SCHEDULES

[F1SCHEDULE 10A

Variations to a UK marketing authorisation

Textual Amendments

F1 Sch. 10A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 5**; 2020 c. 1, Sch. 5 para. 1(1)

Notification procedure for minor variations of type IA

6.—(1) Subject to sub-paragraph (2), where a minor variation of type IA is made, the holder must submit to the licensing authority a notification containing the elements listed in paragraph 9 within 12 months, beginning with the date on which the variation is implemented by the holder.

(2) The notification referred to in sub-paragraph (1) must be submitted immediately after the implementation of the variation in the case of minor variations requiring immediate notification for the continuous supervision of the medicinal product concerned.

(3) Within 30 days beginning with the date on which the licensing authority receives a notification under this paragraph, the measures provided for in paragraph 10 are to be taken.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 6.