STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation)

175.—(1) Regulation 210A [M1] is amended as follows.

(2) In the heading, **[**[F1]after**]** "the Implementing Regulation **[**[F2]insert "and Schedule 12A"**]**.

(3) In paragraph (1)—

[[F3](a) in sub-paragraph (a), at the beginning insert "in relation to a UKMA(NI), UKMA(UK), THR(NI) THR(UK) or Article 126a authorisation,";

(b) after sub-paragraph (a) insert—

"(aa) in relation to a UKMA(GB) or THR(GB), fails to comply with any requirement or obligation contained in a provision of Schedule 12A listed in paragraph (2A); or".**]**

(4) **[**[F4]After paragraph (2) insert**]**—

[[F5]"(2A)**]** The provisions of Schedule 12A mentioned in paragraph (1)(a) are—

(a) Part 1 (pharmacovigilance system master file);

(b) Parts 2 and 3 (minimum requirements for the quality systems in the performance of pharmacovigilance activities);

(c) Part 6 (transmission of reports of suspected adverse reactions);

(d) paragraph 24 (update of risk management plans);

(e) Part 8 (periodic safety update reports); and

(f) Part 9 (post-authorisation safety studies).

[F6](3) . . . . . .

[F6](4) . . . . . ".

[[F7](5) In paragraph (4), after "Implementing Regulation" insert ", or of paragraph 26(8) or 29(1) of Schedule 12A,".**]**

Textual Amendments

F1 Word in reg. 175(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. 137(a)(i)**

F2 Words in reg. 175(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. 137(a)(ii)**

F3 Reg. 175(3)(a)(b) 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. 137(b)**

F4 Words in reg. 175(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. 137(c)(i)**

F5 Words in reg. 175(4) renumbered (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. 137(c)(ii)**

F6 Words in reg. 175(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. 137(c)(iii)**

F7 Reg. 175(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. 137(d)**

Commencement Information

I1 Reg. 175 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Regulation 210A was inserted by S.I. 2013/1855.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 175.