STATUTORY INSTRUMENTS

# 2012 No. 1916

# The Human Medicines Regulations 2012

## PART 3

## Manufacturing and wholesale dealing

*Conditions for holding a wholesale dealer's licence*

**Obligations of licence holder**

**43.**—(1) The licence holder must comply with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive.

(2) The licence holder must ensure, within the limits of the holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met.

(3) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(4) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(5) Subject to paragraph (6), the licence holder must not sell or supply a medicinal product, or offer it for sale or supply, unless—

(a) there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product; and

(b) the sale or supply, or offer for sale or supply, is in accordance with the authorisation.

(6) The restriction in paragraph (5) does not apply to—

(a) the sale or supply, or offer for sale or supply, of a special medicinal product;

(b) the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; or

(c) the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174.

(7) The licence holder must—

(a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—

(i) ordered by the licensing authority or by the competent authority of any EEA State, or

(ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for, the product; and

(c) keep records, in relation to the receipt and dispatch of medicinal products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the name of the medicinal product,

(iv) the quantity of the product received or dispatched, and

(v) the name and address of the person from whom the products were received or to whom they are dispatched.

(8) The licence holder must notify the licensing authority and the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in relation to a medicinal product if the licence holder intends to import the product from another EEA State and is neither—

(a) the holder of an authorisation in relation to the product; nor

(b) acting on behalf of the holder of an authorisation.

(9) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

(10) In this regulation, "marketing authorisation" means—

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

(b) an EU marketing authorisation.