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))

40. In regulation 53 (new regulation 50A to 50J (applications in relation to particular medicinal products))—

(a) in the inserted regulation 50A (requirement for certain applications to include results of paediatric investigation plan)—

(i) in paragraph (1)(a) and (b) for "UK marketing authorisation" substitute " UKMA(GB) or UKMA(UK) "; and

(ii) after paragraph (6) insert—

"(7) In the case of an application for a UKMA(GB) under the unfettered access route, an agreed paediatric investigation plan in respect of the product's marketing authorisation in Northern Ireland applies also to that application as regards the UK marketing authorisation.

(8) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.";

(b) in the inserted regulation 50B(1) (agreement and modification of paediatric investigation plan), after "paediatric investigation plan" insert " for the purposes of an application to which regulation 50A applies ";

(c) in the inserted regulation 50E (application for paediatric use marketing authorisation)—

(i) in paragraph (1) for "UK marketing authorisation" substitute " UKMA(GB) or UKMA(UK) ";

(ii) after paragraph (4) insert—

"(5) This regulation does not remove, in respect of an application for a UKMA(UK), the obligation also to comply with the requirements of the Paediatric Regulation in connection with the agreement of, and compliance with, an EU agreed paediatric investigation plan in relation to Northern Ireland.";

(d) in the inserted regulation 50F(1)(a) and (b) (other applications including paediatric indications), for "UK marketing authorisation" substitute " UKMA(GB) ";

(e) in the inserted regulation 50G (applications relating to orphan medicinal products)—

(i) for paragraph (1) substitute—

"(1) This regulation applies in relation to an application for a UK marketing authorisation for a relevant medicinal product—

(a) in relation to which the applicant intends to demonstrate that the orphan criteria are met, and

(b) which, in the case of an application for a UKMA(NI) or a UKMA(UK), is not a medicinal product designated as an orphan medicinal product in accordance with the Orphan Regulation.";

(ii) in paragraph (2)(b)(i) and (c) for "the United Kingdom" substitute " Great Britain ";

(f) in the inserted regulation 50H(1) and (3) (applications relating to advanced therapy medicinal products), for "UK marketing authorisation" substitute " UKMA(GB) ";

(g) in the inserted regulation 50I (applications relating to conditional marketing authorisations)—

(i) in the heading, at the end insert " for sale or supply in Great Britain only ";

(ii) in paragraph (1), for "UK marketing authorisation" substitute " UKMA(GB) ".

Commencement Information

I1 Sch. 2 para. 40 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 40.