SCHEDULES

[F1SCHEDULE 8A

Material to accompany an application for a parallel import licence

Textual Amendments

F1 Sch. 8A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **26** and Sch. 8A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **26**

6. If requested by the licensing authority, a summary of the applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance **[**F2who resides and operates in the United Kingdom**]**;

F3(b) . . . . . .

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept **[**F4or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom**].]**

Textual Amendments

F2 Words in Sch. 8A para. 6(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Sch. 8A para. 6(b) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Sch. 8A para. 6(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **51(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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