STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements)

151.—(1) Regulation 191 is amended as follows.

(2) In paragraphs (1) and (7), **[**F1after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,"**]**.

(3) In paragraph (2), insert " UK " before "marketing authorisation".

F2(4) . . . . . .

(5) After paragraph (4) insert—

"(4A) A PSUR **[**F3in relation to a product authorised under a UKMA(GB)**]** must also include the content, and be submitted in the format, specified in Part 8 of Schedule 12A.".

(6) After paragraph (8), insert—

"(8A) In the case of a conditional marketing authorisation **[**F4in relation to a product authorised under a UKMA(GB)**]**, the holder must submit PSURs immediately upon the request of the licensing authority and at least every six months beginning with the date on which the authorisation for the medicinal product is granted or renewed by the licensing authority.".

[F5(7) In paragraph (10)—

(a) for sub-paragraph (b) substitute—

"(b) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has not yet been placed on the market within the EEA or Northern Ireland, at least every six months following authorisation until the placing on the market within the EEA or Northern Ireland, or

(ii) in relation to a product authorised under a UKMA(GB), the product has not yet been placed on the market in Great Britain, at least every six months following authorisation until the placing on the market within Great Britain; and";

(b) for sub-paragraph (c) substitute—

"(c) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has been placed on the market within the EEA or Northern Ireland—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that;

(ii) in relation to a product authorised under a UKMA(GB), the product has been placed on the market in Great Britain—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that.".**]**

(8) Omit paragraph (11).

Textual Amendments

F1 Words in reg. 151(2) substituted (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. 118(a)**

F2 Reg. 151(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(b)**

F3 Words in reg. 151(5) 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. 118(c)**

F4 Words in reg. 151(6) 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. 118(d)**

F5 Reg. 151(7) substituted (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. 118(e)**

Commencement Information

I1 Reg. 151 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 151.