1) or regulation 52 or 53 may not refer in its application to the studies mentioned in paragraph (15)(b) for the period of one year beginning on the date on which the licensing authority grants or varies a UK marketing authorisation in relation to the new indication (subject to paragraphs (17) and (18)).

(17) Where the European Commission, or an EEA state, has granted or varied a marketing authorisation in relation to the new indication before the licensing authority does so, the period of one year referred to in paragraph (10) is reduced by the period of time—

(a) beginning on the date on which the EU or EEA state marketing authorisation took effect or was varied; and

(b) ending immediately before the date on which the licensing authority granted or varied the UK marketing authorisation.

(18) If the period of time by which the one year period in paragraph (16) is to be reduced in accordance with paragraph (17) is one year or longer, paragraph (16) does not apply.".

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

57.—(1) Regulation 52 is amended as follows.

(2) In paragraph (1)(a), for "as reference medicinal product" substitute—

"which is or has been authorised for not less than eight years—

(i) under regulation 49(1)(a) (subject to paragraphs (2) and (3) of regulation 51), or

(ii) if the reference medicinal product is an EU reference medicinal product, under Regulation (EC) No 726/2004".

(3) For paragraph (1)(b) substitute—

"(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.".

(4) For paragraph (2), substitute—

"(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).".

(5) In paragraph (3)—

(a) for "Regulation 51(2)" substitute "Paragraphs (2) to (14) of regulation 51"; and

(b) for "it applies" substitute "they apply".

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

58.—(1) Regulation 53 is amended as follows.

(2) In paragraph (1), for the words from "any of the reasons" to the end, substitute "differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product."

(3) For paragraph (2), substitute—

"(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 appropriate pre-clinical tests or clinical trials relating to the differences referred to in paragraph (1).

(2A) 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 (2B), or (as the case may be) as mentioned in paragraph (2C).

(2B) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (2)(b).

(2C) Unless replaced by guidelines published under paragraph (2B), the guidelines published by the EMA under Article 10(4) of the 2001 Directive(**58**) continue to apply on and after exit day as they applied immediately before exit day (subject to any amendments or variations published under that paragraph)."

(4) In paragraph (3) —

(a) for "Regulation 51(2)" substitute "Paragraphs (2) to (8) of regulation 51"; and

(b) for "it applies" substitute "they apply".

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.".

(**58**) 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.

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

60.—(1) Regulation 55 is amended as follows.

(2) In paragraph (1)(a), omit ", the 2001 Directive or Regulation (EC) No 726/2004".

(3) For paragraph (2), substitute—

"(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.".

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".

Amendment of regulation 58 (consideration of application)

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

(2) After paragraph (4), insert—

"(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 sub-paragraphs (a) and (b) in relation to certain types of medicinal products only; and

(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).".

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

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

(ii) at the end insert—

"(d) a proposal to agree, or to refuse to agree, a paediatric investigation plan;

(e) a proposal to grant, or to refuse to grant, or to revoke, a waiver or deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan; and

(f) 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

(c) omit sub-paragraph (2).

(3) In paragraph 12 (licensing authority decision in other cases), in sub-paragraphs (1), (2) and (5)—

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

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

(4) In paragraph 14(a) (application of Part 2), for the words from "Article 2(3)" to the end, substitute "paragraph 1 of Schedule 10A; and".

(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.

(7) Omit paragraph 17.

(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

(ii) omit sub-paragraph (2); and

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

(9) Omit Part 4 (exceptions to Schedule).

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

64. After regulation 58, insert—

"**Paediatric rewards**

58A.—(1) Paragraph (2) applies if—

(a) an application 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, is granted by the licensing authority; and

(b) the licensing authority is satisfied that the material provided by the applicant pursuant to regulation 50A(3) demonstrates compliance with the agreed paediatric investigation plan.

(2) Where this paragraph applies, the licensing authority must—

(a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and

(b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.

(3) Where paragraph (2) applies, 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) and (5)).

(4) Paragraph (3) does not apply if the grant of the application referred to in paragraph (1)(a)—

(a) relates to a new paediatric indication; and

(b) the holder of the UK marketing authorisation—

(i) is entitled to a one year extension of the ten year period referred to in regulation 51(8), under regulation 51(12),

(ii) is entitled to an extension of that ten year period of less than one year by virtue of the application of regulation 51(13), or

(iii) would have been entitled to a one year extension of that ten year period but for the application of regulation 51(14).

(5) If the UK marketing authorisation to which this regulation applies is an orphan marketing authorisation, paragraph (3) does not apply and regulation 58D(5) (orphan rewards) applies.

(6) Paragraphs (7) and (8) apply if the licensing authority grants a UK marketing authorisation in response to an application to which regulation 50E (paediatric use marketing authorisation) applies.

(7) Where this paragraph applies, the medicinal product to which the paediatric use marketing authorisation relates may retain the name of any medicinal product which contains the same active substance and in respect of which the holder of the paediatric use marketing authorisation has been granted a UK marketing authorisation for use in adults.

(8) Where this paragraph applies, the holder of the paediatric use marketing authorisation is entitled to benefit from the periods of data and marketing exclusivity referred to in regulation 51(1) and (8) 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 agreed investigation paediatric 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—

(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.

(2) Paragraph (3) applies if—

(a) an EU marketing authorisation took effect in relation to the medicinal product to which an orphan marketing authorisation relates on or after exit day but before the licensing authority granted the orphan marketing authorisation; and

(b) the EU marketing authorisation was granted on the basis that the product was an orphan medicinal product within the meaning of the Orphan Regulation.

(3) Where this paragraph applies, the period of ten years referred to in paragraph (1) is reduced by the period of time—

(a) beginning on the date on which the EU marketing authorisation took effect; and

(b) ending immediately before the date on which the licensing authority granted the orphan marketing authorisation.

(4) The period of ten years referred to in paragraph (1) may be reduced to six years if, at the end of the fifth year beginning on the date referred to in paragraph (1), the licensing authority is satisfied that the orphan criteria are no longer met in relation to the medicinal product.

(5) The period of ten years referred to in paragraph (1) is extended to twelve years if regulation 58A(2) (paediatric rewards) applies to the orphan marketing authorisation.

(6) Paragraph (1) does not apply if—

(a) the holder of the orphan marketing authorisation consents to the grant or variation of a UK marketing authorisation in relation to a similar medicinal product;

(b) the licensing authority is satisfied that the holder of the orphan marketing authorisation is unable to supply sufficient quantities of the medicinal product to which the orphan marketing authorisation relates; or

(c) a subsequent applicant can establish to the satisfaction of the licensing authority that the medicinal product to which the application relates, although similar to the medicinal product to which the orphan marketing authorisation relates, is safer or more effective than, or clinically superior to, that product.

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(**59**) 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 UK marketing authorisation 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).".

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

65.—(1) Regulation 59(**60**) is amended as follows.

(2) For paragraph (3) substitute—

"(3) An obligation to conduct such studies as are referred to in paragraph (2)(f) must—

(**59**) S.I. 2002/618, as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
(**60**) Regulation 59 was amended by S.I. 2014/1878.

(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.".

(3) After paragraph (3), insert—

"(3A) The Ministers may by regulations make provision specifying the situations in which post-authorisation efficacy studies may be required by virtue of the condition referred to in paragraph (2)(f).

(3B) Paragraph (3)(a) ceases to apply on the coming into force of regulations made under paragraph (3A).".

(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).".

(6) Omit paragraph (5).

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

66. In regulation 60, omit paragraph (9).

Insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority)

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(**61**);

"appropriate documentation", in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing condition or pursuant to a notification under paragraph (12), means—

(a) any certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products that relates to the sample of the batch submitted to the appropriate authority with that certificate; and

(b) such other documentation as the appropriate authority notifies the holder of the UK marketing authorisation to which the sample relates that it requires;

"approved country list for batch testing and certification of biological medicinal products" means the list described in paragraph (5), and "approved country for batch testing and certification of biological medicinal products" means a country included in that list;

"the batch testing condition", in respect of a UK marketing authorisation, is a condition to the effect that, unless the batch testing exemption applies, the holder of the UK marketing authorisation—

(a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and

(b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in the United Kingdom until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the batch is in conformity with the approved specifications in the UK marketing authorisation; and

"the batch testing exemption" means that—

(**61**) 2012 c.7.

(a) a certificate has been issued by a laboratory in a country other than the United Kingdom;

(b) 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

(c) 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 medicinal 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).

(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;

(b) include in that list any conditions or restrictions in that agreement that affect the applicability of the batch testing exemption; 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).".

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) to comply with such other conditions or restrictions as the licensing authority considers essential for the safe and effective use of the medicinal product.".

(3) For paragraph (6) substitute—

"(6) If concerns as described in paragraph (2) apply to more than one medicinal product, 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.".

(4) For paragraph (7) substitute—

"(7) 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

(7A) The Ministers may by regulations make provision specifying the situations in which post-authorisation efficacy studies may be required by virtue of the obligation under paragraph (5).

(7B) Paragraph (7)(a) ceases to apply on the coming into force of regulations made under paragraph (7A).".

(5) Omit paragraph (13).

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

69. In regulation 64(4)(d), for "established in accordance with Articles 21a, 22 and 22a of the 2001 Directive" substitute "imposed under regulations 59 to 61".

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—

(a) the licensing authority grants or varies a UK marketing authorisation;

(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.".

Amendment of regulation 65 (validity of UK marketing authorisation)

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

"(za) regulation 65B;".

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

72. After regulation 65A(**62**), 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 UK marketing authorisation

65C.—(1) A UK marketing authorisation 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 UK marketing authorisation 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(**63**) which applied immediately before exit 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 exit day; or

(b) applications made before exit 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.".

(**62**) Regulation 65A was inserted by S.I. 2014/1878.

(**63**) 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.

Amendment of regulation 66 (application for renewal of authorisation)

74. In regulation 66(2), for "European Union" substitute "United Kingdom".

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

75. In regulation 66A(2)(**64**), for "European Union" substitute "United Kingdom".

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.".

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

77.—(1) Regulation 68(**65**) 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

(b) for "European Union" substitute "United Kingdom".

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

(5) Omit paragraph (9).

(6) In paragraph (10)—

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

(**64**) Regulation 66A was inserted by S.I. 2014/1878.
(**65**) Regulation 68 was amended by S.I. 2013/1855 and 2014/1878.

(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 exit 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 exit 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).".

(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).

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

78. In regulation 69(**66**), omit paragraph (10).

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

79. Omit regulation 70.

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

80.—(1) Regulation 71(**67**) 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

(b) in sub-paragraph (b)—

(i) omit "or Article 20(4) of Regulation (EC) No 726/2004"; and

(**66**) Regulation 69 was amended by S.I. 2014/1878.
(**67**) Regulation 71 was amended by S.I. 2014/1878.

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

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

81. In regulation 72(1) omit "or 70(2) or Article 29(4) of Regulation (EC) No 726/2004".

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

82.—(1) Regulation 73(**68**) is amended as follows.

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

(3) Omit paragraph (5C).

Amendment of regulation 75 (obligation to provide information relating to safety etc)

83. In regulation 75(5)(**69**)—

(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".

Amendment of regulation 76 (obligation in relation to product information)

84. In regulation 76(2)(**70**) for the words from "European medicines web-portal" to the end, substitute "the UK web-portal established in accordance with regulation 203(1)."

Amendment of regulation 77 (record-keeping obligations)

85. In regulation 77, insert "UK" before "marketing authorisation".

Amendment of regulation 78 (obligation to ensure appropriate and continued supplies)

86. In regulation 78, insert "UK" before "marketing authorisation".

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—

(**68**) Regulation 73 was amended by S.I. 2013/2593: regulation 3 inserted sub-paragraphs (5A) to (5C).
(**69**) Regulation 75 was amended by S.I. 2014/1878.
(**70**) Regulation 76 was amended by S.I. 2014/1878.

(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 UK marketing authorisations for advanced therapy medicinal products

78B.—(1) The holder of a UK marketing authorisation 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(**71**),

(ii) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005(**72**), 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(**73**);

(**71**) 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.
(**72**) 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.
(**73**) S.I. 2007/1523.

(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 UK marketing authorisation; and

(d) in the event of the UK marketing authorisation 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 UK marketing authorisation who is subject to the obligations in paragraph (1) remains subject to them even if the UK marketing authorisation is suspended or revoked.".

Omission of regulation 79 (failure to provide information on marketing authorisations to EMA)

88. Omit regulation 79.

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".

(3) In sub-paragraph (a) for "or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008"substitute "in accordance with paragraph 14(1) of Schedule 10A".

(4) In sub-paragraph (b) from "or the European Commission" to the end substitute "in accordance with paragraph 14(3) of Schedule 10A; or".

(5) For sub-paragraph (c) substitute—

"(c) fails 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.".

Omission of regulations 81 to 94 (offences relation to EU marketing authorisations)

90. Omit regulations 81 to 94(**74**).

Omission of regulation 94A (offences relating to Commission Regulation 2016/161)

91. Omit regulation 94A(**75**).

Amendment of regulation 95 (offences in connection with application)

92.—(1) Regulation 95 is amended as follows.

(2) In the introductory words, insert "UK" before "marketing authorisation".

(3) Omit sub-paragraphs (c) and (d).

(**74**) Regulation 82 was previously amended by S.I. 2013/2593 and regulation 84 was amended by S.I. 2013/1855.
(**75**) Regulation 94A was inserted by S.I. 2019/62.

Amendment of regulation 96 (provision of misleading information)

93.—(1) Regulation 96(**76**) is amended as follows.

(2) In paragraph (1)—

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

(b) omit sub-paragraphs (b) and (c).

(3) In paragraph (2), for "these Regulations; or" to the end substitute "these Regulations.".

Amendment of regulation 97 (breach of pharmacovigilance condition)

94.—(1) Regulation 97(**77**), is amended as follows.

(2) In each place where it occurs—

(a) for "a marketing authorisation" substitute "a UK marketing authorisation"; and

(b) for "the marketing authorisation" substitute "the UK marketing authorisation".

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

Amendment of regulation 98 (general offence of breach of Part 5)

95. In regulation 98(2)(a), insert "UK" before "marketing authorisation".

Amendment of regulation 99 (penalties)

96.—(1) Regulation 99 is amended as follows.

(2) In paragraph (1), omit "other than a breach of regulation 79 (failure to provide information on marketing authorisation to EMA)".

(3) Omit paragraph (2).

Amendment of regulation 101 (defences)

97.—(1) Regulation 101(**78**) is amended as follows.

(2) In paragraph (1), insert "UK" before "marketing authorisation".

(3) In paragraph (3), for "any of regulations 88 to 93," substitute "either of regulations".

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—

"(7) The Ministers may by regulations amend paragraphs (4) to (6).

(8) The Ministers may only exercise the power in paragraph (7) if they consider that it is necessary to do so because of new scientific evidence.".

(**76**) Regulation 96 was amended by S.I. 2014/1878.
(**77**) Regulation 97 was substituted by S.I. 2014/1878.
(**78**) Regulation 101 was amended by S.I. 2014/1878.

Amendment of regulation 103 (application for certificate of registration)

99.—(1) Regulation 103 is amended as follows.

(2) In paragraph (4), for "European Union" substitute "United Kingdom".

(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".

Amendment of regulation 104 (consideration of application)

100. Omit regulation 104(5) and (6).

Amendment of regulation 108 (application for renewal of certificate)

101. In regulation 108(2), for "European Union" substitute "United Kingdom".

Amendment of regulation 110 (revocation, variation and suspension of certificate of registration)

102.—(1) Regulation 110(**79**) is amended as follows.

(2) In paragraph (7), for "European Union" substitute "United Kingdom".

(3) Omit paragraph (10).

Omission of regulation 111 (certificates granted under Chapter 4 of Title III of the 2001 Directive)

103. Omit regulation 111.

Amendment of regulation 112 (withdrawal of homoeopathic medicinal product from the market)

104. In regulation 112(1), omit "or regulation 111(2)".

Amendment of regulation 113 (obligation to notify placing on the market etc)

105. In regulation 113(3A)(**80**), omit "in accordance with article 123(2) of the 2001 Directive".

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".

Amendment of regulation 116 (obligation in relation to product information)

107. In regulation 116(2) for "European" to the end substitute "UK web-portal established in accordance with regulation 203(1)."

(**79**) Regulation 110 was amended by S.I.2013/1855.
(**80**) Paragraph (3A) was inserted by S.I. 2013/2593.

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".

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.".

Amendment of regulation 125 (traditional herbal medicinal products)

110. In regulation 125(5)(b), for "European Union" substitute "United Kingdom or a country included in the list published under regulation 125A(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.".

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.

(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.".

Amendment of regulation 127 (application for grant of traditional herbal registration)

113. In regulation 127(3), for "European Union" substitute "United Kingdom".

Amendment of regulation 128 (accompanying material)

114. In regulation 128(3), for "list referred to in Article 16f(1) of the 2001 Directive" substitute "relevant list".

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—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

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), for "Article" to the end substitute "regulation 130A.".

(4) In paragraph (8), for "list referred to in Article 16f(1) of the 2001 Directive" substitute "relevant list".

(5) Omit paragraph (9).

(6) In paragraph (10)(a) for "Article 16h(3) of the 2001 Directive" substitute "regulation 143A".

(7) Omit paragraphs (12) and (13).

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 traditional herbal registration 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.".

Amendment of regulation 133 (application for renewal of registration)

118. In regulation 133(2), for "European Union" substitute "United Kingdom".

Amendment of regulation 135 (revocation, variation and suspension of traditional herbal registration)

119.—(1) Regulation 135(**81**) is amended as follows.

(2) In paragraph (7)(b), for "from states other than EEA States" substitute "countries other than approved countries for import".

(3) Omit paragraph (8).

(4) In paragraph (9), omit sub-paragraph (b) (and the "and" immediately preceding it).

(5) Omit paragraph (11).

Amendment of regulation 136 (revocation by licensing authority: further provisions)

120.—(1) Regulation 136 is amended as follows.

(2) In paragraph (1)(a), for "list referred to in article 16f(1) of the 2001 Directive" substitute "relevant list".

(3) Omit paragraph (3).

(**81**) Regulation 135 was amended by S.I. 2013/1855.

Amendment of regulation 138 (suspension of use etc of traditional herbal medicinal product)

121. Omit regulation 138(10).

Omission of regulation 139 (registrations granted under Chapter 4 of Title III of the 2001 Directive)

122. Omit regulation 139.

Amendment of regulation 140 (withdrawal of traditional herbal medicinal product from the market)

123. In regulation 140(1)(a), for "regulation 135, 136, 139(2) or Article 34(3) of the 2001 Directive" substitute "regulation 135 or 136".

Amendment of regulation 141 (sale etc of suspended traditional herbal medicinal product)

124. In regulation 141(1), omit "or 139(2)".

Amendment of regulation 142 (obligation to notify placing on the market etc)

125. Omit regulation 142(5C)(**82**).

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.

(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.".

(**82**) Regulation 142 was amended by S.I. 2013/2593.

Amendment of regulation 144 (obligation following new herbal monograph)

127. In regulation 144, for "Article 16h(3) of the 2001 Directive" substitute "regulation 143A".

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".

Amendment of regulation 146 (obligation in relation to product information)

129. In regulation 146(2), for "European" to the end substitute "the UK web-portal established in accordance with regulation 203(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.".

Amendment of regulation 149 (urgent safety restrictions)

131.—(1) Regulation 149 is amended as follows.

(2) In the heading to regulation 149, at the end insert "**:** offences".

(3) In sub-paragraph (a), for "or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008" substitute "in accordance with regulation 148A(1)".

(4) In sub-paragraph (b), for "or the European Commission under Article 22(2) of that Regulation" substitute "in accordance with regulation 148A(2)".

(5) For sub-paragraph (c), substitute—

"(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.".

PART 8

Omission of Part 8 (Article 126a authorisations)

Omission of Part 8

132. Omit Part 8.

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

(b) for ", certificate of registration or Article 126a authorisation" substitute "or certificate of registration".

Amendment of regulation 164 (effect of determination)

134. In regulation 164(2)(a) and (b)—

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

(b) for ", certificate of registration or Article 126a authorisation" substitute "or certificate of registration".

PART 10

Amendment of Part 10 (exceptions to requirement for marketing authorisations etc)

Amendment of regulation 168 (use of non-prescription medicines in the course of a business)

135. In regulation 168, in paragraph (8)—

(a) in sub-paragraph (a), for "EEA State" substitute "approved country for import"; and

(b) for sub-paragraph (b) substitute—

"(b) imported from an approved country for import—

(i) 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

(ii) 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.".

Amendment of regulation 169 (mixing of general sale medicinal products)

136. In regulation 169(9)(a), insert "UK" before "marketing authorisation".

Amendment of regulation 171 (exempt advanced therapy medicinal products)

137. In regulation 171(2)(c) for "Regulation (EC) No 726/2004" substitute "regulation 49(1)".

Amendment of regulation 173 (exemption for certain radiopharmaceuticals)

138. In regulation 173(c), insert "UK" before "marketing authorisation".

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 177 (application of Part and interpretation)

139.—(1) Regulation 177(**83**) is amended as follows.

(2) In paragraph (1)—

(a) for "Schedule 33", substitute "Schedules 12A and 33";

(b) omit ", except to the extent set out in paragraph (4)(b),";

(c) in sub-paragraph (a), at the end insert "or";

(d) omit sub-paragraph (c) (and "or" immediately preceding it).

(3) In paragraph (2)—

(a) after "this Part" insert "and Schedule 12A";

(b) in sub-paragraph (a), insert "or" at the end;

(c) omit sub-paragraph (c) (and "or" immediately preceding it).

(4) In paragraph (3)—

(a) for "Schedule 33" substitute "Schedules 12A and 33";

(b) in sub-paragraph (a), at the end insert "or";

(c) omit sub-paragraph (c) (and "or" immediately preceding it).

(5) Omit paragraph (4).

(6) In paragraph (5), omit the definitions of "co-ordination group", "Eudravigilance database", "Implementing Regulation" and "relevant competent authorities".

Amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system)

140.—(1) Regulation 180 is amended as follows.

(2) In paragraph (1), omit "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".

Omission of regulation 181 (delegation of obligations under Part 11)

141. Omit regulation 181.

Amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system)

142.—(1) Regulation 182(**84**) is amended as follows.

(**83**) Regulation 177 was amended by S.I. 2013/1855 and 2014/1878.
(**84**) Regulation 182 was amended by S.I. 2013/1855.

(2) In paragraph (2)(a), for "resides and operates in the EU" substitute "is ordinarily resident, and operates, in the United Kingdom".

(3) In paragraph (3), insert at the beginning "Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation)".

(4) Omit paragraph (6).

Amendment of regulation 184 (obligation on holder to audit pharmacovigilance system)

143. In regulation 184, after paragraph (2) insert—

"(3) The holder must also comply with the requirements of paragraph 13 of Schedule 12A in relation to auditing the pharmacovigilance system.".

Amendment of regulation 185 (recording obligations on the licensing authority)

144. In regulation 185(b), after "by" insert "a holder,".

Amendment of regulation 186 (reporting obligations on the licensing authority)

145. In regulation 186(1)—

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

(b) omit sub-paragraphs (c) to (e).

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.".

Amendment of regulation 187 (recording obligations on holders)

147.—(1) Regulation 187 is amended as follows.

(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".

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)—

(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".

(4) Omit paragraphs (2) and (3).

(5) In paragraph (4)(a), omit "other than monitored publications".

(6) In paragraph (5), omit the definitions of "monitored active substance" and "monitored publication".

(7) Omit paragraph (6).

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".

(3) Omit paragraphs (2) to (4).

Amendment of regulation 190 (signal detection: holder obligation)

150. In regulation 190(1), omit "the EMA and".

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), for "EMA" substitute "licensing authority".

(3) In paragraph (2), insert "UK" before "marketing authorisation".

(4) In paragraph (3), omit—

(a) "or an Article 126a authorisation" in both places it appears; and

(b) "or Article 126a authorisation".

(5) After paragraph (4) insert—

"(4A) A PSUR 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, 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.".

(7) In paragraph (10), for "within the EEA" in each place it appears substitute "in the United Kingdom".

(8) Omit paragraph (11).

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), for "EMA" substitute "licensing authority".

(4) Omit paragraphs (9) to (11).

Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)

153.—(1) Regulation 193 is amended as follows.

(2) Omit paragraph (1)(a).

(3) For paragraph (2) substitute—

"(2) Where one or more of the grounds in paragraph (3) is met, the holder 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) For paragraph (4) substitute—

"(4) Where the licensing authority makes a decision under paragraph (2) following a written request from a holder, it must notify that holder in writing of its decision to approve or refuse the request.".

(5) In paragraph (5)—

(a) for "Article 107c(4) or Article 107c(6) of the 2001 Directive" substitute "paragraph (2)"; and

(b) for "EMA" substitute "licensing authority".

(6) For paragraph (6) substitute—

"(6) Subject to paragraph (6A), 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.

(6A) 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 (6A) 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).".

Omission of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive)

154. Omit regulation 194.

Amendment of regulation 195 (obligation on licensing authority to assess PSURs)

155.—(1) Regulation 195(**85**) is amended as follows.

(2) In the heading, omit "where EU single assessment procedure does not apply".

(3) For paragraph (1) substitute—

"(1) This regulation applies where PSURs relating to a medicinal product 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.".

(5) In paragraph (4), omit the definitions of "EU reference date" and "EU single assessment procedure".

Substitution of regulation 196 (urgent action)

156. For regulation 196(**86**) and the italic heading immediately preceding it substitute—

"Major safety review

Major safety review by the licensing authority

196.—(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—

(**85**) Regulation 195 was amended by S.I. 2014/1878.
(**86**) Regulation 196 was amended by S.I. 2013/2593.

(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.".

Omission of regulation 197 (EU urgent action procedure)

157. Omit regulation 197.

Amendment of regulation 198 (post-authorisation safety studies: general provisions)

158.—(1) Regulation 198 is amended as follows.

(2) In paragraph (2), for "competent authorities of the EEA States in which the study is conducted" substitute "licensing authority".

(3) In paragraph (3)—

(a) in sub-paragraph (c), for "relevant competent authorities" substitute "licensing authority";

(b) in sub-paragraph (d), for "competent authorities of the EEA States in which the study was conducted" substitute "the licensing authority if the study is conducted in the United Kingdom".

Amendment of regulation 199 (submission of draft study protocols for required studies)

159.—(1) Regulation 199 is amended as follows.

(2) In paragraph (2), for "body specified in paragraph (3)" substitute "licensing authority".

(3) Omit paragraphs (3) and (4).

(4) In paragraph (5), omit "Where this paragraph applies".

(5) In paragraph (6), omit sub-paragraph (b) (and "or" immediately preceding it).

(6) Omit paragraphs (7) and (8).

Amendment of regulation 200 (amendment to study protocols for required studies)

160.—(1) Regulation 200 is amended as follows.

(2) In paragraph (2), for "body specified in paragraph (3)" substitute "licensing authority".

(3) Omit paragraphs (3) and (4).

(4) In paragraph (5), omit "Where this paragraph applies".

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

Amendment of regulation 201 (submission and evaluation of final study reports for required studies)

161.—(1) Regulation 201 is amended as follows.

(2) In paragraph (2), for "body specified in paragraph (3)" substitute "licensing authority".

(3) Omit paragraph (3).

(4) In paragraph (4), omit from "for reports" where it first appears to the end.

Omission of regulation 202 (follow up of final study reports)

162. Omit regulation 202.

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.".

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.

(3) In paragraph (2)—

(a) in sub-paragraph (e) for "Article 23 of Regulation (EC) No 726/2004" substitute "the list published by the licensing authority under, or which applies by virtue of, regulation 202A"; and

(b) in sub-paragraph (f), omit "(including by way of the web-based forms referred to in Article 25 of Regulation (EC) No 725/2004".

Omission of regulation 204 (obligation on licensing authority in relation to public announcements)

165. Omit regulation 204.

Amendment of regulation 205 (obligations on holders in relation to public announcements)

166.—(1) Regulation 205 is amended as follows.

(2) In paragraph (2), for "bodies listed in paragraph (3)" substitute "licensing authority".

(3) Omit paragraph (3).

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 makes further provision as to the obligations of a holder and the licensing authority in respect of the performance of pharmacovigilance activities under this Part.

(2) The Ministers may by regulations 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.".

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.

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.".

Amendment of regulation 206 (infringement notices)

170.—(1) Regulation 206(**87**) is amended as follows.

(2) In paragraph (1)—

(a) omit "relevant"; and

(b) after "provision" insert "of this Part or Schedule 12A ("relevant provision").

(3) Omit paragraphs (3) and (4).

Amendment of regulation 207 (offences)

171. In regulation 207(1), after "other than" insert "Schedule 12A (further requirements in respect of pharmacovigilance activities) and".

Amendment of regulation 208 (false and misleading information)

172. In regulation 208, omit "or the EMA".

Amendment of regulation 209 (penalties)

173. In regulation 209(3), omit sub-paragraphs (h) and (i).

Omission of regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004)

174. Omit regulation 210(**88**).

Amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation)

175.—(1) Regulation 210A(**89**) is amended as follows.

(2) In the heading, for "the Implementing Regulation" substitute "Schedule 12A".

(3) In paragraph (1)—

(a) in sub-paragraph (a) for "the Implementing Regulation" substitute "Schedule 12A"; and

(b) in sub-paragraph (b)—

(i) for "the Implementing Regulation" substitute "Schedule 12A", and

(ii) omit "or the EMA".

(4) For paragraph (2) substitute—

(**87**) Regulation 206 was amended by S.I. 2013/1855.
(**88**) Regulation 210 was amended by S.I. 2013/1855.
(**89**) Regulation 210A was inserted by S.I. 2013/1855.

"(2) The provisions of Schedule 12A mentioned in paragraph (1)(a) are—

(a) Part 1 (pharmacovigilance system master file);

(b) Parts 2 and 3 (minimum requirements for the quality systems in the performance of pharmacovigilance activities);

(c) Part 6 (transmission of reports of suspected adverse reactions);

(d) paragraph 24 (update of risk management plans);

(e) Part 8 (periodic safety update reports); and

(f) Part 9 (post-authorisation safety studies).

(3) Subject to paragraph (4), a person guilty of an offence under this regulation is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine.

(4) A person guilty of an offence under this regulation which relates to a breach of paragraph 26(8) or 29(1) of Schedule 12A is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.".

Amendment of regulation 211 (persons liable)

176. In regulation 211, omit from first "or" to "No 726/2004)".

Amendment of regulation 212 (transitional arrangements)

177. In regulation 212, for "182, 186, 188, 191, 192, 198, 199, 200, 201, 202 and 210" substitute "198, 199, 200, 201 and 202".

Amendment of Schedule 33 (transitional arrangements: pharmacovigilance)

178. In Schedule 33, omit paragraphs 1, 2 and 4 to 10.

PART 12

Amendment of Part 12 (dealings with medicinal products)

Amendment of regulation 213 (interpretation of Part 12)

179. In regulation 213(1)(**90**)—

(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"(**91**); and

(c) in the definition of "relevant prescriber", for "EEA health professional" substitute "approved country health professional".

(**90**) Regulation 213 was amended by S.I. 2013/235 and 2014/490 and 1878.
(**91**) The definition was substituted by S.I. 2014/1878.

Amendment of regulation 214 (sale or supply of prescription only medicines)

180.—(1) Regulation 214(**92**) 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.".

Amendment of regulation 216 (exceptions to regulation 215)

181. In regulation 216(2), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 217 (requirements for prescriptions: general)

182. In regulation 217(8)(a)(**93**), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 217A (requirements for prescriptions to be dispensed in an EEA State)

183.—(1) Regulation 217A(**94**) is amended as follows.

(2) In the heading, omit "other than the UK".

(3) In paragraph (2)(a), omit "other than the UK".

(**92**) Regulation 214 was amended S.I. 2013/1855, 2014/490, 2016/186 and 2018/199.
(**93**) Regulation 217 was amended by S.I. 2014/490.
(**94**) Regulation 217A was inserted by S.I. 2014/490.

Amendment of regulation 218 (requirements for prescriptions: EEA health professionals)

184.—(1) Regulation 218(**95**) 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)".

Amendment of regulation 219 (electronic prescriptions)

185. In regulation 219(2)(**96**), for "EEA health professional" substitute "approved country health professional".

Amendment of regulation 219A (electronic prescriptions: EEA health professionals)

186.—(1) Regulation 219A(**97**) 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".

Amendment of regulation 229 (exemption for supply by national health services bodies and local authorities)

187. In regulation 229(3)(f)(**98**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

188. In regulation 230(8)(**99**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 231 (exemption for supply etc under a PGD by independent hospitals etc.)

189. In regulation 231(8), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 232 (exemption for supply etc under a PGD by dental practices and clinics: England and Wales)

190. In regulation 232(8), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(**95**) Regulation 218 was amended by S.I. 2014/490 and 1878 and 2015/903.
(**96**) Regulation 219 was amended by S.I. 2015/903 and 2016/696.
(**97**) Regulation 219A was amended by S.I. 2015/903.
(**98**) Regulation 229 was amended by S.I. 2013/325, 2015/323, 2016/186 and 2018/199.
(**99**) Regulation 230 was amended by S.I. 2013/325.

Amendment of regulation 233 (exemption for supply etc under a PGD by a person conducting a retail pharmacy business)

191. In regulation 233(7)(**100**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)

192. In regulation 234(9)(**101**), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 17 (exemptions for sale, supply or administration by certain persons)

193.—(1) Schedule 17(**102**) is amended as follows.

(2) In the table in Part 1, in column 1 in entry 10, insert "UK" before "marketing authorisations".

(3) In the table in Part 4, in columns 1 and 2 in entry 9, insert "UK" before "marketing authorisation".

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";

(b) in sub-paragraph (b), insert "and" at the end; and

(c) omit sub-paragraph (d) (and "and" immediately preceding it).

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(**103**);

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005(**104**); 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(**105**);".

(**100**) Regulation 233 was amended by S.I. 2013/235 and 2015/1503.
(**101**) Regulation 234 was amended by S.I. 2015/323.
(**102**) Schedule 17 was amended by S.I. 2014/1878, 2015/1503, 2016/186 and 2017/715,
(**103**) 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.
(**104**) 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.
(**105**) S.I. 2007/1523.

Omission of regulation 255A to 255C (enforcement and offences relating to Commission Regulation 2016/161)

196. Omit regulations 255A to 255C(**106**).

PART 13

Omission of Part 12A (sale of medicines to the public at a distance)

Omission of Part 12A

197. Part 12A(**107**) is omitted.

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,".

(3) After paragraph (7) insert—

"(8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product.".

Omission of regulations 257A and 257B (packaging requirements: medicinal products required to bear safety features and associated transitionals)

199. Omit regulations 257A and 257B(**108**).

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 (other than an exempt advanced therapy medicinal product); and

(b) on the immediate packaging of the product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to 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.

(**106**) Regulations 255A to 255C were inserted by S.I. 2019/62.
(**107**) Part 12A was inserted by S.I. 2013/1855.
(**108**) Regulations 257A and 257B were inserted by S.I. 2019/62.

(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

257D.—(1) The licensing authority may publish guidance on packaging and package leaflets which 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.

(2) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission under Article 65 of the 2001 Directive, insofar as that guidance was in force immediately before exit day(**109**), 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.".

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".

(3) In paragraphs 15, 16 and 23, for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(4) Omit paragraph 18A(**110**).

(5) After Part 3 insert—

(**109**) 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.

(**110**) Paragraph (18A) was inserted by S.I. 2019/62.

"PART 4

Outer and immediate packaging: advanced therapy medicinal products

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(**111**), 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(**112**), 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".

(**111**) 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.
(**112**) S.I. 2007/1523.

PART 5

Immediate packaging: blister packs and small packaging (advanced therapy medicinal products)

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"."

Amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)

202. In regulation 259(2), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

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 (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, the information specified in Part 3 of that Schedule,".

(4) In paragraph (3), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 27 (package leaflets)

204.—(1) Schedule 27(**113**) is amended as follows.

(2) In paragraph 8(c)(ii), for "Article 65 of the 2001 Directive", substitute "published under regulation 257D".

(3) In paragraph 11(f), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(4) Omit paragraph 12.

(5) In paragraph 13—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

(6) At the end insert—

(**113**) Schedule 27 was amended by S.I. 2014/1878.

"Part 3

Advanced therapy medicinal products

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.".

Amendment of regulation 266 (language requirements etc)

205.—(1) Regulation 266 is amended as follows.

(2) In paragraph (1), omit "unless either or both of paragraphs (2) and (3) applies".

(3) Omit paragraphs (2) and (3).

Amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)

206. In regulation 267, in each place where it occurs, for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 268 (offence relating to packaging and package leaflets)

207.—(1) Regulation 268(**114**) is amended as follows.

(2) In paragraph (1), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(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".

Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)

208.—(1) Regulation 269(**115**) is amended as follows.

(2) In paragraph (1), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In paragraph (2)(a)—

(**114**) Regulation 268 was amended by S.I. 2019/62.
(**115**) Regulation 269 was amended by S.I. 2015/903 and 2019/62.

(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".

Amendment of regulation 270 (non-compliance with requirements of this Part)

209. In regulation 270(1) and (2), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

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).".

PART 15

Amendment of Part 14 (advertising)

Amendment of regulation 279 (products without a marketing authorisation)

211. In regulation 279—

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

(b) at the end of sub-paragraph (b), insert "or"; and

(c) omit sub-paragraph (d) (and "or" immediately preceding it).

Amendment of regulation 280 (general principles)

212. In regulation 280(1)—

(a) for "marketing authorisation," substitute "UK marketing authorisation or"; and

(b) omit "or Article 126a authorisation".

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";

(b) at the end of sub-paragraph (b) insert "or"; and

(c) omit sub-paragraph (d) (and "or" immediately preceding it).

Amendment of regulation 293 (prohibition of supply to the public for promotional purposes)

214. In regulation 293(1)—

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

(b) for "certificate of registration," substitute "certificate of registration or"; and

(c) omit "or Article 126a authorisation".

Amendment of regulation 295 (abbreviated advertisements)

215. In regulation 295(2)(d)—

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

(b) for "certificate of registration," substitute "certificate of registration or"; and

(c) omit "or Article 126a authorisation".

Amendment of Schedule 30 (particulars for advertisements to persons qualified to prescribe or supply)

216. In paragraphs 1, 2 and 6 of Schedule 30(**116**), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation", substitute "UK marketing authorisation, certificate of registration or traditional herbal registration".

Amendment of regulation 299 (medical sales representatives)

217. In regulation 299(3), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation", substitute "UK marketing authorisation, certificate of registration or traditional herbal registration".

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";

(b) omit sub-paragraph (d).

PART 17

Amendment of Part 16 (enforcement)

Amendment of regulation 322 (validity of proceedings)

219. In regulation 322(1)—

(a) for ", 7" substitute "or 7"; and

(b) omit "or 8 (Article 126a authorisations)".

(**116**) Schedule 30 was amended by S.I. 2014/1878.

Amendment of regulation 323 (enforcement in England, Wales and Scotland)

220.—(1) Regulation 323(**117**) 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).

Amendment of regulation 327 (powers of inspection, sampling and seizure)

221.—(1) Regulation 327(**118**) is amended as follows.

(2) In paragraph (1)(c)—

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

(b) insert "or" at the end of paragraph (vi);

(c) omit paragraph (viii) (and "or" immediately preceding it).

(3) In paragraph (2)—

(a) in sub-paragraph (g)—

(i) in paragraph (ii), after "Part 11" insert "or Schedule 12A" and insert "and" at the end, and

(ii) omit paragraphs (iii), (iv) and (v); and

(b) omit sub-paragraph (h).

(4) Omit paragraph (4A).

(5) In paragraph (5)—

(a) in sub-paragraph (a) for ", (g) or (h)" substitute "or (g)"; and

(b) in sub-paragraph (b) omit " or (4A)".

Amendment of regulation 331 (findings and reports of inspections)

222.—(1) Regulation 331 is amended as follows.

(2) In paragraph (1)—

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

(b) omit sub-paragraph (c) (and "and" immediately preceding it).

(3) In paragraph (4) for sub-paragraph (c) substitute—

"(c) in the case of a holder of a UK marketing authorisation or traditional herbal registration, Part 11 (pharmacovigilance).".

Insertion of regulation 331A (guidelines on inspections)

223. After regulation 331 (finding and reports of inspections) insert—

(**117**) Regulation 323 was amended S.I. 2019/62.
(**118**) Regulation 327 was amended by S.I. 2013/1855 and 2019/62.

"**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 exit day(**119**), are to continue to apply.".

PART 18

Amendment of Part 17 (miscellaneous and general)

Amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)

224. In regulation 341(4)(a), insert "UK" before "marketing authorisation".

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 exit 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

(**119**) 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.

(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.".

Amendment of regulation 345 (immunity from civil liability)

226. In regulation 345(5)—

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

(b) insert "or" after "certificate of registration"; and

(c) omit "or Article 126a authorisation".

Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)

227. In regulation 346(**120**)—

(a) in sub-paragraph (c), omit paragraphs (iia), (iiia), (iva), (xixa), (xxviiii) and (xxviiij); and

(b) in sub-paragraph (d), omit paragraphs (ia) and (ivab).

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.

(**120**) 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.

Consequential amendments

229. Schedule 8 contains consequential amendments.

Revocations of retained direct EU law

230. Schedule 9 contains revocations of retained direct EU law.

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 CareHer Majesty's Treasury

29th March 20191st April 2019