
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Enforcement

Infringement notices

206.—(1) If an enforcement authority has objective grounds for considering that any person (“P”) has contravened any provision of this Part, or of Chapter 3 of Title II of Regulation (EC) No 726/2004, it may serve upon P a notice in writing (referred to in this Part as an “infringement notice”)—

- (a) informing P of the authority’s grounds for considering that P has contravened one or more provision of this Part or of that Chapter;
- (b) specifying the relevant provision of this Part or of that Chapter;
- (c) specifying the measures which P must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;
- (d) requiring P to take those measures, within such period as may be specified in the notice;
- (e) specifying the further action (if any) that the enforcement authority may take.

(2) An infringement notice may include directions as to the measures to be taken by P to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(3) If an enforcement authority serves an infringement notice in accordance with paragraph (1), it shall as soon as is reasonably practicable inform—

- (a) the EMA; and
- (b) the European Commission.

Offences

207.—(1) A person is guilty of an offence if the person commits a breach of a provision in this Part, other than regulation 199(2) or (6) (submission of draft study protocols for required studies).

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

- (a) failure by a holder to comply with any requirement or obligation in this Part; or
- (b) contravention by any person of any prohibition in this Part.

False and misleading information

208. A person is guilty of an offence if the person provides information to the licensing authority or the EMA, pursuant to an obligation in this Part, but that information is false or misleading in a material particular.

Penalties

209.—(1) Subject to paragraph (2), a person guilty of an offence under regulation 207 or 208 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 an offence under regulation 207 which relates to a breach of a provision listed in paragraph (3) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine.

(3) Those provisions are regulations—

- (a) 182(2)(a) and (b), (3) and (5);
- (b) 183(8)(a);
- (c) 184(1)(a) and (b);
- (d) 187(4);
- (e) 188(1)(c) and (e);
- (f) 193(5);
- (g) 198(1) and (3)(a) and (d);
- (h) 199(8); and
- (i) 200(7).

Offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004

210.—(1) A person is guilty of an offence if the person—

- (a) commits a breach of a provision of Regulation (EC) No 726/2004 listed in paragraph (3); or
- (b) provides information which is false or misleading in a material particular to the licensing authority or the EMA pursuant to an obligation in Chapter 3 of Title II of Regulation (EC) No 726/2004.

(2) A breach of a provision listed in paragraph (3) includes any—

- (a) failure to comply with any requirement or obligation contained in any of those provisions;
- (b) contravention of any prohibition contained in any of those provisions; or
- (c) failure to comply with any requirement imposed by the licensing authority or the EMA pursuant to any of those provisions.

(3) Those provisions are—

- (a) Article 16(4), second paragraph(1);

(1) Article 16(4), second paragraph, of Regulation (EC) No 726/2004 (“the Regulation”) imposes an obligation identical to that set out in Article 23(4), second paragraph, of the 2001 Directive; Article 23(4), second paragraph, of the 2001 Directive is transposed at regulation 182(5).

- (b) Article 20(8)(2);
 - (c) Article 21(1) and (2)(3);
 - (d) Article 22(4);
 - (e) Article 28(1), (2) and (5)(5);
 - (f) Article 28a(3)(6); and
 - (g) Article 28b(1)(7), except insofar as it imposes an obligation under Article 107n(1), or the first paragraph of Article 107n(3), of the 2001 Directive.
- (4) Subject to paragraph (5), a person guilty of an offence under this regulation 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.
- (5) A person guilty of an offence under this regulation in relation to a provision of Regulation (EC) No 726/2004 listed in paragraph (6) is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
 - (b) on conviction on indictment to a fine.
- (6) Those provisions are—
- (a) Article 16(4), second paragraph;
 - (b) Article 21(1) insofar as it relates to obligations set out in—
 - (i) the second paragraph of Article 104(2) of the 2001 Directive save the obligation regarding preparing and implementing a corrective action plan,
 - (ii) Article 104(3)(a) of the 2001 Directive,
 - (iii) Article 104(3)(b) of the 2001 Directive, or
 - (iv) the second paragraph of Article 104(3) of the 2001 Directive;
 - (c) Article 21(2) insofar as it relates to the obligation to submit a detailed description of a risk management system;
 - (d) Article 28(1) insofar as it relates to obligations set out in—
 - (i) the second paragraph of Article 107(1) of the 2001 Directive,
 - (ii) the first sentence of Article 107(4) of the 2001 Directive, or
 - (iii) Article 107(5) of the 2001 Directive;
 - (e) Article 28(2) insofar as it relates to the obligation set out in the third paragraph of Article 107c(4) of the 2001 Directive; and

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- (2) Article 20(8) of the Regulation applies Article 107i of the 2001 Directive, which in turn applies Articles 107j and 107k of the 2001 Directive; Article 107k(2) second paragraph is implemented in regulation 197(3).
 - (3) Article 21(1) of the Regulation, first paragraph, cross-refers to obligations set out in Article 104 of the 2001 Directive, implemented in regulation 182 and 185; Article 21(1), second paragraph, and 21(2) of the Regulation are similar in effect to Article 104a of the 2001 Directive, implemented in regulation 183.
 - (4) Article 22 of the Regulation cross-refers to obligations set out in Article 106a(1) of the 2001 Directive; Article 106a(1) is implemented in regulation 205.
 - (5) Article 28(1) and (2) of the Regulation cross-refers to obligations set out in Articles 107, 107a, 107b and 107c of the 2001 Directive; those Articles are implemented in regulations 185, 186, 187, 188, 191, 192 and 193; Article 28(5) of the Regulation applies Articles 107e to 107g of the 2001 Directive; Article 107g of the 2001 Directive is implemented in regulation 194.
 - (6) Article 28a(3) of the Regulation imposes an obligation identical to that set out in the first sentence of Article 107h(3) of the 2001 Directive; Article 107h(3) first sentence is implemented in regulation 190.
 - (7) Article 28b(1) of the Regulation cross-refers to prohibitions and obligations set out in Articles 107m, 107n, 107o, 107p and 107q of the 2001 Directive; those Articles are implemented in regulations 198, 199, 200, 201 and 202; Article 107n(1) and the first paragraph of Article 107n(3), implemented in regulation 199(2) and (6), are excluded as they are enforced otherwise than by way of criminal offence.

- (f) Article 28b(1) insofar as it relates to prohibitions or obligations set out in—
 - (i) Article 107m(3) to (6) of the 2001 Directive,
 - (ii) the second paragraph of Article 107n(3) of the 2001 Directive, or
 - (iii) the last sentence of Article 107o of the 2001 Directive.
- (7) This regulation is subject to regulation [212](#) (transitional arrangements).

Persons liable

211. If an offence under regulation [207\(1\)](#) (offences) or regulation [210\(1\)\(a\)](#) (offences relating to pharmacovigilance obligations under Regulation (EC) No [726/2004](#)) 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.