STATUTORY INSTRUMENTS

2005 No. 2789

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

Requirement that holders of wholesale dealer's licences comply with certain obligations

8.—(1) The holder of a wholesale dealer's licence, insofar as that licence relates to relevant medicinal products, shall—

(a) comply with the guidelines on good distribution practice;

(b) ensure, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale so that the needs of patients in the United Kingdom are covered;

(c) provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the relevant medicinal products which he handles, stores or distributes under his licence as are necessary to maintain the quality of, and ensure proper distribution of the medicinal products which he handles, stores or distributes pursuant to his licence;

(d) inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or premises which have been approved from time to time by the licensing authority.

(2) Subject to paragraph (3), the holder of a wholesale dealer's licence shall not sell or offer for sale or supply any relevant medicinal product unless—

(a) there is a marketing authorization for the time being in force in respect of that product; and

(b) the sale or offer for sale is in conformity with the provisions of that authorisation.

(3) The restriction in paragraph (2) shall not apply to—

(a) the sale or offer for sale of any exempt relevant medicinal product; and

(b) the export to an EEA State, or supply for the purposes of such export, of a relevant medicinal product which may be placed on the market in that State without a marketing authorization by virtue of legislation adopted by that State under Article 5(2) of the Directive.

(4) The holder of a wholesale dealer's licence shall—

(a) keep such documents relating to the sale of medicinal products to which his licence relates as will facilitate the withdrawal or recall from sale of relevant medicinal products in accordance with paragraph (b);

(b) have in place an emergency plan which will ensure effective implementation of the recall from the market of any relevant medicinal products where such recall is—

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

(ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorization for, the product in question;

(c) keep such records, which may be in the form of purchase and sales invoices, or on a computer or in any other form, which give, as a minimum, where any relevant medicinal products are received or dispatched, the following information—

(i) the date of receipt or, as the case may be, dispatch,

(ii) the name of the relevant medicinal product,

(iii) the quantity of relevant medicinal product received or, as the case may be, dispatched, and

(iv) the name and address of, as may be applicable in each case, the person from whom the products are received or to whom they are sold or supplied.

(5) Where the holder of a wholesale dealer's licence imports from another EEA State any relevant medicinal product in respect of which he is not either—

(a) the marketing authorization holder in respect of that product; or

(b) acting on behalf of the marketing authorization holder in importing that product,

he shall notify the marketing authorization holder and the licensing authority of his intention to import it.

(6) The licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any licence granted under Part II of the Act; or

(b) suspending or terminating any licence in accordance with the provisions of Part II of the Act,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence.