SCHEDULES

SCHEDULE 2

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

PART 22

Amendment of Schedule 7 (insertion of new Schedule 33A (Transitional Provision))

193. In Schedule 7 (insertion of new Schedule 33A (Transitional Provision)), in the inserted Schedule 33A—

(a) for "exit day", in each place it occurs, including in headings, substitute " IP completion day ";

(b) for "21 months", in each place it occurs, substitute " 24 months ";

(c) for "33 months", in each place it occurs, substitute " 36 months ";

(d) for paragraph 6(2)(a) substitute—

"(a) insofar as it authorises sale or supply of a medicinal product in Great Britain, has effect on and after IP completion day as a UKMA(GB) granted under regulation 49(1) of these Regulations (but, insofar as it authorises sale or supply of a medicinal product in Northern Ireland, continues to operate in Northern Ireland as an EU marketing authorisation); and";

(e) in paragraph 6(4)(f), for "regulation 51(1) and (2)" substitute " regulation 51A(1) and (6) ";

(f) before paragraph 26 insert—

"**Status of certain UK marketing authorisations granted before IP completion day**

26ZA.—(1) This paragraph applies in relation to a UK marketing authorisation granted by the licensing authority under Chapter 4 of Title III to the 2001 Directive that was in force immediately before IP completion day.

(2) A UK marketing authorisation to which this paragraph applies—

(a) has effect on and after IP completion day as a UKMA(UK) granted under regulation 49(1) of these Regulations; and

(b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).";

(g) in paragraph 26(1)(a)—

(i) omit "or" at the end of subparagraph (iii);

(ii) for "and" at the end of subparagraph (iv) substitute—

"or

(v) is deemed to hold a parallel import licence under paragraph 28(2); and";

(h) in paragraph 26(2), after "continues to apply to a person" insert " where the UK marketing authorisation or parallel import licence authorises sale or supply of the medicinal product in Great Britain ";

(i) in paragraphs 27(1), 33(1), 45(1) and 50(1), after "offence relating to packaging and package leaflets" insert " in Great Britain ";

(j) after paragraph 27 insert—

"**Status of parallel import licences granted before IP completion day**

27A.—(1) This paragraph applies in relation to a parallel import licence granted by the licensing authority that was in force immediately before IP completion day.

(2) A parallel import licence to which this paragraph applies—

(a) has effect on and after IP completion day as a parallel import licence in force in the whole United Kingdom granted under regulation 49(1) of these Regulations; and

(b) is treated as including a statement that it is in force in the whole United Kingdom for the purposes of regulation 49(1C).";

(k) in paragraph 28(2), after "granted under Part 5" insert " , in force in Great Britain only, ";

(l) in paragraph 29, after sub-paragraph (7) insert—

"(8) This paragraph, with the exception of sub-paragraphs (3) and (4), applies equally to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this paragraph (other than in this sub-paragraph) to—

(a) a marketing authorisation or a UK marketing authorisation is to be read as a reference to a parallel import licence for a medicinal product, and

(b) the holder of a UK marketing authorisation is to be read as a reference to the holder of a parallel import licence.";

(m) after paragraph 29 insert—

"**Application of the batch testing requirement to relevant EU marketing authorisations, and batch testing of biological medicinal products in the EEA before IP completion day (regulation 60B)**

29A.—(1) Sub-paragraph (2) applies where—

(a) an EU marketing authorisation was in force before IP completion day,

(b) that authorisation is in force on IP completion day (whether or not it is suspended); and

(c) that authorisation is for a medicinal product of a type that is specified in regulation 60B(2) (requirement to submit samples and other information to the appropriate authority).

(2) Where this sub-paragraph applies, the EU marketing authorisation is deemed to be subject to the batch testing requirement in regulation 60B on and after IP completion day.

(3) Sub-paragraph (4) applies where a holder of an EU marketing authorisation has, before IP completion day, submitted to a competent authority of an EEA State samples for testing from a batch of a medicinal product ("the relevant batch") that—

(a) is the subject of that authorisation; and

(b) is of a type specified in regulation 60B(2).

(4) Where this sub-paragraph applies, the holder of the EU marketing authorisation is deemed to have satisfied the batch testing requirement in regulation 60B in respect of the relevant batch if, before IP completion day—

(a) the competent authority of that EEA State examines the sample from the relevant batch; and

(b) that authority declared it to be in conformity with the approved specifications (within the meaning of Article 114 of the 2001 Directive) before IP completion day.

(5) Sub-paragraphs (5) and (6) of paragraph 29 apply in relation to the appropriate authority's management of the list published under regulation 60A(5) for the purposes of this paragraph and regulation 60B.";

(n) in paragraph 41, in sub-paragraphs (3), (5) and (8)—

(i) in paragraphs (a) and (b), omit "with which the United Kingdom concurred";

(ii) in paragraph (c), omit ", or where such an opinion has been given but the United Kingdom recorded a divergent opinion,";

(o) after paragraph 41 insert—

"**Transitional provision in relation to global marketing authorisations under the 2001 Directive**

41A. Where a relevant medicinal product is subject to a global marketing authorisation as described in Article 6 of the 2001 Directive before IP completion day, a paediatric investigation plan does not need to be carried out in relation to that product.";

(p) omit Part 7 (transitional provision in relation to orphan medicinal products);

(q) in paragraph 44(2), after "continues to apply to a person" insert " , in relation to a certificate of registration in force in Great Britain, ";

(r) in paragraph 49(2), after "continues to apply to a person" insert " , only in relation to a registration in force in Great Britain, and ";

(s) in paragraph 52(1), after "traditional herbal registration" insert " to be in force in Great Britain only ";

(t) in paragraph 53, after "traditional herbal registration" insert " in force in Great Britain only ";

(u) in paragraph 55(1)(a), after "traditional herbal registration" insert " to be in force in Great Britain only ";

(v) omit paragraph 56;

(w) omit paragraph 57;

(x) in paragraph 58—

(i) in sub-paragraph (1)(a), after "specified matter" insert " in relation to a UKMA(GB) or a THR(GB) ";

(ii) in sub-paragraph (2), for "UK marketing authorisation or traditional herbal registration" substitute " UKMA(GB) or THR(GB) ";

(iii) in sub-paragraph (7)(a), after "specified matter" insert " in relation to a UKMA(GB) or a THR(GB) ";

(y) in paragraph 59—

(i) in sub-paragraph (1)(a), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(ii) in sub-paragraph (2)—

(aa) for "revocation" substitute " amendment ";

(bb) for "UK marketing authorisation or traditional herbal registration" substitute " UKMA(GB) or THR(GB) ";

(iii) in sub-paragraph (3)(a), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(z) in paragraph 60—

(i) in sub-paragraph (1)(b), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(ii) in sub-paragraph (2), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(iii) in sub-paragraph (3)(a), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(iv) in sub-paragraph (5)(a), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(aa) in paragraph 61—

(i) in sub-paragraphs (2)(a) and (b), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(ii) in sub-paragraph (4), for "revocation" substitute " amendment ";

(iii) in sub-paragraph (5)(b), after "holder" insert " of a UKMA(GB) or a THR(GB) ";

(iv) in sub-paragraph (6)—

(aa) for "revocation" substitute " amendment ";

(bb) in paragraph (b), after "holder" insert " of a UKMA(GB) or a THR(GB) ".

Commencement Information

I1 Sch. 2 para. 193 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 22.