STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 188 (reporting obligations on holders)

148.—(1) Regulation 188 is amended as follows.

(2) In each place where it occurs, for "Eudravigilance database" substitute " licensing authority ".

(3) In paragraph (1)—

[[F1](za) for "Subject to paragraph (2), the holder" substitute "The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation";**]**

(a) in sub-paragraph (a)—

(i) for "EEA" substitute " United Kingdom ", and

(ii) for "third countries" substitute " countries other than the United Kingdom ";

(b) in sub-paragraph (b), for "EEA" substitute " United Kingdom ";

(c) in sub-paragraph (e), for "EMA and the competent authorities of the EEA States" substitute " licensing authority ".

[[F2](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.".**]**

[[F3](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)".**]**

(5) In paragraph (4)(a), omit "other than monitored publications".

[F4(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).".**]**

(6) In paragraph (5), omit the definitions of "monitored active substance" and "monitored publication".

(7) Omit paragraph (6).

Textual Amendments

F1 Reg. 148(3)(za) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(a)**

F2 Reg. 148(3A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(b)**

F3 Reg. 148(4)(4A) substituted for reg. 148(4) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**

F4 Reg. 148(5A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(d)**

Commencement Information

I1 Reg. 148 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 148.