STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Consideration of application

Conditions of UK marketing authorisation: exceptional circumstances

60.—(1) The licensing authority may—

(a) grant a UK marketing authorisation subject to conditions in accordance with the following paragraphs of this regulation; or

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

(2) The powers in paragraph (1) may be exercised only after consultation with the applicant for the authorisation or (as the case may be) its holder.

(3) The power in paragraph (1)(a) to grant an authorisation subject to conditions may be exercised only—

(a) in exceptional circumstances; and

(b) when the applicant can show that the applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use.

(4) The conditions must relate to a matter addressed by Annex I to the 2001 Directive.

(5) The conditions may, in particular, relate to the safety of the product to which the authorisation relates.

(6) The conditions may, in particular, require that, where there is a serious adverse reaction relating to the use of the product—

(a) the reaction must be reported to the licensing authority; and

(b) such other action as may be specified in the conditions must be taken.

(7) The licensing authority must keep under review—

(a) the conditions under this regulation to which a UK marketing authorisation is subject; and

(b) the holder's compliance with those conditions.

(8) The licensing authority must consider those matters no less frequently than—

(a) at the end of the period of one year beginning with the date on which the authorisation was granted; and

(b) at the end of each subsequent period of one year.

(9) 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.

(10) 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.

(11) 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.