
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Offences

Penalties and supplementary provision about offences

176.—(1) A person guilty of an offence under regulation 175 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) It is a defence for a person charged with an offence under regulation 175(1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(3) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (2), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Changes to legislation:

The Human Medicines Regulations 2012, Section 176 is up to date with all changes known to be in force on or before 19 March 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 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. 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))
- 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. 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. 247A(7) inserted by [S.I. 2024/344 reg. 5\(4\)](#)