
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).

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 335. (See end of Document for details)

Textual Amendments

- 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))

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 335.