STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Enforcement

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 **[**[F1]16(3a)**]**, second paragraph[M1];

(b) Article 20(8)[M2];

(c) Article 21(1) and (2)[M3];

(d) Article 22[M4];

(e) Article 28(1), (2) and (5)[M5];

(f) Article 28a(3)[M6]; and

(g) Article 28b(1)[M7], 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 **[**[F2]16(3a)**]**, 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

(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).

Textual Amendments

F1 Word in reg. 210(3)(a) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **24**

F2 Word in reg. 210(6)(a) substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **24**

Marginal Citations

M1 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).

M2 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).

M3 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.

M4 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.

M5 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.

M6 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.

M7 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.

Changes to legislation:
The Human Medicines Regulations 2012, Section 210 is up to date with all changes known to be in force on or before 19 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- reg. 210 omitted by S.I. 2019/775 reg. 174 (This amendment not applied to legislation.gov.uk. Reg. 174 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 2 para. 136)
- reg. 210 omitted by S.I. 2024/832 reg. 98

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by S.I. 2019/775 reg. 63(2)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by S.I. 2024/832 reg. 142(e)
- Sch. 24 Pt. 1 para. 23 words omitted by S.I. 2024/832 reg. 142(f)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(4) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by S.I. 2024/832 reg. 146
- reg. 3(12)(d)(ia) omitted by S.I. 2024/832 reg. 4(a)
- reg. 4(4)(d)(ia) omitted by S.I. 2024/832 reg. 5
- reg. 43(7)(b)(ii)(bb) words omitted by S.I. 2024/832 reg. 18(b)
- reg. 49(1ZA)-(1ZD) inserted by S.I. 2024/832 reg. 26(a)
- reg. 49(3ZA) inserted by S.I. 2024/832 reg. 26(d)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by S.I. 2019/1385 Sch. 1 para. 5 (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by S.I. 2019/775 reg. 57(2) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by S.I. 2019/775 reg. 58(3) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by S.I. 2019/1385 Sch. 1 para. 6(2) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 55(1)(b)(iii)(bb) substituted by S.I. 2024/832 reg. 43(a)(ii)

- reg. 60A(10A) inserted by S.I. 2024/832 reg. 49(e)
- reg. 68(11H)-(A12) inserted by S.I. 2024/832 reg. 56(b)
- reg. 173(e) inserted by S.I. 2017/1322 Sch. 4 para. 2(2)(b) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(c) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(g) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 257(9) inserted by S.I. 2024/832 reg. 110(c)
- reg. 257AA257AB inserted by S.I. 2024/832 reg. 111
- reg. 327(1)(c)(va) omitted by S.I. 2024/832 reg. 128(a)
- reg. 346(2)(c)(iia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iiia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iva) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xviia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xxviiij) omitted by S.I. 2024/832 reg. 132(b)
- reg. 347B inserted by S.I. 2024/832 reg. 133