SCHEDULES

[F1SCHEDULE 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

Quality system

8.—(1) Any holder, and the licensing authority, must establish and use a quality system that is adequate and effective for the performance of their pharmacovigilance activities.

(2) The quality system must cover organisational structure, responsibilities, procedures, processes and resources, appropriate resource management, compliance management and record management.

(3) The quality system must be based on all of the following activities—

(a) quality planning: establishing structures and planning integrated and consistent processes;

(b) quality adherence, namely carrying out tasks and responsibilities in accordance with quality requirements;

(c) quality control and assurance, namely monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are being carried out; and

(d) quality improvements, namely correcting and improving the structures and processes where necessary.

(4) All elements, requirements and provisions adopted for the quality system must be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality plans, quality manuals and quality records.

(5) All persons involved in the procedures and processes of the quality systems established by the licensing authority for the performance of pharmacovigilance activities shall be responsible for the good functioning of those quality systems, and must ensure a systematic approach towards quality and towards the implementation and maintenance of the quality system.

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, PART 2.