STATUTORY INSTRUMENTS

# 2013 No. 1855

# The Human Medicines (Amendment) Regulations 2013

## PART 2

## Amendment of the Human Medicines Regulations 2012

**Substitution of regulation 37**

**11.** For regulation 37 (manufacturing and assembly) substitute—

"**Manufacturing and assembly**

**37.**—(1) This regulation applies in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The licence holder must comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(3) Unless paragraph (10) applies, the licence holder shall use active substances as starting materials only if—

(a) those substances have been manufactured in accordance with good manufacturing practice for active substances; and

(b) those substances have been distributed in accordance with the guidelines on good distribution practice for active substances.

(4) The licence holder shall verify—

(a) that the manufacturer or distributor of an active substance used by the licence holder has complied with the requirements of good manufacturing practice and good distribution practice for active substances by means of audits performed—

(i) directly by the licence holder, or

(ii) by a person acting on behalf of the licence holder under a contract;

(b) that unless the active substance is imported from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder are registered with the competent authority of a member State in which they are established; and

(c) the authenticity and quality of the active substance.

(5) The licence holder shall ensure that—

(a) excipients are suitable for use in a medicinal product by—

(i) ascertaining what the appropriate good manufacturing practice is, and

(ii) ensuring that the ascertained good manufacturing practice is applied;

(b) the suitability of the excipient is ascertained on the basis of a formalised risk assessment as described in paragraph 5 of Article 47(**1**) of the 2001 Directive;

(c) the assessment under sub-paragraph (b) takes account of—

(i) the source,

(ii) requirements under other quality systems,

(iii) intended use of the excipients, and

(iv) previous instances of quality defects,

(d) the authenticity and quality of any excipient used is verified; and

(e) the measures taken under this paragraph are documented by the licence holder.

(6) The licence holder must maintain such staff, premises and equipment as are necessary for the stages of manufacture and assembly of medicinal products undertaken by the licence holder in accordance with—

(a) the manufacturer's licence; and

(b) the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applying to the medicinal products.

(7) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.

(8) The licence holder must not manufacture or assemble medicinal products on premises other than those specified in the licence as approved by the licensing authority for the purpose.

(9) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—

(a) the standards of quality and safety specified in Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components(**2**); or

(b) equivalent standards.

(10) The requirements in paragraphs (3) to (5) do not apply in relation to the manufacture or assembly of special medicinal product to which regulation 167 (supply to fulfil special needs) applies.

(11) The licence holder must immediately inform the competent authority of a member State and, where applicable, the marketing authorisation holder, of medicinal products which come within the scope of manufacturing authorisation which the licence holder—

(a) knows or suspects; or

(b) has reasonable grounds for knowing or suspecting,

to be falsified."

(**1**) Paragraph 5 of Article 47 was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(**2**) OJ No L 91, 30.3.2004, p25; relevant amending instrument is Commission Implementing Directive 2011/38/EU (OJ No L 97, 12.4.2011, p28).