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))

48. In regulation 65 (amendment of regulation 59 (conditions of UK marketing authorisation or parallel import licence: general)—

(a) after paragraph (1) insert—

"(1A) In paragraph (3) for "An obligation" substitute " In relation to a UKMA(NI) or UKMA(UK), an obligation ".";

(b) omit paragraph (2);

(c) for paragraph (3) substitute—

"(3) After paragraph (3), insert—

"(3A) In relation to a UKMA(GB), an obligation to conduct such studies as are referred to in paragraph (2)(f) must—

(a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and

(b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.

(3B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the condition referred to in paragraph (2)(f).

(3C) Paragraph (3A)(a) ceases to apply on the coming into force of regulations made under paragraph (3B).".";

(d) for paragraph (6) substitute—

"(6) In paragraph (5) for "marketing authorisation" substitute "UKMA(NI) or UKMA(UK).".

Commencement Information

I1 Sch. 2 para. 48 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 48.