
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 17

Miscellaneous and general

Provisions relating to offences

Contravention due to fault of another person

335.—(1) This regulation applies where—

- (a) a contravention of a provision referred to in paragraph (6) constitutes an offence; and
- (b) a person (“A”) contravenes the provision by reason of the act or omission of another person (“B”).

(2) B may be charged with and convicted of the offence, whether or not proceedings are also brought against A.

(3) If B is convicted B is liable to the same punishment as would have been imposed on A if A had been convicted of the offence.

(4) If A is charged with the offence it is a defence for A to prove on the balance of probabilities that—

- (a) A exercised all due diligence to avoid contravening the provision; and
- (b) the contravention was due to the act or omission of B.

(5) A may not rely on the defence in paragraph (4) unless not later than seven clear days before the date of the hearing A serves on the prosecutor a notice in writing of any information held by A which identifies, or assists in identifying, B.

(6) The provisions mentioned in paragraph (1) are—

- (a) regulation 251 (compliance with standards specified in certain publications);
- (b) regulations [^{F1}268, 268A, 269 and 269A] (offences relating to packaging and package leaflets);
- (c) regulation 273 (child resistant containers for regulated medicinal products);
- (d) regulation 275 (colouring of aspirin and paracetamol products for children);
- (e) any prohibition or requirement in Chapter 2 of Part 14 (advertising); and
- (f) regulations 305(4) and 306(7) and (8) (notices not to publish, or to cease to publish, an advertisement).

F1 Words in reg. 335(6)(b) substituted (31.12.2020) by [S.I. 2019/775](#), [reg. 224ZA](#) (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1488), [reg. 1](#), [Sch. 2 para. 183](#))

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))

Warranty as defence

336.—(1) This regulation applies where proceedings are brought against a person (“the defendant”) for an offence under these Regulations in respect of a contravention of a provision mentioned in paragraph (3).

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

- (a) the substance or article to which the contravention relates (the “relevant substance or article”) was sold to the defendant in the United Kingdom as—
 - (i) a substance or article which could be lawfully sold, supplied or offered for sale or supply, or
 - (ii) a substance or article which could be lawfully sold, supplied or offered for sale or supply under the name or description or for the purpose under or for which it was sold;
- (b) the relevant substance or article was sold with a written warranty certifying a matter specified in paragraph (a), and that if the warranty were true the alleged offence would not have been committed;
- (c) at the time of the commission of the alleged offence the defendant had no reason to believe that the matter certified in the warranty was otherwise; and
- (d) at the time of the commission of the alleged offence the relevant substance or article was in the same state as when the defendant purchased it.

(3) The provisions are—

- (a) regulation 251 (compliance with standards specified in certain publications);
- (b) regulations [^{F2}268, 268A, 269 and 269A] (offences relating to packaging and package leaflets);
- (c) regulation 273 (child resistant containers for regulated medicinal products); and
- (d) regulation 275 (colouring of aspirin and paracetamol products for children).

(4) A warranty is not to be a defence under this regulation unless, no later than three clear days before the date of the hearing, the defendant sends to the prosecutor, and to the person who gave the warranty to the defendant—

- (a) a copy of the warranty;
- (b) a notice stating that the defendant intends to rely on it; and
- (c) the name and address of the person from whom the defendant received the warranty.

(5) Where the defendant is an employee of the person who purchased the substance or article under the warranty, the defendant is entitled to rely on the provisions of this regulation in the same way as the employer.

(6) The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and to give evidence.

(7) The court may adjourn the hearing in order to enable a person to appear and give evidence in accordance with paragraph (6).

(8) For the purposes of this regulation, a name or description entered in an invoice is to be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description without contravening a provision mentioned in paragraph (3).

(9) In the application of this regulation and regulation 337 to Scotland, references to the defendant are to be construed as references to the accused.

F2 Words in reg. 336(3)(b) substituted (31.12.2020) by [S.I. 2019/775](#), **reg. 224ZB** (as inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), [reg. 1](#), **Sch. 2 para. 183**)

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](#)))

Offences in relation to warranties and certificates

337.—(1) It is an offence for a defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336 (3)—

- (a) intentionally to apply a warranty given in relation to one substance or article to a different substance or article; or
- (b) intentionally to apply to one substance or article a certificate issued under regulation 330 or paragraph 19 of Schedule 31 in relation to a sample of a different substance or article.

(2) A person who intentionally or recklessly gives a purchaser a false warranty certifying a matter specified in regulation 336(2)(a) is guilty of an offence.

(3) If the defendant in proceedings for an offence under these Regulations in respect of a contravention of a provision mentioned in regulation 336(3) relies successfully on a warranty given to the defendant or to the defendant's employer, proceedings for an offence under paragraph (2) may be brought in accordance with paragraph (4).

(4) Proceedings may be brought, as the prosecutor chooses—

- (a) before a court which has jurisdiction in the place where a sample of the substance or article to which the warranty relates was taken; or
- (b) before a court which has jurisdiction in the place where the warranty was given.

(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 or to imprisonment for a term not exceeding two years, or to both.

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](#)))

Offences by bodies corporate and partnerships

338.—(1) If an offence under these Regulations committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, an officer of the body corporate, or a person purporting to act as an officer of the body corporate, that officer or person (as well as the body corporate) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(2) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and omissions of a member in connection with the member's functions of management as it applies to an officer of the body corporate.

(3) If an offence under these Regulations is—

- (a) committed by a Scottish partnership; and
- (b) proved to have been committed with the consent or connivance of, or to be attributable to neglect on the part of, a partner of the partnership,

the partner (as well as the partnership) is guilty of the offence and is liable to be proceeded against and punished accordingly.

(4) In this regulation “officer” in relation to a body corporate means a director, secretary or other similar officer of the body corporate.

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](#)))

Changes to legislation:

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