STATUTORY INSTRUMENTS

2019 No. 775

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

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 61 (conditions of UK marketing authorisation)

68.—(1) Regulation 61 is amended as follows.

(2) For paragraph (4), substitute—

"(4) The obligation in this paragraph is—

(a) to conduct a post-authorisation safety study; or

(b) **[**F1in relation to a UKMA(GB),**]** to comply with such other conditions or restrictions as the licensing authority considers essential for the safe and effective use of the medicinal product.".

[F2(2A) In paragraph (6), after "one medicinal product" insert "authorised by a UKMA(NI) or UKMA(UK)".**]**

[F3(3) After paragraph (6) insert—

"(6A) If concerns as described in paragraph (2) apply to more than one medicinal product authorised by a UKMA(GB), the licensing authority—

(a) must, where the obligation is to conduct a post-authorisation safety study, encourage the UK marketing authorisation holders concerned to conduct a joint study, and

(b) may, where the obligation is to comply with any other conditions or restrictions, encourage the UK marketing authorisation holders concerned to take co-ordinated action to comply with the conditions or restrictions.".**]**

[F4(3A) In paragraph (7) for "The obligation under paragraph (5) shall" substitute "In relation to a UKMA(NI) or UKMA(UK), the obligation under paragraph (5) must".**]**

[F5(4) After paragraph (7) insert—

"(7A) In relation to a UKMA(GB), the obligation under paragraph (5) must—

(a) be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive; and

(b) take into account the scientific guidance that applies under regulation 205B in relation to post-authorisation efficacy studies.

(7B) The Secretary of State may by regulations make provision in respect of Great Britain specifying the situations in which post-authorisation efficacy studies may be required by virtue of the obligation under paragraph (5).

(7C) Paragraph (7A)(a) ceases to apply on the coming into force of regulations made under paragraph (7B).".**]**

[[F6](5) In paragraph (13), after "notify the EMA" insert ", in relation to a UKMA(NI) or UKMA(UK),".**]**

Textual Amendments

F1 Words in reg. 68(2) 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. 51(a)**

F2 Reg. 68(2A) 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. 51(b)**

F3 Reg. 68(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. 51(c)**

F4 Reg. 68(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. 51(d)**

F5 Reg. 68(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. 51(e)**

F6 Reg. 68(5) 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. 51(f)**

Commencement Information

I1 Reg. 68 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 68.