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 1

Pharmacovigilance system master file

Structure of the pharmacovigilance system master file

1.—(1) The information in the pharmacovigilance system master file must be accurate and reflect the pharmacovigilance system in place.

(2) The holder may, where appropriate, use separate pharmacovigilance systems for different categories of medicinal products and if it does so, each such system must be described in a separate pharmacovigilance system master file.

(3) All medicinal products for which the holder obtained a UKMA(GB) in accordance with these Regulations must be covered by a pharmacovigilance system master file.

Content of the pharmacovigilance system master file

2. The pharmacovigilance system master file must, as a minimum, contain—

(a) the following information relating to the qualified person responsible for pharmacovigilance—

(i) a description of the responsibilities demonstrating that the qualified person for pharmacovigilance has sufficient authority over the pharmacovigilance system in order to promote, maintain and improve compliance with pharmacovigilance tasks and responsibilities,

(ii) a summary curriculum vitae of the qualified person responsible for pharmacovigilance,

(iii) contact details of the qualified person for pharmacovigilance,

(iv) details of back-up arrangements to apply in the absence of the qualified person responsible for pharmacovigilance, and

(v) responsibilities and contact details of the nominated person (where a person is nominated under regulation 182(2A));

(b) a description of the organisational structure of the holder, including the list of each site where one or more of the following pharmacovigilance activities are undertaken—

(i) individual case safety report collection and evaluation,

(ii) safety database case entry,

(iii) periodic safety update report production,

(iv) signal detection and analysis,

(v) risk management plan management,

(vi) pre and post-authorisation study management, and

(vii) management of safety variations to the terms of a UK marketing authorisation;

(c) a description of the location of, functionality of and operational responsibility for computerised systems and databases used to receive, collate, record and report safety information, and an assessment of their fitness for purpose;

(d) a description of data handling and recording and of the process used for each of the following pharmacovigilance activities—

(i) the continuous monitoring of the risk-benefit balance of each medicinal product, the result of that monitoring and the decision-making process for taking appropriate measures,

(ii) operation of each risk management system and of the monitoring of the outcome of risk minimisation measures,

(iii) collection, assessment and reporting of individual case safety reports,

(iv) drafting and submission of periodic safety update reports, and

(v) procedures for communicating safety concerns and safety variations to the summary of product characteristics and package leaflet to healthcare professionals and the general public;

(e) a description of the quality system for the performance of pharmacovigilance activities, including—

(i) a description of—

(aa) the organisational structure for the performance of pharmacovigilance activities,

(bb) a summary description of the training concept, including a reference to the location of training files and qualifications records, and

(cc) instructions on critical processes,

(ii) a description of the record management system referred to in paragraph 12, including the location of the documents used for pharmacovigilance activities,

(iii) a description of the system for monitoring the performance of the pharmacovigilance system; and

(f) where applicable, a description of the activities or services subcontracted by the holder.

Content of the Annex to the pharmacovigilance system master file

3. The pharmacovigilance system master file must have an Annex containing the following documents—

(a) a list of medicinal products covered by the pharmacovigilance system master file, including the name of each medicinal product, the international non-proprietary name

(INN) of each active substance and the countries other than the United Kingdom in which the products covered are authorised to be marketed;

(b) a list of written policies and procedures for the purpose of complying with Part 11 of these Regulations;

(c) the list of any sub-contracts falling within paragraph 6(1);

(d) a list of the tasks that have been delegated by the qualified person for pharmacovigilance;

(e) a list of all scheduled and completed audits;

(f) where applicable, a list of the performance indicators that support the quality system for pharmacovigilance specified in paragraph 2(e);

(g) where applicable, a list of other pharmacovigilance system master files held by the same holder; and

(h) a logbook containing a record of any alteration of the content of the pharmacovigilance system master file made within the preceding 5 year period, except any alteration of the content that is specified in of paragraph 2(a)(ii) to (iv) or this paragraph.

Maintenance of the pharmacovigilance system master file

4.—(1) The holder must keep the pharmacovigilance system master file up to date and, where necessary, revise it to take account of experience gained, and of technical and scientific progress.

(2) The pharmacovigilance system master file and its Annex must be subject to version control and, in particular, must indicate the date when it was last updated by the holder.

(3) Any deviations from the pharmacovigilance procedures, their impact and their management must be documented in the pharmacovigilance system master file until resolved.

Form of the documents contained in the pharmacovigilance system master file

5.—(1) The pharmacovigilance system master file documents must be complete and legible.

(2) Subject to sub-paragraph (1), in the pharmacovigilance system master file—

(a) where appropriate, information may be provided in the form of charts or flow diagrams;

(b) all documents must be indexed and archived so as to ensure their accurate and ready retrieval throughout the period for record-keeping; and

(c) the particulars and documents may be presented in modules in accordance with the system delineated in detail in the guidance on good pharmacovigilance practices which applies by virtue of regulation 205B.

(3) The pharmacovigilance system master file may be stored in electronic form provided that the media used for storage remain readable over time, and a clearly arranged printed copy can be made available for audits and inspections.

Subcontracting

6.—(1) The holder may subcontract certain activities of the pharmacovigilance system to third parties, but if it does so it must nevertheless retain full responsibility for the completeness and accuracy of the pharmacovigilance system master file.

(2) The holder must draw up a list of the existing subcontracts between it and the third parties referred to in sub-paragraph (1), specifying each product and each country concerned.

Availability and location of the pharmacovigilance system master file

7.—(2) The holder must ensure that the qualified person and nominated person (where a person is nominated under regulation 182(2A)) for pharmacovigilance have permanent access to the pharmacovigilance system master file.

(3) For the purposes of regulation 182(2)(b), the licensing authority may limit its request to specific parts or modules of the pharmacovigilance system master file and the holder is to bear the costs of submitting the copy of the pharmacovigilance system master file.

(4) The licensing authority may request the holder to submit a copy of the logbook referred to in paragraph 3(h) at regular intervals.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 1.