STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Offences relating to EU marketing authorisations

[F1Application of regulations 81 to 94

A81. Regulations 81 to 94 apply in relation to medicinal products for sale or supply in Northern Ireland **[**F2(that are not in Northern Ireland by virtue of regulation 167A)**].]**

Textual Amendments

F1 Reg. A81 inserted (31.12.2020) by S.I. 2019/775, regs. 1, **90** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 67**)

F2 Words in reg. A81 inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **13**

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); F3...

(b) the second paragraph of Article 13(4) of Regulation (EC) No 726/2004 (requirement to notify that product is to be withdrawn from the **[**F4market); or**]**

[F5(c) Article 14b of Regulation (EC) No 726/2004 (requirement to notify suspending of marketing of the product etc).**]**

(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.

Textual Amendments

F3 Word in reg. 82(1)(a) omitted (11.11.2013) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(2)**

F4 Words in reg. 82(1)(b) substituted (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(3)**

F5 Reg. 82(1)(c) added (11.11.2013) by The Human Medicines (Amendment) (No. 2) Regulations 2013 (S.I. 2013/2593), regs. 1(2), **4(4)**

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 **[**F6 16(3a)**]** of Regulation (EC) No 726/2004 (data on risk-benefit balance).

Textual Amendments

F6 Word in reg. 84(2) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **18**

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.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Offences relating to EU marketing authorisations.