STATUTORY INSTRUMENTS

2013 No. 1855

The Human Medicines (Amendment) Regulations 2013

PART 2

Amendment of the Human Medicines Regulations 2012

Substitution of regulation 327

29.—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.

(2) For paragraph (1)(c) substitute—

"(c) in relation to an application under Parts 3 or 5 to 8 in order to verify any statement made by an applicant for—

(i) a manufacturer's licence,

(ii) a wholesale dealer's licence,

(iii) a brokering registration,

(iv) registration as an importer, manufacturer or distributor of active substances,

(v) a marketing authorisation,

(vi) a certificate of registration,

(vii) a traditional herbal registration, or

(viii) an Article 126a authorisation;

(d) in relation to a person's notification to sell medicinal products at a distance under Part 12A."

(3) For paragraphs (2) to (4) substitute—

"(2) The things mentioned in paragraph (1) are—

(a) a substance or article appearing to the inspector to be a medicinal product or an active substance;

(b) an article appearing to the inspector to be—

(i) a container or package used or intended to be used to contain a medicinal product or an active substance, or

(ii) a label or leaflet used or intended to be used in connection with a medicinal product or an active substance;

(c) plant or equipment, including computer equipment, appearing to the inspector to be used or intended to be used in connection with the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;

(d) any process of manufacture or assembly of medicinal products or active substances;

(e) the way in which medicinal products or active substances, or the materials used in the manufacture of medicinal products or active substances, are tested at any stage in the process of manufacture or assembly;

(f) information and documents relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;

(g) information and documents relating to the safety of medicinal products or active substances, including information and documents relating to compliance with—

(i) conditions imposed under any of regulations 59 (conditions of UK marketing authorisation: general), 60 (conditions of UK marketing authorisation: exceptional circumstances), 61 (conditions of UK marketing authorisation: new obligations post-authorisation) or 105 (conditions of certificate of registration),

(ii) the requirements of Part 11 (pharmacovigilance),

(iii) obligations and conditions under Articles 10a(1), 14(7), 14(8), 16 or 57(2) of Regulation (EC) No 726/2004,

(iv) the requirements of Chapter 3 (pharmacovigilance) of Title II of Regulation (EC) No 726/2004,

(v) the requirements of the Implementing Regulation as defined in regulation 177(5) (pharmacovigilance: interpreting provision), and

(vi) obligations under regulations 75 (obligation to provide information relating to safety) and 76 (obligation in relation to product information).

(3) The inspector may for the purposes specified in paragraph (1) take or purchase a sample of a substance or article which appears to the inspector to be—

(a) a medicinal product or an active substance which is, or is intended to be, sold or supplied; or

(b) a substance or article used, or intended to be used, in the manufacture of a medicinal product or an active substance.

(4) The inspector may for the purposes specified in paragraph (1) require a person carrying on a business which consists of or includes the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances, or a person employed in connection with such a business, to produce information or documents relating to the business which are in the person's possession or under the person's control."

(4) For paragraph (6) substitute—

"(6) The inspector may seize and retain a substance or article appearing to the inspector to be a medicinal product or an active substance if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that substance or article."