STATUTORY INSTRUMENTS

2019 No. 775

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

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 177 (application of Part and interpretation)

139.—(1) Regulation 177 [M1] is amended as follows.

[[F1](2) After paragraph (1) insert—

"(1A) Schedule 12A applies in relation to medicinal products that are the subject of a UKMA(GB) ora THR(GB).".**]**

(3) In paragraph (2)—

(a) after "this Part" insert " and Schedule 12A ";

[F2](b) . . . . . .

[F3](c) . . . . . .

(4) In paragraph (3)—

(a) for "Schedule 33" substitute " Schedules 12A and 33 ";

[F4](b) . . . . . .

[F5](c) . . . . . .

[F6](5) . . . . . .

[[F7](6) In paragraph (5)—

(a) for "Schedule 33" substitute "Schedules 33 and 33A";

(b) in paragraph (c) of the definition of "relevant post-authorisation safety study", omit "and"; and

(c) after that definition, insert—

""signal" means, in relation to a UKMA(GB) or THR(GB), information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, which is judged to be of sufficient likelihood to justify verificatory action; and".**]**

Textual Amendments

F1 Reg. 139(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. 107(a)**

F2 Reg. 139(3)(b) 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. 107(b)**

F3 Reg. 139(3)(c) 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. 107(b)**

F4 Reg. 139(4)(b) 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. 107(c)**

F5 Reg. 139(4)(c) 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. 107(c)**

F6 Reg. 139(5) 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. 107(d)**

F7 Reg. 139(6) 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. 107(e)**

Commencement Information

I1 Reg. 139 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 177 was amended by S.I. 2013/1855 and 2014/1878.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 139.