SCHEDULES

SCHEDULE 2

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

PART 4

Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

47. In regulation 64 (insertion of provisions concerning consideration of certain applications for UK marketing authorisations)—

(a) in the inserted regulation 58A (paediatric rewards)—

(i) for paragraph (1) substitute—

"(1) Paragraph (2) applies if—

(a) an application—

(i) to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or

(ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,

is granted by the licensing authority; and

(b) the licensing authority is satisfied that the material provided by the applicant pursuant to—

(i) regulation 50A(3), where paragraph (1)(a)(i) applies; or

(ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,

demonstrates compliance with the agreed paediatric investigation plan.";

(ii) for paragraph (3) substitute—

"(3) Where—

(a) paragraph (2) applies; or

(b) an application to which Article 7 or 8 of the Paediatric Regulation applies—

(i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or

(ii) confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,

the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).";

(iii) for paragraph (4)(b) substitute—

"(b) the holder of the UK marketing authorisation is entitled to a one year extension of the ten year period referred to in regulation 51A(6), under regulation 51A(12).";

(iv) after paragraph (4) insert—

"(4A) Paragraph (3) does not apply where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is not in force in the same part of the United Kingdom as the supplementary protection certificate.

(4B) Where—

(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does cover the whole of the United Kingdom; and

(b) the UK marketing authorisation in which the statement of compliance is included is in force in in Great Britain only or in Northern Ireland only,

the extension provided for in paragraph (3) only applies in relation to Great Britain only or Northern Ireland only (as appropriate).";

(v) in paragraph (8), for "regulation 51(1) and (8)" substitute " regulation 51A(1) and (6) ";

(b) in the inserted regulation 58B (publication of information relating to paediatric marketing authorisations), in paragraph (1)(a) for "agreed investigation paediatric plan" substitute " agreed paediatric investigation plan ";

(c) in the inserted regulation 58C (consideration of applications relating to orphan medicinal products), in paragraph (1), after "application for a UK marketing authorisation" insert " (including an application under the unfettered access route) ";

(d) in the inserted regulation 58D (orphan rewards), omit paragraphs (2) and (3);

(e) in the inserted regulation 58F(1)(b) (consideration of applications relating to conditional marketing authorisations), for "UK marketing authorisation" substitute " UKMA(GB) ".

Commencement Information

I1 Sch. 2 para. 47 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, Paragraph 47.