STATUTORY INSTRUMENTS

2013 No. 1855

The Human Medicines (Amendment) Regulations 2013

PART 2

Amendment of the Human Medicines Regulations 2012

Amendment of regulation 8

3. In regulation 8 (general interpretation)—

(a) in paragraph (1)—

(i) after the definition of "the 2001 Directive" insert—

""active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;";

(ii) for the definition of "assemble" substitute—

""assemble", in relation to a medicinal product or an active substance, includes the various processes of dividing up, packaging and presentation of the product or substance, and "assembly" has a corresponding meaning;";

(iii) after the definition of "the British Pharmacopoeia" insert—

""brokering" means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;";

(iv) after the definition of "the European Pharmacopoeia" insert—

""excipient" means any constituent of a medicinal product other than the active substance and the packaging material;";

(v) for the definition of "export" substitute—

""export" means export, or attempt to export, from the United Kingdom, whether by land, sea or air;";

(vi) before the definition of "the Good Manufacturing Practice Directive" insert—

""falsified medicinal product" means any medicinal product with a false representation of—

(a) its identity, including its packaging and labelling, its name or its composition (other than any unintentional quality defect) as regards any of its ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) its history, including the records and documents relating to the distribution channels used;

"Fees Regulations" means the Medicines (Products for Human Use) (Fees) Regulations 2013(**1**);";

(vii) after the definition of "immediate packaging" insert—

""import" means import, or attempt to import, into the United Kingdom, whether by land, sea or air;";

(viii) after the definition of "pharmacy medicine", insert—

""physiotherapist independent prescriber" means a person—

(a) who is a registered physiotherapist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;

"podiatrist independent prescriber" means a person—

(a) who is a registered podiatrist; and

(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a podiatrist independent prescriber;";

(b) after paragraph (7), insert—

"(8) References in these Regulations to—

(a) good manufacturing practice for active substances relate to the principles and guidelines for good manufacturing practice adopted by the European Commission under the third paragraph of Article 47(**2**) of the 2001 Directive;

(b) good distribution practice for active substances relate to the guidelines on good distribution practices for active substances adopted by the European Commission under the fourth paragraph of Article 47 of the 2001 Directive."

(**1**) S.I. 2013/532.

(**2**) Paragraphs 3 and 4 of Article 47 were substituted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).