
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 17

Miscellaneous and general

General

Presumptions

340.—(1) Paragraph (2) applies for the purposes of proceedings under these Regulations for an offence consisting of offering a medicinal product for sale by retail in contravention of regulation 220 (sale or supply of products not subject to general sale) or 221 (sale or supply of products subject to general sale).

(2) If it is proved that the medicinal product in question was found on a vehicle from which medicinal products are sold, it is to be presumed, unless the contrary is proved, that the person in charge of the vehicle offered the medicinal product for sale.

(3) Paragraph (4) applies for the purposes of proceedings under these Regulations for an offence consisting of a contravention of a provision within paragraph (5), where it is proved that the medicinal product in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products.

(4) It is to be presumed, unless the contrary is proved, that the person charged possessed the medicinal product for the purpose of sale or supply.

(5) The provisions within this paragraph are regulations 268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons) and 276 (offences: requirements relating to child safety) to the extent that they establish an offence based on possession of a medicinal product for the purpose of sale or supply.

Decisions under these Regulations

341.—(1) Where the licensing authority notifies a person of a decision under these Regulations, it must—

- (a) state its reasons for the decision; and
- (b) inform the person of any action the person may take under these Regulations to challenge that decision and of the time for taking that action.

(2) Paragraph (1) is without prejudice to any other provision of these Regulations concerning notification by the licensing authority.

(3) The licensing authority must publicise any decision under these Regulations to which paragraph (4) applies in such manner as it thinks fit.

(4) Those decisions are—

- (a) a decision to grant or revoke a marketing authorisation;

- (b) a decision to grant or revoke a certificate of registration; and
- (c) a decision to grant or revoke a traditional herbal registration.

Time limits for provision of information etc

342.—(1) This regulation applies if—

- (a) by any provision of these Regulations a person is required to provide—
 - (i) any information or document to the licensing authority or to the Ministers, or
 - (ii) any assistance to the licensing authority or to the Ministers; and
- (b) no time is specified in that provision within which the obligation must be performed.

(2) The obligation must be performed within such time as may be specified in a written notice given to the person by the licensing authority or the Ministers (as the case may be).

Service of documents

343.—(1) A notice or other document required or authorised by any provision of these Regulations to be served on a person, or to be given or sent to a person, may be served, given or sent—

- (a) by delivering it to the person;
- (b) by sending it by post to the person’s usual or last known residence or place of business in the United Kingdom;
- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or by sending it by post to the secretary or clerk of the body corporate at that office; or
- (d) in the case of a Scottish partnership by delivering it to a partner or by sending it by post to the address of the principal office of the partnership; or
- (e) if the person consents in writing to the use of electronic communication, by a means of electronic communication.

(2) Where a notice or other document is sent by means of electronic communication it is treated for the purposes of these Regulations as received on the day on which it is sent, unless the contrary is proved.

Payment of expenses by Ministers

344.—(1) If a person enforces a provision of these Regulations in accordance with functions conferred under Part 16 (enforcement), the relevant Minister must pay such amounts as the person may reasonably require in respect of expenses incurred in the course of enforcement.

(2) In paragraph (1) “the relevant Minister” means—

- (a) in relation to enforcement in England, Wales, and Scotland, the Secretary of State; and
- (b) in relation to enforcement in Northern Ireland, the Minister for Health, Social Services and Public Safety.