
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 15

British Pharmacopoeia

British Pharmacopoeia and compendia

317.—(1) The British Pharmacopoeia Commission (in this Part referred to as “the BPC”) must, at such intervals as it thinks appropriate, prepare or cause to be prepared editions of the British Pharmacopoeia, containing such relevant information relating to substances, combinations of substances and articles falling within paragraph (2) as the BPC thinks appropriate.

(2) The substances, combinations of substances, and articles falling within this paragraph are—

- (a) substances, combinations of substances and articles (whether medicinal products or not) which are or may be used in the practice of medicine or surgery (other than veterinary medicine or veterinary surgery), dentistry or midwifery; and
- (b) substances, combinations of substances and articles used in the manufacture of anything falling within paragraph (a).

(3) The BPC may also, at such intervals as it thinks appropriate, prepare or cause to be prepared—

- (a) a compendium (other than the British Pharmacopoeia) containing such relevant information relating to substances, combinations of substances and articles within paragraph (2) as the BPC thinks appropriate; and
- (b) a compendium containing such relevant information as the BPC thinks appropriate in relation to—
 - (i) substances, combinations of substances and articles (whether veterinary medicinal products or not) which are or may be used in the practice of veterinary medicine or veterinary surgery; and
 - (ii) substances, combinations of substances and articles used in the manufacture of anything falling within sub-paragraph (i).

(4) The Ministers must arrange for the publication of anything prepared or caused to be prepared by the BPC under this regulation.

(5) In this Part—

- (a) a reference to preparing a thing or causing it to be prepared includes amending it, or causing it to be amended;
- (b) a reference to publication includes publication by electronic means; and
- (c) “relevant information”, in relation to a substance, combination of substances or article, means information consisting of descriptions of, standards for, or notes or other matter relating to the substance, combination of substances or article.

Lists of names

318.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared a list of names which appear to it to be suitable—

- (a) to be used as the names of substances, combinations of substances or articles falling within regulation 317(2) or (3)(b); and
- (b) to be placed at the head of monographs relating to those substances, combinations of substances or articles in any edition of the British Pharmacopoeia or in a compendium prepared under that regulation.

(2) Where a list has been prepared in accordance with paragraph (1), the Ministers must cause it to be published.

Other documents

319.—(1) The BPC must, at such intervals as it thinks appropriate, prepare or cause to be prepared other documents (in addition to those falling within regulation 317 or 318) containing such relevant information relating to substances, combinations of substances or articles falling within regulation 317(2) or (3)(b) as the BPC thinks appropriate.

(2) Where a document has been prepared in accordance with paragraph (1), the Ministers may cause it to be published.

Supplementary provisions

320.—(1) Anything published in accordance with a provision of this Part (other than regulation 319 (“a publication”)) must specify the date on which it is to take effect.

(2) The Ministers must give notice of the date mentioned in paragraph (1) by notices published in the London, Edinburgh and Belfast Gazettes not less than 21 days before that date.

(3) Where in any proceedings an enforcement authority produces a copy of a publication, it shall be presumed that the copy is a true copy of the edition of that publication that was in force at the time when the events that are the subject of the proceedings took place, unless evidence is adduced to the contrary.

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.