STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Consideration of application

Conditions of UK marketing authorisation: new obligations post-authorisation

61.—(1) After the granting of a UK marketing authorisation, the licensing authority may impose an obligation on the holder of the authorisation in accordance with either or both of —

(a) paragraph (4), in a case where paragraph (2) applies; or

(b) paragraph (5), in a case where paragraph (3) applies.

(2) This paragraph applies if there are concerns about the risks of a medicinal product that is the subject of a marketing authorisation.

(3) This paragraph applies if the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly.

(4) The obligation in this paragraph is to conduct a post-authorisation safety study.

(5) The obligation in this paragraph is to conduct a post-authorisation efficacy study.

(6) If concerns as described in paragraph (2) apply to more than one medicinal product, the licensing authority shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study.

(7) The obligation under paragraph (5) shall be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive while taking account of the scientific guidance referred to in Article 108a of the 2001 Directive.

(8) Where the licensing authority imposes an obligation under paragraph (4) or (5), it must without delay give written notice to the holder of —

(a) the imposition of the obligation;

(b) the justification for the imposition;

(c) the objectives and timeframe for submission and conduct of the study; and

(d) the opportunity to present written observations in accordance with paragraph (9) and the time limit specified for doing so.

(9) Where the holder so requests within the period of thirty days beginning on the day after the receipt by the holder of the notice referred to in paragraph (8), the licensing authority must provide the holder of the authorisation with an opportunity to present written observations in response to the imposition of the obligation within the time limit specified by the licensing authority in the notice.

(10) Where the holder presents written observations under paragraph (9), the licensing authority must withdraw or confirm the imposition of the obligation under paragraph (4) or (5) on the basis of the written observations as soon as is reasonably practicable.

(11) Paragraph (12) applies where the licensing authority—

(a) imposes an obligation under paragraph (4) or (5) and the holder does not present written representations under paragraph (9); or

(b) confirms the imposition of an obligation under paragraph (10).

(12) Where this paragraph applies, the licensing authority must vary the marketing authorisation to include the obligation as a condition of the marketing authorisation as if it were a condition imposed under regulation 59 (conditions of UK marketing authorisations: general).

(13) The licensing authority must notify the EMA that the marketing authorisation is subject to a condition included in accordance with paragraph (12).

(14) The holder of the authorisation must incorporate any condition included in a marketing authorisation in accordance with paragraph (12) into the risk management system for the product.

(15) Schedule 11, which makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject, shall apply in relation to the variation or removal of a condition included in a marketing authorisation in accordance with paragraph (12).