STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Obligations on holders in relation to pharmacovigilance system

Obligation on holder to operate pharmacovigilance system

182.—(1) The holder must operate a pharmacovigilance system.

(2) The holder must (as part of its pharmacovigilance system)—

(a) have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance who resides and operates in the EU**[**F1or United Kingdom**]** and is responsible for the establishment and maintenance of the pharmacovigilance system;

(b) maintain and make available on the request of the licensing authority a pharmacovigilance system master file **[**F2and ensure it is permanently and immediately available for inspection electronically in the United Kingdom at the single point from which the reports referred to in regulation 187(4) are accessible**]**;

(c) operate a risk management system for the product in accordance with the risk management plan (if any) for the product (subject to regulation 183);

(d) monitor the outcome of the risk minimisation measures which are contained in the risk management plan (if any) for the product or which are laid down as conditions of the authorisation of the product under regulations 59 to 61 (conditions of UK marketing authorisation); and

(e) update the risk management system for the product and monitor pharmacovigilance data to determine whether in relation to the product—

(i) there are new risks,

(ii) risks have changed, or

(iii) there are changes to the risk-benefit balance.

[F3(2A) Where the person the holder has permanently and continuously at its disposal under paragraph (2)(a) ("the qualified person") does not reside and operate in the United Kingdom, the holder must nominate a contact person for pharmacovigilance at a national level who reports to the qualified person, resides and operates in the United Kingdom and has permanent access to the pharmacovigilance system master file.

(2B) Paragraph (2A) has effect from the day twelve months after IP completion day.**]**

[F4(3) Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation) the holder must keep the licensing authority informed at all times of the name and contact details of—

(a) the appropriately qualified person mentioned in paragraph (2)(a); and

(b) the nominated person mentioned in paragraph (2A).

(3A) The holder must—

(a) ensure that the pharmacovigilance system master file is accessible electronically from the single point within the United Kingdom from which the reports referred to in regulation 187(4) are accessible; and

(b) immediately notify the licensing authority of any change to the single point where the pharmacovigilance system master file may be accessed electronically.**]**

(4) The holder must use its pharmacovigilance system to—

(a) evaluate scientifically all information relevant to the product;

(b) consider options for minimising and preventing the risk presented by the use of the product; and

(c) take appropriate measures as soon as is reasonably practicable to—

(i) investigate the potential risks of the product,

(ii) communicate the risks, and

(iii) implement actions for minimising and preventing the risks, including updating the risk management system for the product.

(5) Where the licensing authority requests that the pharmacovigilance system master file is made available under paragraph (2)(b), the holder must submit a copy of the pharmacovigilance system master file to the licensing authority before the end of the period of 7 days beginning on the day after the day when the request was made.

F5(6) . . . . . .

Textual Amendments

F1 Words in reg. 182(2)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(a)**)

F2 Words in reg. 182(2)(b) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2A)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**)

F3 Reg. 182(2A)(2B) inserted (31.12.2020) by S.I. 2019/775, **reg. 142(2B)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**)

F4 Reg. 182(3)(3A) substituted for reg. 182(3) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(c)**)

F5 Reg. 182(6) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **142(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Exception to obligation to operate risk management system

183.—(1) The holder is not required to operate a risk management system under regulation 182(2)(c) in relation to a medicinal product which has an authorisation or registration that was granted before 21st July 2012.

(2) The licensing authority may impose an obligation on the holder to operate a risk management system in relation to a medicinal product referred to in paragraph (1) if there are concerns about new or changed risks affecting the risk-benefit balance of that product.

(3) Paragraphs (4) to (6) apply where the licensing authority imposes an obligation to operate a risk management system on the holder under paragraph (2).

(4) The licensing authority must without delay notify the holder in writing of—

(a) the imposition of the obligation;

(b) the justification for the obligation;

(c) the timeframe for submission of the detailed description of the risk management system required under paragraph (8)(a); and

(d) the opportunity to present written observations in accordance with paragraph (5).

(5) Where the holder so requests before the end of the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (4), the licensing authority must provide the holder with an opportunity to present written observations in response to the imposition of the obligation within such a time limit as the licensing authority may specify.

(6) Where a holder presents written observations under paragraph (5), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (2), having regard to the written observations, as soon as is reasonably practicable.

(7) Paragraphs (8) and (9) apply where the licensing authority—

(a) imposes an obligation under paragraph (2) and the holder does not present written obligations under paragraph (5); or

(b) confirms the imposition of the obligation under paragraph (2) pursuant to paragraph (6).

(8) The holder must—

(a) submit to the licensing authority in writing a detailed description of the risk management system which it intends to introduce for the product in accordance with the timeframe set out in the notification under paragraph (4); and

(b) comply with the obligation to operate a risk management system.

(9) Where the imposition relates to a product with a UK marketing authorisation, the licensing authority must vary the authorisation to include the measures to be taken as part of the risk management system as conditions of the authorisation as if they were conditions imposed under regulation 59 (conditions of UK marketing authorisations: general).

Obligation on holder to audit pharmacovigilance system

184.—(1) The holder must—

(a) perform a regular audit of its pharmacovigilance system;

(b) place a note concerning the main findings of each audit on the pharmacovigilance system master file on completion of each audit; and

(c) ensure that an appropriate corrective action plan is prepared and implemented as soon as is reasonably practicable after completion of each audit.

(2) The holder may remove the note placed on the pharmacovigilance system master file under paragraph (1)(b) when all the measures in the corrective action plan under paragraph (1)(c) have been fully implemented.

[[F6](3) The holder of a UKMA(GB) or THR(GB) must also comply with the requirements of paragraph 13 of Schedule 12A in relation to auditing the pharmacovigilance system.**]**

Textual Amendments

F6 Reg. 184(3) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **143** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 112**); 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, Cross Heading: Obligations on holders in relation to pharmacovigilance system.