STATUTORY INSTRUMENTS

2013 No. 1855

The Human Medicines (Amendment) Regulations 2013

PART 2

Amendment of the Human Medicines Regulations 2012

Substitution of regulation 44

15. For regulation 44 (requirement for wholesale dealers to deal only with specified persons) substitute—

"**Requirement for wholesale dealers to deal only with specified persons**

44.—(1) Unless paragraph (2) applies, the licence holder must 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;

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

(c) where the supplier is not the holder of a manufacturer's licence, where the supply is in accordance with the principles and guidelines of good distribution practice,

but this paragraph does not apply in relation to the distribution of medicinal products directly received from a third country but not imported into the EU.

(2) From 28th October 2013 the licence holder must 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;

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

(c) where the medicinal product is directly received from a third country ("A") for export to a third country ("B"), the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A; or

(d) where the supplier is not the holder of a manufacturer's licence, where the supply is in accordance with the principles and guidelines of good distribution practice.

(3) Where a medicinal product is obtained in accordance with paragraph (1), (2)(a) or (b), the licence holder must verify that—

(a) the wholesale dealer who supplies the product complies with the principles and guidelines of good distribution practices; or

(b) the manufacturer or importer who supplies the product holds a manufacturing authorisation.

(4) Unless paragraph (5) applies, 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,

but this paragraph does not apply in relation to medicinal products which are distributed by way of wholesale dealing to a person in a third country.

(5) From 28th October 2013, 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;

(d) a person who may lawfully administer those products; or

(e) in relation to supply to persons in third countries, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.

(6) Where a medicinal product is supplied to a person who is authorised or entitled to supply medicinal products to the public in accordance with paragraph (4)(c), (5)(c) or (e), the licence holder must enclose with the product a document stating the—

(a) date on which the supply took place;

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

(c) quantity of product supplied;

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

(e) batch number of the medicinal products bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive.

(7) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (6) 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."