



# Medicines Act 1968

## 1968 CHAPTER 67

### PART III

#### FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

##### *Additional provisions*

#### **65 Compliance with standards specified in monographs in certain publications**

- (1) No person shall, in the course of a business carried on by him.—
- (a) sell a medicinal product which has been demanded by the purchaser by, or by express reference to, a particular name, or
  - (b) sell or supply a medicinal product in pursuance of a prescription given by a practitioner in which the product required is described by, or by express reference, to a particular name,
- if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.
- (2) No person shall, in the course of a business carried on by him, sell or supply a medicinal product which, in the course of that business, has been offered or exposed for sale and has been so offered or exposed for sale by, or by express reference to, a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.
- (3) Where a medicinal product is sold or supplied in the circumstances specified in subsection (1) or subsection (2) of this section, and the name in question is the name, not of the product itself, but of an active ingredient of the product, then for the purposes of the subsection in question the product shall be taken not to comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with the standard so specified.
- (4) Subject to subsection (7) of this section, in this section " publication " means one of the following, that is to say, the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex and any compendium published under Part VII

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*Status: This is the original version (as it was originally enacted).*

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of this Act; " the relevant monograph ", in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription, or offered or exposed for sale, by or by express reference to a particular name.—

- (a) if, together with that name, there was specified a particular edition of a particular publication, means the monograph (if any) headed by that name in that edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name ;
- (b) if, together with that name, there was specified a particular publication, but not a particular edition of that publication, means the monograph (if any) headed by that name in the current edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name, or, in default of such a monograph, means the monograph headed by that name in the latest edition of the specified publication which contained a monograph so headed;
- (c) if no publication was specified together with that name, means the appropriate current monograph (if any);

and " current" means current at the time when the medicinal product in question is demanded, described in a prescription, or offered or exposed for sale, as mentioned in subsection (1) or subsection (2) of this section.

- (5) In this section " the appropriate current monograph ", in relation to a particular name, means—
  - (a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or
  - (b) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of a compendium published under Part VII of this Act, or
  - (c) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmaceutical Codex or the British Veterinary Codex.
- (6) Subject to subsection (8) of this section, for the purposes of this section an edition of a publication—
  - (a) if it is the current edition of that publication, shall be taken as it is for the time being in force (that is to say, together with any amendments, additions and deletions made to it up to the time referred to in subsection (4) of this section), or
  - (b) if it is an edition previous to the current edition of that publication, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that publication (that is to say, together with any amendments, additions and deletions made to it up to that time),

and any monograph in an edition of a publication shall be construed in accordance with any general monograph or notice or any appendix, note or other explanatory material which is contained in that edition and is applicable to that monograph, and any reference in this section to compliance with the standard specified in a monograph shall be construed accordingly.

- (7) In relation to any time on or after the date on which, by notice published in the Gazette by or on behalf of the Health Ministers, it is declared that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July 1964 is to have effect for the purposes of this section, subsections (1) and (2) of

this section shall have effect as if, after the words " that name is ", in each place where those words occur, there were inserted the words " or is an approved synonym for, " subsection (4) of this section shall have effect as if, before the words "the British Pharmacopoeia ", there were inserted the words " the European Pharmacopoeia ", and after the words " headed by that name ", in each place where those words occur, there were inserted the words " or by a name for which it is an approved synonym ", and subsection (5) of this section shall have effect as if for paragraph (a) of that subsection there were substituted the following paragraphs:—

- “(a) the monograph (if any) headed by that name, or by a name for which it is an approved synonym, in the current edition of the European Pharmacopoeia, or
- (aa) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or”.

- (8) For the purposes of this section, an edition of the European Pharmacopoeia—
- (a) if it is the current edition of that Pharmacopoeia at the time in question, shall be taken as it is for the time being in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice published as mentioned in subsection (7) of this section before the time referred to in subsection (4) of this section, have been declared to have effect for the purposes of this section), and
  - (b) if it is an edition previous to the current edition of that Pharmacopoeia, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that Pharmacopoeia in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared so to have effect),

and a name shall be taken to be an approved synonym for a name at the head of a monograph in the European Pharmacopoeia if, by a notice so published and not withdrawn by any subsequent notice so published, it has been declared to be approved by the Medicines Commission as a synonym for that name.