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))

57. In regulation 77 (amendment of regulation 68 (revocation, variation and suspension of UK marketing authorisation or parallel import licence))—

(a) in paragraph (3), for sub-paragraph (b) substitute—

"(b) for "established in the European Union" substitute—

"established in—

(a) the United Kingdom; or

(b) in relation to a UKMA(NI), either the United Kingdom or the European Union,

in accordance with the requirements of these Regulations.".";

(b) for paragraph (5) substitute—

"(5) In paragraph (9)(a) omit "other than the United Kingdom".";

(c) in paragraph (8)—

(i) in the inserted paragraph (11E), for "exit day" in both places it occurs substitute " IP completion day ";

(ii) after the inserted paragraph (11F), insert—

"(11G) Condition P is that the licensing authority thinks that the revocation, variation or suspension is necessary or expedient in light of the Protocol on Ireland/Northern Ireland in the withdrawal agreement.".

Commencement Information

I1 Sch. 2 para. 57 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 57.