

Island of Guernsey

Ordinance of the States **XXV** **1982**

Made 29th September, 1982.
Came into Operation 29th September, 1982.

The Pharmacists, Poisons and Pharmacy (Amendment) Ordinance, 1982

THE STATES, on the representations of the States Board of Health, hereby order:—

1. The Pharmacists, Poisons and Pharmacy Ordinance, 1970, as amended (a), is hereby further amended as follows: Amendments
to Ordinance
of 1970.

- (a) in sub-paragraph (iii) of paragraph (a) of subsection (1) of section seventeen thereof immediately after the words “monograph in” there are inserted the words “the European Pharmacopoeia or, if there is no appropriate monograph in that publication,”;
- (b) in sub-paragraph (i) of paragraph (b) of subsection (1) of section seventeen thereof immediately after the words “monograph in” there are inserted the words “the European Pharmacopoeia or, if there is no appropriate monograph in that publication,”;

(a) Recueil d'Ordonnances Tome XVI, p. 236; Tome XVII, p. 121; Tome XIX, pp. 73 and 195; Tome XX, p. 342 and Ordinance No. IX of 1977.

- (c) in paragraph (a) of subsection (2) of section seventeen thereof immediately after the words "monograph in" there are inserted the words "the European Pharmacopoeia or, if there is no appropriate monograph in that publication,";
- (d) in paragraph (b) of subsection (2) of section seventeen thereof immediately after the words "contained in" there are inserted the words "the European Pharmacopoeia or, if there is no appropriate monograph in that publication,";
- (e) in subsection (2) of section seventeen thereof —
 - (i) immediately after the words "surgical dressing in" there are inserted the words "the European Pharmacopoeia or";
 - (ii) immediately after the words "addition of the letters" there are inserted the letters, abbreviations and word "“Ph. Eur.” or";
- (f) in subsection (4) of section seventeen thereof immediately after the words "monographs in" there are inserted the words "the European Pharmacopoeia or, if there is no appropriate monograph in that publication,";
- (g) in subsection (1) of section thirty-two thereof the words "the British Pharmacopoeia" are repealed and the words "the European Pharmacopoeia or, if there is no appropriate monograph in that publication, the British Pharmacopoeia or the British Pharmaceutical Codex" are substituted therefor;

- (h) immediately after section thirty-three thereof there is inserted the following additional section numbered “33A” —

“General
standard
of quality
and purity
of medicines.

33A. Subject to the provisions of the next succeeding section a person shall not sell any medicine unless it is of a standard of quality or purity not less than that laid down for that medicine in the European Pharmacopoeia, or the British Pharmacopoeia or the British Pharmaceutical Codex, and if the medicine is not the subject of a monograph in any of those publications, then it must be of a standard of quality or purity not less than that needed to obtain a product licence under the Medicines Act 1968.”;

- (i) the marginal note to section thirty-four thereof is deleted and the following marginal note is substituted therefor —
“Standard of quality and purity of medicines specified in the Fourteenth Schedule.”;
- (j) in section thirty-four thereof the words “the British Pharmacopoeia” are repealed and the words “the European Pharmacopoeia or, if there is no appropriate monograph in that publication, the British Pharmacopoeia or the British Pharmaceutical Codex, and if the medicine is not the subject of a monograph in any of those publications, then it must be of a standard of quality or purity not less than that needed to obtain a product licence under the Medicines Act 1968” are substituted therefor;

- (k) immediately after subsection (2) of section forty thereof there is inserted the following additional subsection numbered “(3)” —

“(3) Any power conferred by this section to make an order shall be construed as including a power exercisable in like manner to vary or repeal the order.”;

- (l) immediately after section forty thereof there is inserted the following additional section numbered “40A” —

“Compliance with standards specified in monographs in certain publications. 40A. (1) A person shall not in the course of a business carried on by him, —

- (a) sell any medicine which has been demanded by the purchaser by, or by express reference to, a particular name; or
- (b) sell or supply any medicine in pursuance of a prescription given by an authorised medical practitioner, authorised dentist or authorised veterinary surgeon in which the medicine 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 the monograph.

(2) A person shall not, in the course of a business carried on by him, sell or supply any medicine 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 medicine does not comply with the standard specified in that monograph.

(3) Where any medicine 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 medicine itself, but of an active ingredient of the medicine, then for the purposes of the subsection in question the medicine 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 the provisions of subsection (7) of this section, in this section the expression "publication" means one of the following, that is to say, the British Pharmacopoeia, the British Pharma-

ceutical Codex, the British Veterinary Codex and any compendium published under Part VII of the Medicines Act 1968 (hereafter in this section referred to as “the Act of 1968”); the expression “the relevant monograph”, in relation to the sale or supply of any medicine 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):

Provided that where in relation to a particular name a monograph is by order of the Board declared to be a monograph to which the provisions of this definition shall not apply that monograph shall not be deemed to be the relevant monograph in relation to that name for the purposes of this Ordinance; and the expression "current" means current at the time when the medicine 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 expression “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 the Act of 1968; 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 the provisions of 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 the Board by order declares that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July, 1964, shall 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 in accordance with the provisions of subsection (7) of section sixty-five of the Act of 1968 by the Health Ministers as defined in section one of the Act of 1968 before the time referred to in subsection (4) of this section, have been declared to have effect in the United Kingdom for the purposes of the said section sixty-five of the Act of 1968); 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 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 it is for the time being a synonym approved in accordance with the provisions of subsection (8) of the said section sixty-five of the Act of 1968 by the Medicines Commission established under section two of the Act of 1968 as a synonym for that name.

(9) Every order made by the Board under this section shall be laid before a meeting of the States as soon as may be after the making thereof and if, at that meeting or at the next subsequent meeting, the States resolve that the order be annulled the order shall cease to have effect but without prejudice to anything done thereunder or to the making by the Board of a new order.

(10) Any power conferred by this section to make an order shall be construed as including a power exercisable in like manner to vary or repeal the order.”;

- (m) in subsection (1) of section forty-two thereof —
- (i) the definition relating to the expressions ““British Pharmaceutical Codex”, “British Pharmacopoeia”, “British National Formulary” and “British Veterinary Codex”” is repealed;
 - (ii) immediately after the definition of the expression “dispensing” there is inserted the following additional definition:— ““European Pharmacopoeia”, “British Pharmaceutical Codex”, British Pharmacopoeia”, British National Formulary”, and “British Veterinary Codex”, include supplements”;
- (n) section forty-three thereof is repealed.

2. This Ordinance shall have effect in the Extent.
Islands of Guernsey and Herm.

3. This Ordinance may be cited as the Citation.
Pharmacists, Poisons and Pharmacy (Amendment)
Ordinance, 1982.

4. This Ordinance and the Collective
Pharmacists, Poisons and Pharmacy Ordinances, 1970 to 1977, title.
may be cited together as the Pharmacists, Poisons
and Pharmacy Ordinances, 1970 to 1982.

K. H. TOUGH

Her Majesty's Greffier.