STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

Manufacturing and wholesale dealing

Conditions for holding a wholesale dealer's licence

Conditions for wholesale dealer's licence

42.—(1) Regulations 43 to 45 apply to the holder of a wholesale dealer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products).

(2) Those provisions are regulations 43(2), (5) and (8) and 44.

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the 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.

Requirement for wholesale dealers to deal only with specified persons

44.—(1) The licence holder may not obtain supplies of medicinal products from anyone except—

(a) the holder of a manufacturer's licence or wholesale dealer's licence in relation to products of that description; or

(b) a person who holds an authorisation granted by another EEA State authorising the manufacture of products of that description or their distribution by way of wholesale dealing.

(2) The licence holder may distribute medicinal products by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence relating to those products;

(b) the holder of an authorisation granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing;

(c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale; or

(d) a person who may lawfully administer those products.

(3) Where a medicinal product is supplied to a person pursuant to paragraph (2)(c), the licence holder must enclose with the product a document stating—

(a) the date on which the supply took place;

(b) the name and pharmaceutical form of the product supplied;

(c) the quantity of product supplied; and

(d) the name and address of the licence holder.

(4) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (3) for at least five years beginning immediately after the date on which the information is supplied; and

(b) ensure that the record is available to the licensing authority for inspection.

Requirement as to responsible persons

45.—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person") who in the opinion of the licensing authority—

(a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and

(b) has adequate experience relating to those activities and procedures.

(2) Those functions are—

(a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and

(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applicable to those products.

(3) The licence holder must notify the licensing authority of—

(a) any change to the responsible person; and

(b) the name, address, qualifications and experience of the responsible person.

(4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

(a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or

(b) is failing to carry out the functions referred to in paragraph (2) adequately or at all.

(6) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a responsible person.