SCHEDULES

SCHEDULE 2

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

PART 10

Amendment of Part 11 (amendment of Part 11 (Pharmacovigilance))

109. In regulation 140 (amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system))—

(a) in paragraph (2)—

(i) before "omit" insert—

"(a) after "its pharmacovigilance system" insert " relating to medicinal products for sale or supply in Great Britain " and";

(ii) from "omit" to the end becomes sub-paragraph (b);

(b) after paragraph (2) insert—

"(2A) After paragraph (1) insert—

"(1A) The licensing authority must perform a regular audit of its pharmacovigilance system relating to medicinal products for sale or supply in Northern Ireland and report the results of that audit to the European Commission."."";

(c) after paragraph (3) insert—

"(4) After paragraph (2) insert—

"(3) The results of the audit referred to in paragraph (1A) must be reported to the European Commission—

(a) on the first occasion no later than 21st September 2021;

(b) every two years after the first occasion."."

Commencement Information

I1 Sch. 2 para. 109 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 109.