STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 192 (obligation to submit periodic safety reports: derogation from general requirements)

152.—(1) Regulation 192 is amended as follows.

(2) In paragraph (1)(a), insert " UK " before "marketing authorisation".

(3) In paragraph (3), **[**[F1]after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]**

[[F2](4) In paragraph (9), after "paragraph (3)(a)" insert "from the holder of a UKMA(UK), UKMA(NI), THR(UK), THR(NI) or Article 126a authorisation".**]**

Textual Amendments

F1 Words in reg. 152(3) 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. 119(a)**

F2 Reg. 152(4) 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. 119(b)**

Commencement Information

I1 Reg. 152 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 152.