STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Signal detection

Signal detection: licensing authority obligations

189.—(1) The licensing authority must in relation to each medicinal product—

(a) monitor the data in the Eudravigilance database to determine whether there are any relevant changes;

(b) assess updates to the risk management system for the product;

(c) monitor the outcome of risk minimisation measures contained in the risk management plan (if any); and

(d) monitor the outcome of conditions imposed under regulations 59 to 61 (conditions of UK marketing authorisations) (if any).

(2) The licensing authority must collaborate with the EMA in carrying out its functions under paragraph (1).

(3) The licensing authority must inform the bodies specified in paragraph (4) without delay if it detects any relevant changes in relation to a medicinal product.

(4) The bodies specified in this paragraph are—

(a) the EMA; and

(b) the relevant competent authorities.

(5) In this regulation "relevant changes" in relation to a medicinal product means—

(a) new risks;

(b) risks that have changed; or

(c) changes to the risk-benefit balance.

Signal detection: holder obligation

190.—(1) The holder must inform the EMA and the licensing authority without delay if it detects any relevant changes in relation to the product.

(2) In this regulation, "relevant changes" has the meaning given in regulation 189(5).