STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

General provisions relating to offences

Offences in connection with application

95. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a marketing authorisation for a relevant medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product;

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular;

(c) **[**F1, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,**]** fails to provide the EMA with any information that is relevant to the evaluation of the safety, quality or efficacy of the product as required by paragraph (7) or (11) in the "Introduction and general principles" of Annex 1 to the 2001 Directive as applied by Article 6(1) of Regulation (EC) No 726/2004; or

(d) **[**F2, in relation to an EU marketing authorisation for a product for sale or supply in Northern Ireland,**]** provides to the EMA any information of the kind described in sub-paragraph (c) that is false or misleading in a material particular.

F1 Words in reg. 95(c) inserted (31.12.2020) by S.I. 2019/775, **reg. 92(a)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 69**)

F2 Words in reg. 95(d) inserted (31.12.2020) by S.I. 2019/775, **reg. 92(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 69**)

[F3**Offences in connection with parallel import licence application**

95A. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal product, the person—

(a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or

(b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular.**]**

F3 Reg. 95A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **16** and reg. 95A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **16**

Provision of false or misleading information

96.—(1) The holder of a marketing authorisation **[**F4or parallel import licence**]** is guilty of an offence if the holder provides any information to which paragraph (2) applies that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product but that is false or misleading in a material particular to—

(a) the licensing authority;

(b) the EMA; or

(c) the competent authorities of other EEA States.

(2) This paragraph applies to information about the product that is supplied pursuant to the obligations in—

(a) these Regulations; or

(b) Regulation (EC) No 726/2004.

(3) This regulation is without prejudice to the operation of regulation 95.

F4 Words in reg. 96(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 96(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(o)**

Breach of pharmacovigilance condition

[F5**97.**—(1) The holder of a marketing authorisation or a parallel import licence is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of a UK marketing authorisation or parallel import licence: general).

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation is subject by virtue of regulation 60 (conditions of a UK marketing authorisation: exceptional circumstances) **[**F6, regulation 60A (condition as to the testing of samples by the appropriate authority)**]** or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).**]**

F5 Reg. 97 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **17** and reg. 97 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **17**

F6 Words in reg. 97(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **94(3)**; 2020 c. 1, Sch. 5 para. 1(1)

General offence of breach of provision of this Part

98.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

(a) failure by the holder of a marketing authorisation **[**F7or parallel import licence**]** to comply with any requirement or obligation in this Part:

(b) contravention by any person of any prohibition in this Part; or

(c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

F7 Words in reg. 98(2)(a) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 98(2)(a) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(p)**

Penalties

99.—(1) A person guilty of an offence under this Part, other than a breach of regulation 79 (failure to provide information on marketing authorisations to EMA), is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

(2) A person guilty of a breach of regulation 79 is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment, to a fine.

Persons liable

100. If a breach of regulation 95 (offences in connection with application) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

Defences

101.—(1) Paragraph (2) applies if the holder of a marketing authorisation **[**F8or parallel import licence**]** is charged with an offence under this Part in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

(a) the holder communicated the terms of the authorisation to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulations 73(3) or 78, or an offence under any of regulations 88 to 93, 95 and 96, to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

F8 Words in reg. 101(1) inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **4** and words in reg. 101(1) inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **4(2)(q)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: General provisions relating to offences.