SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 1

Amendment of Part 2 (amendment of Part 1 (General))

1. In regulation 4 (definitions in relation to advanced therapy medicinal products), in the inserted regulation 2A, in paragraphs (1) and (10), after "In these Regulations," insert "in their application to products for sale or supply in Great Britain only,".

2. In regulation 5 (amendment of regulation 3 (scope of Regulations: special provisions))—

(a) for paragraph (2)(b) and (c) substitute—

"(b) after paragraph (i) insert—

"(ia) the EU marketing authorisation,".";

(b) for paragraph (3)(b) and (c) substitute—

"(b) after paragraph (i) insert—

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

3. In regulation 6 (amendment of regulation 4 (special provision for pharmacies etc) substitute—

"**6.** In regulation 4—

(a) in paragraph (4)(d)—

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

(ii) after paragraph (i) insert—

"(ia) the EU marketing authorisation,";

(b) in paragraph (6) for "269 (offences relating to packaging and package leaflets: other persons)" substitute "269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)".".

4. In regulation 7 (amendment of regulation 5 (classification of medicinal products))—

(a) for paragraph (2) substitute—

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

(b) in paragraph (3)—

(i) omit sub-paragraph (a);

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

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

(c) in paragraph (4)—

(i) for sub-paragraph (a) substitute—

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

(ii) omit sub-paragraph (b);

(d) in paragraph (5) for "omit sub-paragraph (b)" to the end substitute "in sub-paragraph (b), before "an Article" insert "in the case of a medicinal product for sale or supply in Northern Ireland,".."; and

(e) in paragraph (6)—

(i) for sub-paragraph (a) substitute—

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

(ii) omit sub-paragraph (b).

5. For regulation 8 (amendment of Schedule 1 (further provisions for classification of medicinal products)) substitute—

"**8.** In Schedule 1—

(a) in paragraph 1—

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

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

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

6. Omit regulation 9 (amendment of regulation 6 (the licensing authority and the Ministers)).

7. In regulation 10 (amendment of regulation 8 (general interpretation))—

(a) in paragraph (2)—

(i) in the definition of—

(aa) "Annex I to the 2001 Directive", after "means" insert ", in relation to UKMA(GB),";

(bb) "conditional marketing authorisation", for "UK marketing authorisation" substitute "UKMA(GB)";

(ii) at the appropriate place in the list of definitions to be inserted, insert—

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

""nursing home" has the meaning given by article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003(**1**);"; and

""parallel import licence" has the meaning given in regulation 48(2);";

""qualifying Northern Ireland goods" has the same meaning that it has in the European Union (Withdrawal) Act 2018, including any meaning defined for

(**1**) S.I. 2003/431 (N.I. 9); article 11 is amended by S.R. 2009 No. 114.

the purposes of that Act from time to time by regulations made under the power conferred by section 8C(6) of that Act;";

""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));";

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

(b) in paragraph (3)—

(i) before sub-paragraph (a) insert—

"(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;";";

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

"(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;";";

(iii) in sub-paragraph (b) (amendment of definition of "homoeopathic medicinal product") for "substitute "the British Pharmacopoeia"" to the end substitute—

"substitute—

"(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;".";

(iv) omit sub-paragraph (d) (amendment of definition of "name");

(v) in sub-paragraph (e) (amendment of definitions of "pharmacovigilance system", "pharmacovigilance system master file" and "post-authorisation safety study") for "for "marketing authorisation, traditional" to the end substitute "for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation"";

(vi) for sub-paragraph (j) (amendment of definition of "the summary of the product characteristics") substitute—

"(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;";";

(vii) for sub-paragraph (k) (amendment of definition of "UK marketing authorisation") substitute—

"(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.";";

(c) in paragraph (4) omit subparagraphs (i), (ii), (iv), (vii), (viii), (ix), (x), (xi) and (xii);

(d) after paragraph (7) insert—

"(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).".".