STATUTORY INSTRUMENTS

# 2019 No. 775

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

## PART 2

Amendment of Part 1 (General)

**Amendment of regulation 8 (general interpretation)**

**10.**—(1) Regulation 8 [M1] 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 [M2]; 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 [M3];";

""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 **[**[F1], in relation to UKMA(GB),**]** Annex I to the 2001 Directive, as modified in accordance with Schedule 8B;";

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

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

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

""conditional marketing authorisation" means a **[**[F2]UKMA(GB)**]** granted under regulation 49(1)(a) in accordance with regulation 58F;";

""country" means a country or territory;";

""Directive 2001/18/EC" means Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration [M4];";

**[**[F3]""EU agreed paediatric investigation plan" means a paediatric investigation plan agreed in accordance with the Paediatric Regulation;"**]**;

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

""medical device"—

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

(b) to the extent necessary for the practical application of that definition, also or instead has the meaning given in regulation 69 of those Regulations [M5];";

**[**[F3]""nursing home" has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003; "; and**]**

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

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

""Orphan Regulation" means Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [M6] 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;";

**[**[F3]""parallel import licence" has the meaning given in regulation 48(2);"**]**;

**[**[F3]""qualifying Northern Ireland goods" has the same meaning that it has in the European Union (Withdrawal) Act 2018, including any meaning defined for the purposes of that Act from time to time by regulations made under the power conferred by section 8C(6) of that Act;"**]**;

""supplementary protection certificate" has the meaning given in section 128B(2) of the Patents Act 1977 [M7];"; and

**[**[F3]""under the unfettered access route" means an application for—

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

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

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

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

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

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

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

**[**[F3]""withdrawal agreement" has the meaning given in section 39 of the European Union (Withdrawal Agreement) Act 2020;"**]**;

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

**[**[F4](za) in the definition of "advanced therapy medicinal product", after "means" insert ", in the case of a medicinal product for sale or supply by the holder of a UKMA(NI) or UKMA(UK),";

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

"and—

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

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

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

**[**F5(a) for the definition of "the Good Manufacturing Practice Directive" substitute—

""the Good Manufacturing Practice Directive" means—

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

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

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

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

(b) in the definition of "homoeopathic medicinal product", in paragraph (b), for "in any pharmacopoeia used officially in an EEA State" **[**F6substitute—

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

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

(c) in the definition of "import"M8, insert at the end " and "imported" is to be construed accordingly ";

F7(d) . . . . . .

(e) in the definition of "pharmacovigilance system", "pharmacovigilance system master file" and "post-authorisation safety study", **[**F8for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation"**]**

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

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

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

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

**[**F9(j) in the definition of "traditional herbal registration", after "these Regulations" insert—

"and—

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

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

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

[F10(k) for the definition of "UK marketing authorisation" substitute—

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

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

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

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

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

F11(i) . . . . . .

F12(ii) . . . . . .

(iii) "care home" M9,

F13(iv) . . . . . .

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

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

F14(vii) . . . . . .

F15(viii) . . . . . .

F16(ix) . . . . . .

F17(x) . . . . . .

F18(xi) . . . . . .

F19(xii) . . . . . .

(xiii) "third country".

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

(6) In paragraph (6)(a)—

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

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

(7) In paragraph (8) M10, for "References" substitute " Subject to regulation C17(6), references ".

[F20(8) After paragraph (8) insert—

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

**Textual Amendments**

**F1** Words in reg. 10(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(i)(aa)**

**F2** Word in reg. 10(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(i)(bb)**

**F3** Words in reg. 10(2) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(a)(ii)**

**F4** Reg. 10(3)(za)(zb) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(i)**

**F5** Reg. 10(3)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(ii)**

**F6** Words in reg. 10(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(iii)**

**F7** Reg. 10(3)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(iv)**

**F8** Words in reg. 10(3)(e) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(v)**

**F9** Reg. 10(3)(j) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(vi)**

**F10** Reg. 10(3)(k) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(b)(vii)**

**F11** Reg. 10(4)(i) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F12** Reg. 10(4)(ii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F13** Reg. 10(4)(iv) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F14** Reg. 10(4)(vii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F15** Reg. 10(4)(viii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F16** Reg. 10(4)(ix) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F17** Reg. 10(4)(x) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F18** Reg. 10(4)(xi) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F19** Reg. 10(4)(xii) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(c)**

**F20** Reg. 10(8) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 7(d)**

## Commencement Information

**I1** Reg. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

## Marginal Citations

**M1** 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.

**M2** S.I. 2002/618. It was amended by S.I. 2008/2936.

**M3** Regulation 137 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

**M4** OJ No. L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350.
**M5** Regulation 69 is inserted by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.
**M6** OJ No. L 018, 22.01.2000, p. 1.
**M7** 1977 c. 37. Section 128B was inserted by S.I. 2007/3293 and subsection (2) was amended by S.I.2014/2411.
**M8** The definition of "import" was inserted by S.I. 2013/1855.
**M9** The definition of "care home" was inserted by S.I. 2019/62.
**M10** Paragraph (8) was inserted by S.I. 2013/1855.

**Changes to legislation:**
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 10.