STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Consideration of application

Conditions of UK marketing authorisation: general

59.—(1) The licensing authority may—

(a) grant a UK marketing authorisation subject to one or more of the conditions in paragraph (2); or

(b) vary or remove a condition in paragraph (2) to which the UK marketing authorisation is subject.

(2) Those conditions are—

(a) to take certain measures for ensuring the safe use of the medicinal product and include them in the risk management plan;

(b) to conduct post-authorisation safety studies;

(c) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Part 11;

(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;

(e) the existence of an adequate pharmacovigilance system; and

(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed.

(3) An obligation to conduct such studies as are referred to in paragraph (2)(f) must be based on the delegated acts adopted pursuant to Article 22b of the 2001 Directive, while taking into account the scientific guidance referred to in Article 108a of the 2001 Directive.

(4) The marketing authorisation must lay down deadlines for the fulfilment of the conditions in paragraph (2) where necessary.

(5) The licensing authority must notify the EMA of any marketing authorisation that it has granted subject to a condition included in accordance with this regulation.

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

(7) Schedule 11 makes provision about advice and representations in relation to proposals to vary or remove a condition to which a UK marketing authorisation is subject.