STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Recording, reporting and assessment of pharmacovigilance data

Recording obligations on the licensing authority

185. The licensing authority must record all suspected adverse reactions to medicinal products that—

(a) occur in the United Kingdom; and

(b) are reported to it by a patient or a patient's carer, a health care professional, a coroner or a procurator fiscal.

Reporting obligations on the licensing authority

186.—(1) The licensing authority must—

(a) when it receives a suspected adverse reaction report from a person mentioned in regulation 185(b), follow up the report with that person as appropriate;

(b) ensure that reports of suspected adverse reactions in the United Kingdom may be submitted to it, whether by the UK web-portal or by other means;

(c) collaborate with the EMA and the holders of authorisations or registrations in the detection of duplicates of suspected adverse reaction reports;

(d) submit reports of serious suspected adverse reactions that it has recorded under regulation 185 electronically to the Eudravigilance database before the end of the period of 15 days beginning on the day following the day on which the report was received; and

(e) submit reports of non-serious suspected adverse reactions it has recorded under regulation 185 electronically to the Eudravigilance database before the end of the period of 90 days beginning on the day following the day on which the report was received.

(2) Paragraph (3) applies where the licensing authority has received a report of a suspected adverse reaction arising from an error associated with the use of a medicinal product.

(3) The licensing authority must (in addition to meeting the requirements in paragraph (1) in respect of the report) ensure that the report is made available to any statutory body with functions in relation to patient safety within the United Kingdom.

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

Recording obligations on holders

187.—(1) Subject to paragraph (2), the holder must record all suspected adverse reactions to the product occurring in the EEA or in third countries which are brought to its attention irrespective of whether the reaction—

(a) is reported spontaneously by patients or health care professionals; or

(b) occurred in the context of a post-authorisation study.

(2) Paragraph (1) does not apply where the suspected adverse reaction occurred in the context of a clinical trial within the meaning of the Clinical Trials Regulations.

(3) The holder must not refuse to consider reports of suspected adverse reactions to the product received electronically or by any other appropriate means from patients or from health care professionals.

(4) The holder must ensure that reports recorded under paragraph (1) are accessible (electronically or physically) at a single point within the EEA.

Reporting obligations on holders

188.—(1) Subject to paragraph (2), the holder must in relation to the product—

(a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the EEA and third countries before the end of the period of 15 days beginning on the da*y* following the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the Eudravigilance database a report on all non-serious suspected adverse reactions that occur in the EEA before the end of the period of 90 days beginning on the day following the day on which the holder gained knowledge of the reaction;

(c) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;

(d) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and

(e) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.

(2) The holder is not required to submit a report of a suspected adverse reaction to the product under paragraph (1)(a) or (b), or to provide follow-up information under paragraph (1)(d), where—

(a) the suspected adverse reaction relates to a medicinal product which contains a monitored active substance; and

(b) the suspected adverse reaction is recorded in a monitored publication.

(3) Paragraph (4) applies to medicinal products containing a monitored active substance.

(4) The holder must—

(a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1).

(5) In this regulation—

"monitored active substance" means an active substance on the list of active substances being monitored by the EMA published under Article 27 of Regulation (EC) No 726/2004;

"monitored publication" means a publication on the list of publications being monitored by the EMA published under Article 27 of Regulation (EC) No 726/2004; and

"the specified time period" means—

(a) in the case of serious adverse reactions, the period of 15 days beginning on the day following the day on which the follow up information became known to the holder; and

(b) in the case of non-serious adverse reactions, the period of 90 days beginning on the day following the day on which the follow up information became known to the holder.

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