STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Post-authorisation safety studies

Post-authorisation safety studies: general provisions

198.—(1) A relevant post-authorisation safety study—

(a) may not be conducted where the act of conducting the study promotes the use of a medicinal product; and

(b) may not provide for payments to health care professionals for participating in the study except in compensation for time and expenses incurred.

(2) The licensing authority may require the holder for the product which is the subject of a relevant post-authorisation safety study to submit the protocol and progress reports for the study to the competent authorities of the EEA States in which the study is conducted.

(3) The holder for the product which is the subject of a relevant post-authorisation safety study must—

(a) comply with a requirement imposed by the licensing authority under paragraph (2) (if any);

(b) while the study is being conducted—

(i) monitor the data generated, and

(ii) consider its implications for the risk-benefit balance of the product which is the subject of the study;

(c) communicate to the relevant competent authorities any new information that arises at any point during the study which might influence the evaluation of the risk-benefit balance for that product as soon as is reasonably practicable after it becomes known to the holder; and

(d) send the final report on the study to the competent authorities of the EEA States in which the study was conducted before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended.

(4) This regulation is subject to regulation 212 (transitional arrangements).

Submission of draft study protocols for required studies

199.—(1) This regulation applies to a relevant post-authorisation safety study that is to be conducted pursuant to a condition of a UK marketing authorisation imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).

(2) The holder for the product which is the intended subject of the study must submit a draft protocol for the study to the body specified in paragraph (3) before the study is commenced.

(3) The body specified in this paragraph is—

(a) where the study is to be conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a draft protocol is submitted to the licensing authority under paragraphs (2) and (3)(a).

(5) Where this paragraph applies, the licensing authority, before the end of the period of 60 days beginning on the day after the day on which the draft protocol is submitted, must issue—

(a) a letter endorsing the draft protocol;

(b) a letter objecting to the draft protocol on the grounds that—

(i) it considers that the conduct of the study promotes the use of a medicinal product, or

(ii) it considers that the design of the study does not fulfil the study objectives; or

(c) a letter notifying the holder for the product which is the intended subject of the study that the study is a clinical trial within the meaning of the Clinical Trials Regulations.

(6) A study may not commence unless a letter endorsing the draft protocol has been issued by—

(a) the licensing authority under paragraph (5)(a); or

(b) the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(7) Paragraph (8) applies where a letter endorsing the draft protocol has been issued by the Pharmacovigilance Risk Assessment Committee under Article 107n(2) of the 2001 Directive.

(8) Where this paragraph applies, the holder for the product which is the intended subject of the study must forward the protocol to the competent authorities of the EEA States in which the study is to be conducted before commencing the study.

(9) In this regulation, "a letter" includes email correspondence.

(10) This regulation is subject to regulation 212 (transitional arrangements).

Amendment to study protocols for required studies

200.—(1) This regulation applies where a study to which regulation 199 applies has been commenced.

(2) The holder for the product which is the subject of the study must submit any substantial amendments to the study protocol to the body specified in paragraph (3) before their implementation.

(3) The body specified in this paragraph is—

(a) where the study is being conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (5) applies where a proposed amendment to a study protocol is submitted to the licensing authority under paragraphs (2) and (3)(a).

(5) Where this paragraph applies, the licensing authority must as soon as is reasonably practicable—

(a) assess the amendment; and

(b) inform the holder of its endorsement of, or objection to, the proposed amendment.

(6) Paragraph (7) applies where the proposed amendment to a study protocol is submitted to the Pharmacovigilance Risk Assessment Committee under paragraphs (2) and (3)(b).

(7) Where this paragraph applies, the holder who submitted the amendment must inform the competent authorities of the EEA States in which the study is being conducted of any amendment to the study protocol approved by the Pharmacovigilance Risk Assessment Committee as soon as is reasonably practicable.

(8) This regulation is subject to regulation 212 (transitional arrangements).

Submission and evaluation of final study reports for required studies

201.—(1) This regulation applies where a study to which regulation 199 applies has been completed.

(2) Subject to paragraph (4), the holder for the product which is the subject of the study must submit electronically, before the end of the period of 12 months beginning on the day after the day on which data collection for the study ended, to the body specified in paragraph (3)—

(a) a final study report; and

(b) an abstract of the study results.

(3) The body specified in this paragraph is—

(a) where the study was conducted in the United Kingdom only, the licensing authority; or

(b) in all other cases, the Pharmacovigilance Risk Assessment Committee.

(4) Paragraph (2) does not apply where a written waiver has been granted by the licensing authority for reports falling under paragraph (3)(a), or by the Pharmacovigilance Risk Assessment Committee for reports falling under paragraph (3)(b).

(5) The holder must without delay—

(a) evaluate whether the results of a final study report submitted under paragraph (2) have an impact on the authorisation or registration of the medicinal product to which the report relates; and

(b) if necessary, submit an application to vary the authorisation or registration for the product.

(6) This regulation is subject to regulation 212 (transitional arrangements).

Follow-up of final study reports

202.—(1) This regulation applies where—

(a) the Pharmacovigilance Risk Assessment Committee has made recommendations concerning an authorisation or registration or a class of authorisations or registrations based on a final study report under Article 107q(1) of the 2001 Directive; and

(b) an agreement on the action to be taken in respect of the authorisation or registration or the class of authorisations or registrations has been reached by the co-ordination group under the procedure laid out in Article 107q(2) of the 2001 Directive ("the agreement").

(2) The licensing authority must implement the measures set out in the agreement in accordance with the implementation timetable determined in the agreement.

(3) Paragraph (4) applies where—

(a) the agreement requires a variation to be made to one or more authorisation or registration; and

(b) the terms of the agreement are known to the holder or holders for the product or products which is, or which are, the subject of the agreement.

(4) Where this paragraph applies, each holder must submit to the licensing authority in accordance with the terms of the agreement (including its implementation timetable) an application for a variation including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.

(5) This regulation is subject to regulation 212 (transitional arrangements).