STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 1

General

Citation and commencement

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

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

Medicinal products

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

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

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

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

(ii) making a medical diagnosis.

(2) These Regulations do not apply to—

(a) whole human blood; or

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

Modifications etc. (not altering text)

C1 Reg. 2 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

[F1Definition of advanced therapy medicinal product etc.

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

(a) a gene therapy medicinal product;

(b) a somatic cell therapy medicinal product; or

(c) a tissue engineered product.

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

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

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

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

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

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

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

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

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

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

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

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

(6) A tissue engineered product may contain—

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

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

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

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

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

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

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

(8) Cells or tissues are engineered if they—

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

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

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

(a) cutting;

(b) grinding;

(c) shaping;

(d) centrifugation;

(e) soaking in antibiotic or antimicrobial solutions;

(f) sterilisation;

(g) irradiation;

(h) cell separation, concentration or purification;

(i) filtering;

(j) lyophilisation;

(k) freezing;

(l) cryopreservation; and

(m) vitrification.

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

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

(b) the cellular part of which—

(i) contains viable cells or tissues; or

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

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

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

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

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

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

(b) a gene therapy medicinal product,

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

Textual Amendments

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

Scope of these Regulations: special provisions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) on a large scale; or

(b) by an industrial process.

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

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

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

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

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

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

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

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

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

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

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

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

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

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

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

(a) a **[**[F4]UK**]** marketing authorisation;

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

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

Textual Amendments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) For the purposes of this regulation—

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

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

(6) This regulation ceases to have effect on 1st April **[**F7**]**2026**].]**

Textual Amendments

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

F7 Word in reg. 3A(6) substituted (E.W.S.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024 (S.I. 2024/344), regs. 1(2), **3** and (N.I.) (31.3.2024) by The Human Medicines (Amendments Relating to Coronavirus and Influenza) Regulations (Northern Ireland) 2024 (S.R. 2024/68), regs. 1(2), **3**

Special provisions for pharmacies etc

4.—(1) Regulations 17(1) (manufacturing of medicinal products: requirement for licence) and 46 (requirement for authorisation) do not apply where any provision of section 10 of the Medicines Act 1968 **M1** so provides.

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

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

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

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

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

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

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

(i) the **[**F8UK**]** marketing authorisation,

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

(ii) the certificate of registration,

(iii) the traditional herbal registration, or

(iv) the Article 126a authorisation,

that relates to the authorised medicinal product.

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

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

Textual Amendments

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

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

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

Marginal Citations

M1 Section 10(1) was amended by paragraph 10(a) of Part 1 of Schedule 8 to S.I. 2006/2407, paragraph 5(a) of Schedule 3 to the Regulation of Care (Scotland) Act 2001, and article 3 of S.I. 1971/1445. Section 10(2) was repealed by paragraph 10(b) and (3)(b) was repealed by paragraph 10(c) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(4) was amended and section 10(5) and (6) inserted by article 3 of S.I. 1971/1445. Section 10(6A) was repealed by paragraph 10(d) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(7) was inserted by article 3 of S.I. 1971/1445, and amended by regulation 3 of S.I. 1993/834. Section 10(7A) to (7C) was inserted by the Health Act 2006 section 26(1), and section 10(7A) was amended by paragraph 10(e) of Part 1 of Schedule 8 to S.I. 2006/2407. Section 10(8) was inserted by S.I. 1971/1445 article 3. Section 10(9) was inserted by paragraph 5(a) of Schedule 3 to the Regulation of Care (Scotland) Act 2001.

Classification of medicinal products

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

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

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

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

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

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

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

(a) a UK marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

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

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

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

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

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

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

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

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

(i) the assembly, or

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

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

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

(a) a UK marketing authorisation; or

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

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

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

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

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

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

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

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

(d) the result of—

(i) the assembly, or

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

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

Textual Amendments

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

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

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

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

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

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

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

The licensing authority and the Ministers

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

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

(3) Any function that—

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

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

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

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

(a) they relate to medicinal products; and

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

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

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

(a) the Secretary of State; and

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

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

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

Textual Amendments

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

Advertisements relating to medicinal products

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

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

(a) door-to-door canvassing;

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

(c) the supply of samples;

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

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

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

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

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

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

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

(ii) adverse reaction warnings,

(iii) trade catalogues, and

(iv) price lists,

provided that no product claim is made; or

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

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

General interpretation

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

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

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

[[F21]"active implantable medical device"—

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

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

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

"administer" means administer to a human being—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"blood component" means any of the following—

(a) red cells;

(b) white cells;

(c) platelets; and

(d) plasma;

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

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

"business" includes—

(a) a professional practice;

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

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

(i) the National Health Service Act 2006 [M2],

(ii) the Health and Personal Social Services (Northern Ireland) Order 1972 [M3] and the Health and Social Care (Reform) Act (Northern Ireland) 2009 [M4],

(iii) the National Health Service (Wales) Act 2006 [M5],

(iv) the National Health Service (Scotland) Act 1978 [M6];

[F26]...

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

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

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

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

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

(a) the patient;

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

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

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

"the Clinical Trials Directive" means Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [M7];

"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004 [M8];

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

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

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

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

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

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

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

"community practitioner nurse prescriber" means a person—

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

(b) against whose name is recorded in the professional register an annotation signifying that the person is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;

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

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

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

(a) perfuming them;

(b) cleansing them;

(c) protecting them;

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

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

(f) combating body odours or normal body perspiration;

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

"dentist" means a person registered in the dentists register under section 14 of the Dentists Act 1984 M9;

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

F30 …

F31 …

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

"doctor" means a registered medical practitioner;

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

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

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

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

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

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

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

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

(a) by means of an electronic communications network within the meaning of section 32(1) of the Communications Act 2003 [M10]; or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"the Health and Care Professions Council register" means the register established and maintained by the Health and Care Professions Council under article 5 of the **[**F40Health Professions Order 2001**]**M11;

"health care professional" means—

(a) a doctor;

(b) a dentist;

(c) a pharmacist;

(d) a pharmacy technician registered in Part 2 F41... of the Register of pharmacists and pharmacy technicians established and maintained under article 19(2) of the Pharmacy Order 2010 M12;

(e) a registered nurse;

(f) a registered midwife;

(g) a registered optometrist;

(h) a registered osteopath as defined in section 41 of the Osteopaths Act 1993 M13;

(i) a registered chiropractor as defined in section 43 of the Chiropractors Act 1994 M14;

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

(k) a person registered in the dental care professionals register established and maintained under section 36B of the Dentists Act 1984 M15 as a member of a profession complementary to dentistry specified by regulation 2 of the General Dental Council (Professions Complementary to Dentistry) Regulations 2006 M16;

"health centre" means a health centre maintained under—

(a) section 2 or 3 of the National Health Service Act 2006 [M17];

(b) section 2 or 3 of the National Health Service (Wales) Act 2006 [M18];

(c) section 36(1)(b) of the National Health Service (Scotland) Act 1978 [M19]; or

(d) article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972 [M20];

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

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

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

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

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

(a) the European Pharmacopoeia; or

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

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

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

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

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

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

[[F44]"import" means import, or attempt to import, into the United Kingdom, whether by land, sea or air **[**[F45]and "imported" is to be construed accordingly**]**;**]**

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

"intermediate product" means a substance which—

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

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

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

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

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

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

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

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

"marketing authorisation" means—

(a) a UK marketing authorisation; or

(b) an EU marketing authorisation;

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

[[F21]"medical device"—

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

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

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

"name" in relation to a medicinal product means—

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

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

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

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

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

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

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

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

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

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

"NHS primary dental services" means—

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

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

(c) in relation to Scotland, dental services under the National Health Service (Scotland) Act 1978 or personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997 [M21]; and

(d) in relation to Northern Ireland, general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972 or personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997 [M22];

"NHS primary medical services" means—

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

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

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

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

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

"nurse independent prescriber" means a person who—

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

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

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

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

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

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

(c) a pharmacist;**]**

"optometrist independent prescriber" means a person—

(a) who is a registered optometrist; and

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

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

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

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

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

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

(a) a container of the product;

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

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

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

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

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

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

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

"the Paediatric Regulation" means Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004M23;

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

[F46"paramedic independent prescriber" means a person—

(a) who is a registered paramedic; and

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

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

"pharmacist" means—

(a) in relation to Great Britain a person registered in Part 1 F47... of the Register of pharmacists and pharmacy technicians maintained under article 19(2) of the Pharmacy Order 2010 M24; and

(b) in relation to Northern Ireland a person registered in the register of pharmaceutical chemists for Northern Ireland F48... maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 M25;

"pharmacist independent prescriber" means a person who—

(a) is a pharmacist; and

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

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

"pharmacovigilance system" means a system used by the holder of a **[**F49UK marketing authorisation, EU marketing authorisation**]**, traditional herbal registration or Article 126a authorisation, or by the licensing authority, to fulfil the tasks and responsibilities set out in Part

11 and designed to monitor the safety of authorised or registered medicinal products and detect any change to their risk-benefit balance;

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

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

[F50"physiotherapist independent prescriber" means a person—

(a) who is a registered physiotherapist; and

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

"podiatrist independent prescriber" means a person—

(a) who is a registered podiatrist; and

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

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

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

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

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

(c) measuring the effectiveness of risk management measures;

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

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

(a) the summary of the product characteristics;

(b) the immediate and outer packaging; and

(c) the package leaflet;

"the professional register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001 M26;

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

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

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

(b) where an application for a licence is made before 30th April 2013, in so far as the application relates to activities in respect of traditional herbal medicinal products, a person who has been engaged in activities in respect of traditional herbal medicinal

products equivalent to those in Part 3 of Schedule 7 on or before 30th April 2011 and continues to be so engaged at the time when the application is made;

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

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

"radionuclide" means a radioactive isotope;

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

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

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

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

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

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

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

"registered optometrist" means a person whose name is entered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989 M27F55...;

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

"registered pharmacy" means—

(a) in relation to Great Britain, premises entered in the register required to be kept under article 19 of the Pharmacy Order 2010 for the purposes of sections 74A and 74J of the Medicines Act 1968 M28; and

(b) in relation to Northern Ireland, premises entered in the register required to be kept under section 75 M29 of the Medicines Act 1968;

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

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

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

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

[F58"Regulation (EC) No 726/2004" means Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for

the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency **[**F59, as it has effect in EU law**]**;**]**

"Regulation (EC) No 1394/2007" means Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004M30;

"Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products M31**[**F60, as it has effect in EU law**]**;

"the relevant EU provisions" means the provisions of legislation of the European Union relating to medicinal products for human use, except to the extent that any other enactment provides for any function in relation to any such provision to be exercised otherwise than by the licensing authority;

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

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

"the relevant register" means—

(a) in relation to a pharmacist—

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

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

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

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

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

(i) chiropodists and podiatrists,

(ii) physiotherapists, F64...

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

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

(v) paramedics;**]**

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

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

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

"serious adverse reaction" means an adverse reaction that—

(a) results in a person's death;

(b) threatens a person's life;

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

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

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

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

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

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

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

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

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

(e) gases and vapours;

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

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

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

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

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

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

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

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

(a) a pharmacist;

(b) a registered midwife;

(c) a registered nurse;

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

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

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

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

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

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

(a) who is a registered radiographer; and

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

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

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

F73 …

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

"traditional herbal registration" means a traditional herbal registration granted by the licensing authority under these Regulations **[F74**and—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) regulation 50 and Schedule 8, and

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

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

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

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

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

(a) a **[**F80**]**UK**]** marketing authorisation is to a condition to which the authorisation is subject by virtue of regulation 59(1) **[**F81, 60(1) or 60A**]**; and

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

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

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

(b) they are in the same pharmaceutical form.

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

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

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

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

Textual Amendments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Modifications etc. (not altering text)

C2 Reg. 8(1) applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by S.I. 2012/1916, reg. 1(2), Sch. 34 paras. 57(b), **64** (with Sch. 32))

Marginal Citations

M2 2006 c.41.

M3 S.I. 1972/1265 (N.I. 14).

M4 2009 c.1 (N.I.).

M5 2006 c.42.

M6 1978 c.29.

M7 OJ No L 121, 1.5.2001, p.34. Directive 2001/20/EC was last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).

M8 S.I. 2004/1031, to which there are amendments not relevant to these Regulations.

M9 1984 c.24. Section 14 was substituted by the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) articles 2 and 6 and further amended by the European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regulations 109 and 111. Other amendments of the Dentists Act are not relevant to these Regulations.

M10 2003 c.21.

M11 S.I. 2002/254, as amended by S.I. 2009/1182. There are other amendments that are not relevant.

M12 S.I. 2010/231.

M13 1993 c.21. Section 41 was amended by S.I. 2007/3101 regulations 206 and 214.

M14 1994 c.17.

M15 1984 c.24. Section 36B was inserted by S.I. 2005/2011, articles 2(1) and 29.

M16 S.I. 2006/1440, Schedule.

M17 2006 c.41.

M18 2006 c.42.

M19 1978 c.29. Concurrent functions under section 36(1) were transferred to the National Waiting Times Board by article 4(2)(c) and (4) of S.S.I. 2002/305.

M20 S.I. 1972/1265 (N.I. 14), as amended by S.I. 1984/1158 (N.I. 8), S.I. 1986/595 (N.I. 4) and 2004/311 (N.I. 2).

M21 1997 c.46.

M22 S.I. 1997/1177 (N.I. 7).

M23 OJ No L 378, 27.12.2006, p.1. Regulation (EC) No 1901/2006, as amended by Regulation (EC) No 1902/2006 (OJ No L 378, 27.12.2006, p.20) .

M24 S.I. 2010/231.

M25 S.I. 1976/1213 (N.I. 22), as amended by S.R. 2008 No. 192.

M26 S.I. 2002/253, as amended by S.I. 2009/1182.

M27 1989 c.44; section 7(a) was amended by S.I. 2005/848, articles 2 and 7(1).

M28 1968 c.67. Sections 74A and 74J were inserted by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231.
M29 Section 75 was amended by article 68 of and paragraph 1 of Schedule 4 to S.I. 2010/231
M30 OJ No L 324, 10.12.2007, p.121.
M31 OJ No L 334, 12.12.2008, p.7.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 1.