STATUTORY INSTRUMENTS

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The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Offences relating to EU marketing authorisations

Obligation to update information supplied in connection with EU application

81. An applicant for an EU marketing authorisation is guilty of an offence if that person fails to supply updated information to the EMA in accordance with Article 8(3) of the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004.

EU marketing authorisations: failure to notify placing on market etc

82.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to notify the EMA in accordance with—

(a) the first paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify date of placing of product on the market); or

(b) the second paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify that product is to be withdrawn from the market).

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requires under the third paragraph of Article 13(4) of Regulation (EC) No 726/2004 (information as to sales and prescriptions)—

(a) where the period within which the information must be provided is specified in a written notice given to the holder by the EMA, before the end of that period; or

(b) otherwise, as soon as is reasonably practicable after receipt of the request.

EU marketing authorisations: failure to take account of technical and scientific progress

83. The holder of an EU marketing authorisation is guilty of an offence if the holder fails to apply to vary the marketing authorisation as required by Article 16(1) of Regulation (EC) No 726/2004 (obligation to take account of scientific and technical progress).

EU marketing authorisations: failure to provide information as to safety etc

84.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide information to the EMA, the Commission or the licensing authority as required by Article 16(2) of Regulation (EC) No 726/2004 (new information which might entail amendment of particulars or documents) as soon as is reasonably practicable after becoming aware of the information.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to provide the EMA with information that it requests as required by the first paragraph of Article 16(4) of Regulation (EC) No 726/2004 (data on risk-benefit balance).

EU marketing authorisations: failure to update product information

85.—(1) The holder of an EU marketing authorisation for a medicinal product is guilty of an offence if the holder fails to ensure that the product information relating to the product is kept up to date with current scientific knowledge, as required by Article 16(3) of Regulation (EC) No 726/2004.

(2) In this regulation "current scientific knowledge" includes the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004.

EU marketing authorisations: breach of pharmacovigilance condition etc

86.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to comply with—

(a) any obligation to which the marketing authorisation is subject by virtue of Articles 10a(1) or 14(7); or

(b) any condition to which the authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to incorporate into the risk management system for the product as required by Article 14a of Regulation (EC) No 726/2004—

(a) any recommendation referred to in Article 9(4)(c), (ca), (cb) or (cc);

(b) any obligation to which the authorisation is subject by virtue of Articles 10a(1) or 14(7) ; or

(c) any condition to which the marketing authorisation is subject by virtue of Article 14(8),

of Regulation (EC) No 726/2004.