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))

115. In regulation 148 (amendment of regulation 188 (reporting obligations on holders))—

(a) in paragraph (3), before sub-paragraph (a) insert—

"(za) for "Subject to paragraph (2), the holder" substitute " The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation ";";

(b) after paragraph (3) insert—

"(3A) After paragraph (1) insert—

"(1A) The holder of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation must, in relation to the product—

(a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the UK and other countries before the end of the period of 15 days beginning on the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the Eudraviligance database a report on all non-serious suspected adverse reactions that occur in an EEA State or Northern Ireland before the end of the period of 90 days beginning on the day on which the holder gained knowledge of the reaction;

(c) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and

(d) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.".";

(c) for paragraph (4) substitute—

"(4) In paragraph (2)—

(a) after "holder" insert " of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation ";

(b) for "paragraph (1)(a) or (b)" substitute " paragraph (1A)(a) or (b) "; and

(c) for "paragraph (1)(d)" substitute " paragraph (1A)(c) ".

(4A) In paragraph (3) for "paragraph (4)" substitute " paragraph (4A) ".";

(d) after paragraph (5) insert—

"(5A) After paragraph (4) insert—

"(4A) The holder of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation must—

(a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1A).".".

Commencement Information

I1 Sch. 2 para. 115 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 115.