STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

Manufacturing and wholesale dealing

Grant etc of licences

Manufacturing of medicinal products

17.—(1) A person may not except in accordance with a licence (a "manufacturer's licence")—

(a) manufacture, assemble or import from a state other than an EEA State any medicinal product; or

(b) possess a medicinal product for the purpose of any activity in sub-paragraph (a).

(2) Paragraph (1) is subject to paragraphs (3) to (5).

(3) Paragraph (1) applies in relation to an investigational medicinal product only—

(a) if the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration; and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that authorisation, certificate or registration.

(4) In paragraph (3), "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

(b) an EU marketing authorisation.

(5) Paragraph (1) does not apply to a person who, in connection with the importation of a medicinal product from a state other than an EEA State—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(6) Paragraph (1) does not apply to a person who imports a medicinal product for administration to himself or herself or to any other person who is a member of that person's household.