

SCHEDULES

[^{F1}SCHEDULE 12A

Further provision as to the performance of pharmacovigilance activities

Textual Amendments

- F1** Sch. 12A inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, **Sch. 6** (as amended by [S.I. 2019/1385](#), reg. 1, **Sch. 1 para. 9** and [S.I. 2020/1488](#), reg. 1, **Sch. 2 para. 192**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 2

Minimum requirements for the quality systems for the performance of pharmacovigilance activities by the licensing authority and holders

Performance indicators

9.—(1) The holder and the licensing authority may use performance indicators to continuously monitor the good performance of pharmacovigilance activities.

(2) The licensing authority may publish a list of performance indicators.]

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 9.