STATUTORY INSTRUMENTS

# 2019 No. 775

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

## 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—

(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(**1**), 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(**2**) 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(**3**); 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(**4**);";

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

""Annex I to the 2001 Directive" means 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(**5**);";

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

""medical device"—

(**1**) Schedule 1 was amended by S.I. 2014/490.
(**2**) 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.
(**3**) S.I. 2002/618. It was amended by S.I. 2008/2936.
(**4**) Regulation 137 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
(**5**) OJ No. L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350.

(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(**6**);";

""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(**7**) 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(**8**);"; 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,

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"(**9**), 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";

(**6**) Regulation 69 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
(**7**) OJ No. L 018, 22.01.2000, p. 1.
(**8**) 1977 c. 37. Section 128B was inserted by S.I. 2007/3293 and subsection (2) was amended by S.I.2014/2411.
(**9**) The definition of "import" was inserted by S.I. 2013/1855.

(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"(**10**),

(iv) "Commission Regulation 2016/161"(**11**),

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

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

(vii) "healthcare institution"(**12**),

(viii) "hospice"(**13**),

(ix) "marketing authorisation",

(x) "Paediatric Regulation",

(xi) "the Pharmacovigilance Risk Assessment Committee",

(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)(**14**), 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.

(**10**) The definition of "care home" was inserted by S.I. 2019/62.
(**11**) The definition of "Commission Regulation 2016/161" was inserted by S.I. 2019/62.
(**12**) The definition of "healthcare institution" was inserted by S.I. 2019/62.
(**13**) The definition of "hospice" was inserted by S.I. 2019/62.
(**14**) Paragraph (8) was inserted by S.I. 2013/1855.