
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 16

Enforcement

Supplementary provisions and offences

334.—(1) An inspector entering any premises by virtue of regulation 325 or of a warrant under regulation 326 may be accompanied by such persons, and take such equipment, as the inspector thinks appropriate.

(2) Where an inspector enters premises in pursuance of a warrant under regulation 326, the inspector must, if the property is unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespass as they were before the inspector entered.

(3) It is an offence for a person—

- (a) intentionally to obstruct an inspector;
- (b) intentionally to fail to comply with a requirement properly made under regulation 327 by an inspector; or
- (c) without reasonable cause, to fail to give an inspector any other assistance or information which the inspector may reasonably require in order to perform a function under these Regulations.

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(5) A person who knowingly makes a false statement in giving information as mentioned in paragraph (3)(c) is guilty of an offence.

(6) A person who breaches the prohibition in regulation 332(1) (restrictions on disclosure of information) is guilty of an offence.

(7) A person who is guilty of an offence under paragraph (5) or (6) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years, or to both.

(8) Nothing in this regulation is to be read as requiring a person to answer a question or to give information if doing so might incriminate that person or the spouse or civil partner of that person.

(9) In this regulation “occupier”, in relation to a ship, aircraft, or vehicle, is to be read in accordance with regulation 326(4).

Changes to legislation: *The Human Medicines Regulations 2012, Section 334 is up to date with all changes known to be in force on or before 17 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. (See end of Document for details) View outstanding changes*

Modifications etc. (not altering text)

- C1** Regs. 332-339 applied (with modifications) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg 47(1), Sch. 9 (as substituted (14.8.2012) by [S.I. 2012/1916](#), reg. 1(2), Sch. 34 paras. 57(b), **64** (with [Sch. 32](#)))

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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)(iia) 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)(xviiia) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 346(2)(c)(xxviii) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 347B inserted by [S.I. 2024/832 reg. 133](#)