
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 17

Miscellaneous and general

Provisions relating to offences

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 268 and 269 (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.