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 3

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

Management of human resources

10.—(1) The holder must have sufficient competent and appropriately qualified and trained personnel available for the performance of pharmacovigilance activities.

(2) For the purposes of sub-paragraph (1), the holder must—

(a) ensure that the qualified person responsible for pharmacovigilance has acquired adequate theoretical and practical knowledge for the performance of pharmacovigilance activities; and

(b) where the qualified person has not completed basic medical training in accordance with Article 24 of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, ensure that the qualified person responsible for pharmacovigilance is assisted by a medically trained person, with such assistance being duly documented.

(3) The duties of the managerial and supervisory staff, including the qualified person responsible for pharmacovigilance, must be defined in job descriptions and their hierarchical relationships must be defined in an organisational chart.

(4) The holder must ensure that the qualified person responsible for pharmacovigilance has sufficient authority to influence the performance of the quality system and the pharmacovigilance activities of the holder.

(5) All personnel involved in the performance of pharmacovigilance activities must receive initial and continued training in relation to their role and responsibilities, and the holder must keep training plans and records for documenting, maintaining and developing the competences of personnel and make them available for audit or inspection.

(6) The holder must provide appropriate instructions on the processes to be used in case of urgency, including business continuity.

Compliance management

11.—(1) Specific quality system procedures and processes must be in place in order to ensure the following—

(a) the continuous monitoring of pharmacovigilance data, the examination of options for risk minimisation and prevention and that appropriate measures are taken by the holder;

(b) the scientific evaluation by the holder of all information on the risks of medicinal products, as referred to in regulation 182(4)(a);

(c) the submission of accurate and verifiable data on serious and non-serious adverse reactions to the licensing authority within the time limits provided for in regulation 188(1)(a) or (b);

(d) the quality, integrity and completeness of the information submitted on the risks of medicinal products, including processes to avoid duplicate submissions;

(e) effective communication by the holder with the licensing authority, including communication on—

(i) new risks or changed risks,

(ii) the pharmacovigilance system master file,

(iii) risk management systems,

(iv) risk minimisation measures,

(v) periodic safety update reports,

(vi) corrective and preventive actions, and

(vii) post-authorisation studies;

(f) the update of product information by the holder in the light of scientific knowledge, including the assessments and recommendations made public via the UK web-portal, and on the basis of a continuous monitoring by the holder of information published on that web-portal; and

(g) appropriate communication by the holder of relevant safety information to healthcare professionals and patients.

(2) Where a holder has subcontracted some of its pharmacovigilance tasks, it must retain responsibility for ensuring that an effective quality system is applied in relation to those tasks.

Record management and data retention

12.—(1) A holder must record all pharmacovigilance information and ensure that it is handled and stored so as to allow for accurate reporting, interpretation and verification of that information.

(2) A holder must put in place a record management system for all documents used for pharmacovigilance activities that ensures—

(a) the retrievability of those documents; and

(b) the traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process.

(3) A holder must establish mechanisms enabling the traceability and follow-up of adverse reaction reports.

(4) A holder must arrange for the elements referred to in sub-paragraph (2) to be kept for at least five years, beginning with the day after the system as described in the pharmacovigilance system master file has been formally terminated by the holder.

(5) Pharmacovigilance data and documents relating to individual authorised medicinal products must be retained as long as the product is authorised and for at least 10 years, beginning with the date on which the UKMA(GB) ceased to exist.

Audit

13.—(1) Risk-based audits of the quality system must be performed at regular intervals to ensure that the quality system complies with the quality system requirements set out in paragraphs 8, 10, 11 and 12, and to determine its effectiveness.

(2) The audits referred to in sub-paragraph (1) must be conducted by individuals who have no direct involvement in or responsibility for the matters or processes being audited.

(3) Following a risk-based audit—

(a) any corrective action, including a follow-up audit of deficiencies, must be taken where necessary;

(b) a report on the results of the audit must be drawn up for each audit and follow-up audit;

(c) the audit report must be sent to the management responsible for the matters audited; and

(d) the dates and results of audits and follow-up audits must be documented in accordance with regulation 184(1)(b).**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 3.