STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 4

Requirement for authorisation

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46.—(1) A person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product.

(2) A person may not sell or supply, or offer to sell or supply, a medicinal product otherwise than in accordance with the terms of—

(a) a marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(3) A person may not possess an unauthorised medicinal product if the person knows or has reasonable cause to believe that the product is intended to be sold or supplied to another person within the European Economic Area.

(4) A person may not in the circumstances mentioned in paragraph (5)—

(a) manufacture or assemble a medicinal product; or

(b) procure the sale, supply, manufacture or assembly of a medicinal product.

(5) Those circumstances are that the person knows or has reasonable cause to believe that the medicinal product has been or is intended to be sold or supplied contrary to paragraph (1).

(6) For the purposes of this regulation a medicinal product is unauthorised if none of the following is in force for the product—

(a) a marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(7) This regulation is subject to—

(a) Part 10 (exceptions to requirement for marketing authorisation etc); and

(b) Article 83 of Regulation (EC) No 726/2004 (authorisation of placing on the market of medicinal product for compassionate reasons).

(8) A medicinal product is not unauthorised for the purposes of this regulation if—

(a) it is sold or supplied, or offered for sale or supply, for export to an EEA State; and

(b) the product may lawfully be sold or supplied in that state by virtue of legislation adopted by that state in compliance with the 2001 Directive.

(9) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of a medicinal product to a person outside the European Economic Area.

(10) Paragraphs (1) and (2) do not apply to the sale, supply, or offer for sale or supply, of an investigational medicinal product to a person specified in regulation 13(1) of the Clinical Trials Regulations for the purposes of administering that product in a clinical trial, provided that the conditions specified in regulation 13(2) of those Regulations are satisfied.

(11) Paragraph (3) does not apply to possession of an investigational medicinal product by a person who knows or has reasonable cause to believe—

(a) that the investigational medicinal product is intended to be sold or supplied within the European Economic Area; and

(b) that paragraph (10) will apply to the sale or supply.

Breach of requirement

47.—(1) A person who breaches regulation 46 is guilty of an offence.

(2) 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, to imprisonment not exceeding two years or to both.

(3) It is to be presumed for the purposes of regulation 46(3) that, if a person ("P") knows or has reasonable cause to believe that a medicinal product is intended to be sold or supplied to another person, P knows or has reasonable cause to believe that the other person is within the European Economic Area.

(4) Paragraph (3) does not apply if P proves that P did not know or have reasonable cause to believe that the person was within the European Economic Area.

(5) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (4), the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

(6) Paragraph (7) applies if the holder of a marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation is charged with an offence under this regulation in respect of anything that—

(a) has been manufactured or assembled to the holder's order by another person; and

(b) has been so manufactured or assembled as not to comply with the terms of the authorisation, certificate or registration.

(7) Where this paragraph applies, it is a defence for the holder to prove that—

(a) the holder communicated the terms of the authorisation, certificate or registration to the other person; and

(b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.