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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 15**

**British Pharmacopoeia**

**Specified publications**

**321.**—(1) In this regulation “specified publication” means any of the following—

- (a) the European Pharmacopoeia;
- (b) the British Pharmacopoeia;
- (c) the Cumulative List of Recommended International Nonproprietary Names;
- (d) a compendium prepared and published under regulation [317](#); or
- (e) a list of names prepared and published under regulation [318](#).

(2) Paragraph (3) applies if an authorisation refers to a specified publication, but not to a particular edition of the publication.

(3) Where this paragraph applies, in order to determine whether anything done at a time when the authorisation is in force is done in accordance with the authorisation, the reference to a specified publication is to be construed as a reference to the edition of the specified publication in force at that time, unless the authorisation expressly provides otherwise.

(4) In paragraph (3) the reference to the edition of a specified publication in force at a particular time is a reference to the edition of that publication in force, under whatever title, at that time.

(5) In this regulation “authorisation” means any of the following—

- (a) a manufacturer’s licence;
- (b) a wholesale dealer’s licence;
- (c) a marketing authorisation;
- (d) an Article 126a authorisation;
- (e) a certificate of registration; or
- (f) a traditional herbal registration.