



Medicines Act 1968

1968 CHAPTER 67

PART VII

BRITISH PHARMACOPOEIA AND OTHER PUBLICATIONS

Modifications etc. (not altering text)

- C1** Part. VII (ss. 99-103) modified (1.1.1995) by [S.I. 1994/3144, reg.9\(9\)](#)
- C2** Pt. VII amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by [Medicines \(Marketing Authorisations Etc.\) Amendment Regulations 2005 \(S.I. 2005/2759\), regs. 1\(a\), 2\(12\)](#)

98 **F1**

Textual Amendments

- F1** S. 98 repealed by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\), s. 303\(2\), Sch. 8](#)

99 **New editions of British Pharmacopoeia, and other compendia.**

- (1) The appropriate body shall, at any such time as may be determined in accordance with subsection (5) of this section, prepare or cause to be prepared a new edition of the British Pharmacopoeia, containing such relevant information relating to substances and articles to which this subsection applies as may be so determined.
- (2) The substances and articles to which the preceding subsection applies are—
 - (a) substances and articles (whether medicinal products or not) which are or may be used in the practice of medicine (other than veterinary medicine), surgery (other than veterinary surgery), dentistry or midwifery, and
 - (b) substances and articles used in the manufacture of substances or articles falling within the preceding paragraph.

Status: Point in time view as at 01/10/2006.

Changes to legislation: Medicines Act 1968, Part VII is up to date with all changes known to be in force on or before 12 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (3) Without prejudice to subsection (1) of this section, the appropriate body may, at any such time as may be determined in accordance with subsection (5) of this section, prepare or cause to be prepared any such compendium or edition as is mentioned in either of the following paragraphs, that is to say—
- (a) a compendium (other than the British Pharmacopoeia) containing such relevant information relating to substances and articles to which subsection (1) of this section applies, or any class of such substances and articles, as may be so determined, or, where such a compendium has been published under this section, a new edition of that compendium;
 - (b) a compendium containing such relevant information relating to substances and articles to which this paragraph applies, or any class of such substances and articles, as may be so determined, or, where such a compendium has been published under this section, a new edition of that compendium.
- (4) The substances and articles to which subsection (3)(b) of this section applies are—
- (a) substances and articles (whether [^{F2}veterinary medicinal products] or not) which are or may be used in the practice of veterinary medicine or veterinary surgery, and
 - (b) substances and articles used in the manufacture of substances and articles falling within the preceding paragraph.
- (5) Anything falling to be determined for the purposes of subsection (1) or subsection (3) of this section—
- (a) except where the appropriate body is the Commission, shall be determined in accordance with directions given by the Commission, or
 - (b) where the appropriate body is the Commission, shall be determined by the Commission.
- (6) Where the appropriate body has prepared or caused to be prepared a new edition of the British Pharmacopoeia or any such compendium or new edition of a compendium as is mentioned in [^{F3}subsection (3)] of this section, then, on the recommendation of the Commission, the ^{F4}... Ministers shall cause it to be published^{F5}...
^{F6}...
- (7) In this Part of this Act^{F7}—
- “the appropriate body”, in relation to any work falling to be prepared under this Part of this Act, means the committee (if any) established under section 4 of this Act whose functions consist of or include the preparation of that work or, if for the time being there is no such committee, means the Commission^{F8};
- “relevant] information”, in relation to any substances or articles, means any information consisting of descriptions of, standards for, or notes or other matter relating to, those substances or articles; and
- [^{F9}“veterinary medicinal product” has the same meaning as in the Veterinary Medicines Regulations 2006].

Textual Amendments

- F2** Words in s. 99(4)(a) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 50(a)** (with regs. 2(4), 3)

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- F3** Words in s. 99(6) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(b\)\(i\)](#) (with [regs. 2\(4\), 3](#))
- F4** Word in s. 99(6) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(b\)\(ii\)](#) (with [regs. 2\(4\), 3](#))
- F5** Words in s. 99(6) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(b\)\(iii\)](#) (with [regs. 2\(4\), 3](#))
- F6** S. 99(6) proviso repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), [Sch. 1 Pt. 17](#) Group 7
- F7** Word in s. 99(7) inserted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(c\)\(i\)](#) (with [regs. 2\(4\), 3](#))
- F8** Word in s. 99(7) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(c\)\(ii\)](#) (with [regs. 2\(4\), 3](#))
- F9** Words in s. 99(7) inserted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1, Sch. 8 para. 50\(c\)\(iii\)](#) (with [regs. 2\(4\), 3](#))

100 Lists of names.

- (1) The appropriate body shall, whenever—
 - (a) if the appropriate body is a committee established under section 4 of this Act, they are directed by the Commission to do so, or
 - (b) if that body is the Commission, the Commission consider it expedient to do so, prepare or cause to be prepared a list of names appearing to that body to be suitable names to be used as the names of any substances and articles to which subsection (1) or subsection (3)(b) of section 99 of this Act applies and to be placed at the head of monographs relating to those substances or articles in any edition of the British Pharmacopoeia, or in any compendium or edition of a compendium, prepared under that section.
- (2) Where any such list has been prepared in pursuance of the preceding subsection, then, on the recommendation of the Commission, the Ministers shall cause it to be published.
- (3) A list may be prepared and published under this section in substitution for, and so as to supersede, any list previously prepared and published thereunder.

101 Other publications.

- (1) The appropriate body shall, whenever—
 - (a) if the appropriate body is a committee established under section 4 of this Act, they are directed by the Commission to do so, or
 - (b) if that body is the Commission, the Commission consider it expedient to do so, prepare or cause to be prepared publications of any such description not falling within section 99 or section 100 of this Act as may be determined for the purposes of this subsection, being publications containing such relevant information relating to substances and articles to which subsection (1) or subsection (3)(b) of section 99 of this Act applies as may be so determined.
- (2) Where the appropriate body has prepared or caused to be prepared a publication under this section, then, on the recommendation of the Commission, [^{F10}the Ministers] may cause it to be published and may arrange for it to be made available for sale to the public or to be otherwise distributed as the Ministers ^{F11}... may determine.

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- (3) In relation to a journal or other publication of a periodical nature a direction of the Commission under subsection (1)(a) of this section, or a recommendation of the Commission under subsection (2) of this section, may be given either—
- (a) in relation to a particular issue of the publication, or
 - (b) so as to have effect, while the direction or recommendation remains in force, in relation to each successive issue of the publication.
- (4) Subsection (5) of section 99 of this Act shall have effect for the purposes of subsection (1) of this section as it has effect for the purposes of subsections (1) and (3) of that section.

Textual Amendments

- F10** Words in s. 101(2) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 51\(a\)](#) (with regs. 2(4), 3)
- F11** Word in s. 101(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 51\(b\)](#) (with regs. 2(4), 3)

102 Supplementary provisions.

- (1) The provisions of subsections (1) to (6) of section 99 of this Act shall have effect in relation to the preparation and publication of amendments of—
- (a) the British Pharmacopoeia (whether it is the edition of the Pharmacopoeia current immediately before the vesting date or any new edition of it published under that section), and
 - (b) any compendium, or new edition of a compendium, published under that section,
- as those provisions have effect in relation to the preparation and publication of new editions of the British Pharmacopoeia or any such compendium, as the case may be.
- (2) At any time on or after the vesting date the ^{F12}... Ministers may publish any amendment of the British Pharmacopoeia or of any such compendium which in the opinion of [^{F13}the Ministers] is necessary for the purpose of giving effect to the Convention referred to in section 65(7) of this Act.
- (3) The provisions of section 100 of this Act shall have effect in relation to the preparation and publication of amendments of any list published under that section as those provisions have effect in relation to the preparation and publication of any such list.
- (4) Copies of—
- (a) any new edition of the British Pharmacopoeia or of any compendium or new edition of a compendium published under section 99 of this Act;
 - (b) any list published under section 100 of this Act; and
 - (c) any such amendment as is mentioned in the preceding provisions of this section,
- shall, in accordance with arrangements made by the ^{F14}... Ministers, be made available for sale to the public.
- (5) Every such copy shall specify the date on which the subject-matter contained in it (whether it is a new edition of the British Pharmacopoeia, or a compendium or new edition of a compendium, or a list of names, or an amendment) is to take effect; and the

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^{F15}... Ministers shall also give notice of that date by notices published in the Gazette not less than twenty-one days before that date.

(6) Any document purporting to be such a copy as is mentioned in subsection (4) of this section, and to be printed by a person named in the relevant notices published in the Gazette as being a person authorised by the ^{F16}... Ministers to print copies of the subject-matter contained in it, shall be received in evidence as being a true copy of that subject-matter and shall be evidence (and, in Scotland, shall be sufficient evidence) of the date on which that subject-matter came into operation.

(7) In this section ^{F17}... “amendment” includes addition and deletion.

Textual Amendments

- F12** Word in s. 102(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(a\)\(i\)](#) (with regs. 2(4), 3)
- F13** Words in s. 102(2) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(a\)\(ii\)](#) (with regs. 2(4), 3)
- F14** Word in s. 102(4) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(b\)](#) (with regs. 2(4), 3)
- F15** Word in s. 102(5) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(c\)](#) (with regs. 2(4), 3)
- F16** Word in s. 102(6) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(d\)](#) (with regs. 2(4), 3)
- F17** Words in s. 102(7) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 52\(e\)](#) (with regs. 2(4), 3)

103 Construction of references to specified publications.

- (1) In this section “specified publication” means any of the following, that is to say—
- (a) the European Pharmacopoeia;
 - (b) the British Pharmacopoeia;
 - (c) the British Pharmaceutical Codex;
 - ^{F18}(ca) the International Pharmacopoeia;
 - (cb) the Cumulative List of Recommended International Nonproprietary Names;]
 - ^{F19}(d)
 - (e) the British National Formulary;
 - (f) the Dental Practitioners’ Formulary;
 - (g) any compendium prepared under subsection (3) and published under subsection (6) of section 99 of this Act; and
 - (h) any list of names prepared and published under section 100 of this Act.
- (2) Where any licence granted or certificate issued under Part II of this Act refers to a specified publication, but not to a particular edition of that publication, then, for the purpose of determining whether anything done, at a time when the licence or certificate is in force, is done in accordance with the licence or certificate, the reference shall, unless the licence or certificate otherwise expressly provides, be construed as a reference to the current edition of that publication as in force at that time.
- (3) Where under any enactment [^{F20}contained in this Act or in any other] Act (whether passed before or after the passing of this Act) there is power to make any regulations,

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rules, order, list or other instrument which is to have effect by virtue of, or for the purposes of, that enactment, and an instrument made in the exercise of that power—

- (a) could be made so as to refer to the current edition of a specified publication as in force at the time when the instrument is made, but
- (b) could not, apart from this subsection, be made so as to refer to the current edition of a specified publication as in force at a subsequent time,

the power to make the instrument may (unless, in the case of an enactment passed after this Act, the enactment otherwise expressly provides) be exercised so as to refer to the current edition of a specified publication as in force at such time (whether before, at or after the time when the instrument is made) as may be specified in, or determined in accordance with, the instrument.

- (4) Where any such power as is mentioned in subsection (3) of this section (in this subsection referred to as “the primary power”) includes power to vary instruments made in the exercise of the primary power, subsection (3) of this section shall have effect in relation to any exercise of the power to vary any such instrument (whether the instrument was made before, or is made after, the passing of this Act) as it has effect in relation to any exercise of the primary power.
- (5) In this section any reference to the current edition of a specified publication as in force at a particular time is a reference to the edition of that publication in force [^{F21}, under whatever title,] at that time together with any amendments, additions and deletions made to it up to that time; and any reference to making an instrument in the exercise of a power conferred by an enactment shall be construed as including a reference to issuing or approving such an instrument.

Textual Amendments

- F18** S. 103(1)(ca)(cb) inserted by [Health and Medicines Act 1988 \(c.49, SIF 113:2, 84\), s. 22\(1\)](#)
- F19** S. 103(1)(d) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\), reg. 1, Sch. 8 para. 53](#) (with regs. 2(4), 3)
- F20** Words substituted by [Health and Medicines Act 1988 \(c. 49, SIF 113:2, 84\), s. 22\(4\)](#)
- F21** Words inserted by [Health and Medicines Act 1988 \(c. 49, SIF 113:2, 84\), s. 22\(6\)](#)

Modifications etc. (not altering text)

- C3** S. 103 applied (with modifications) (1.1.1995) by [S.I. 1994/3144, reg. 9\(8\)](#)
- C4** S. 103 amendment to earlier affecting provision [SI 1994/3144 reg. 9 \(30.10.2005\)](#) by [Medicines \(Marketing Authorisations Etc.\) Amendment Regulations 2005 \(S.I. 2005/2759\), regs. 1\(a\), 2\(12\)](#)

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