Medicines Act 1968

1968 CHAPTER 67

PART I

ADMINISTRATION

Modifications etc. (not altering text)
C1 Pt. I (ss. 1-5) modified (3.4.1992) by S.I. 1992/605, **regs. 2(3)**, 3

1 Ministers responsible for administration of Act.

(1) In this Act—

(a) "**[**F1the Ministers**]**" means the following Ministers, that is to say, **[**F2the Secretary of State F3...**]** and the Minister of Health and Social Services for Northern Ireland, and, in the case of anything falling to be done by **[**F1the Ministers**]**, means those Ministers acting jointly;

F4(b) . . . . . .

F4...

F5(2) . . . . . .

Textual Amendments
F1 Words in s. 1(1)(a) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 2(a)(i)** (with regs. 2(4), 3)
F2 Words in s. 1(1)(a) substituted (27.12.1999) by S.I. 1999/3142, art. 5, **Sch. para. 1(1)** (with art. 4)
F3 Words in s. 1(1)(a) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 2(a)(i)** (with regs. 2(4), 3)
F4 S. 1(1)(b) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 2(a)(ii)** (with regs. 2(4), 3)
F5 S. 1(2) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 2(b)** (with regs. 2(4), 3)

Modifications etc. (not altering text)

C2 Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**

C3 S. 1 extended (3.4.1992) by S.I. 1992/605, **regs. 2(4)**, 3

[F6]2 Establishment of Medicines Commission.

. . . . . .

Textual Amendments

F6 S. 2 repealed (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **2(2)**

Modifications etc. (not altering text)

C4 Pt. I (ss. 1–5) extended by S.I. 1984/187, **art. 2**

C5 S. 2: Certain functions made exercisable (S.) (30.6.1999) by virtue of S.I. 1999/1748, art. 3, **Sch. 1 para. 3**

[F7]2A. Establishment of the Commission on Human Medicines

(1) There shall be established a body of persons to be called the Commission on Human Medicines (referred to in this Act as "the Commission") to perform the functions assigned to the Commission by or under this Act.

(2) The Ministers shall appoint the members of the Commission.

(3) The Commission shall have at least eight members.

(4) The Ministers shall appoint the chairmen of the Expert Advisory Groups referred to in paragraphs (a) to (c) of paragraph 4(1) of Schedule 1A to this Act as members of the Commission.

(5) The Ministers shall appoint one of the members of the Commission to be chairman of the Commission.**]**

Textual Amendments

F7 S. 2A inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **3**

[F8 3 Functions of the Commission

(1) The Commission shall give to **[**F9either or both of the Ministers**]** advice on matters—

(a) relating to the execution of this Act,

(b) relating to the exercise of any power conferred by this Act,

(c) **[**F10relating to the execution of the Marketing Authorization Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations,**]**

(d) relating to the exercise of any power conferred by those regulations, or

(e) otherwise relating to medicinal products,

where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question, to do so.

(2) Without prejudice to the preceding subsection, and to any other duties or powers imposed or conferred on the Commission by or under this Act, **[**F11the Marketing Authorization Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations**]**, it shall be the duty of the Commission—

(a) to—

(i) give advice with respect to safety, quality or efficacy in relation to medicinal products,

(ii) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given, and

(iii) undertake the functions mentioned in section 4(4) of this Act,

except in so far as those functions are for the time being assigned to a committee established under section 4 of this Act; and

(b) to advise the licensing authority in cases where the authority—

(i) are required by the provisions of Part 2 of this Act, or by the provisions of **[**F12the Marketing Authorization Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations**]**, to consult the Commission with respect to any matter arising under those provisions, or

(ii) without being required to do so, elect to consult the Commission with respect to any matter arising under any of those provisions.**]**

Textual Amendments

F8 S. 3 substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **4**

F9 Words in s. 3(1) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 3** (with regs. 2(4), 3)

F10 S. 3(1)(c) substituted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 1(2)**

F11 Words in s. 3(2) substituted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 1(3)(a)**

F12 Words in s. 3(2)(b)(i) substituted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 1(3)(b)**

Modifications etc. (not altering text)

C6 Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**

C7 S. 3 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(3)**
S. 3 modified (1.1.1995) by S.I. 1994/3144, **reg.9(1)**

C8 S. 3 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)**

4 Establishment of committees.

(1) The Ministers**F13**...**F14**... may by order establish one or more committees under this section.

(2) A committee may be so established for any purpose, or combination of purposes, **[**F15connected with—

(a) the execution of this Act **[**F16, the Marketing Authorisation Regulations**][**F17, the Homoeopathic Regulations, the Herbal Regulations**]**or the Clinical Trials Regulations, or

(b) the exercise of any power conferred by this Act or those regulations,

either generally or in relation to any particular class of substances or articles to which any provision of this Act or those regulations applies.**]**

(3) Without prejudice to the generality of subsection (2) of this section, in relation to any such class of substances or articles a committee may be established under this section for either or both of the following purposes, that is to say—

(a) giving advice with respect to safety, quality or efficacy, or with respect to all or any two of those matters;

(b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given.

(4) A committee or committees may be established under this section for the purpose of performing any function under Part VII of this Act in relation to the British Pharmacopoeia or in relation to any such compendium or list of names or other publication as is mentioned in that Part of this Act.

[F18(4A) A committee established under this section shall have at least eight members.**]**

(5) The Ministers F19... shall appoint the members of the committee, and shall appoint one of those members to be chairman of the committee.

F20(5A) . . . . . .

[F21(6) In this Act "the appropriate committee", for the purposes of any provision of this Act under which a function falls to be performed, means—

(a) in a case where—

(i) a committee has been established under this section for purposes which consist of or include any of those specified in subsection (3) of this section, and

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission.**]**

Textual Amendments

F13 Words in s. 4(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 4(a)** (with regs. 2(4), 3)

F14 Words in s. 4(1) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **5(2)**

F15 Words in s. 4(2) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 2**

F16 Words in s. 4(2)(a) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **5(3)**

F17 Words in s. 4(2)(a) inserted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 2**

F18 S. 4(4A) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **5(4)**

F19 Words in s. 4(5) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 4(b)** (with regs. 2(4), 3)

F20 S. 4(5A) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 4(c)** (with regs. 2(4), 3)

F21 S. 4(6) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **5(5)**

Modifications etc. (not altering text)

C9 Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**

C10 S. 4 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(3)**
S. 4 modified (1.1.1995) by S.I. 1994/3144, **reg. 9(1)**

C11 S. 4 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)**

C12 S. 4(1)(5): Certain functions made exercisable (S.) (30.6.1999) by S.I. 1999/1748, art. 3, **Sch. 1 para. 3**

C13 S. 4(2)(3) modified (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, **s. 63(8)** (with ss. 64(9), 65(4)); S.I. 2002/1095, **art. 2(1)**

C14 s. 4(5) amended (S.) (1.7.1999) by S.I. 1999/1750, art. 4, **Sch. 3** (with art. 7)

5 Supplementary provisions as to Commission and committees.

(1) The provisions of **[**F22Schedule 1A**]** to this Act shall have effect with respect to the Commission, to any committee established under section 4 of this Act and to the other matters mentioned in that Schedule.

[F23(2) The Commission shall, at such time in each year as the Ministers may direct, send to the Ministers F24... a report with respect to—

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.**]**

[F25(3) Each committee established under section 4 of this Act shall, at such time in each year as the Ministers may direct, send to the Ministers F26... a report with respect to—

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.**]**

(4) Subject to the next following subsection, the Ministers, after consultation with the Commission, may by order—

(a) add to, revoke or vary any of the provisions of **[**F27Schedule 1A**]** to this Act in its application to the Commission, or

(b) confer on the Commission any new function for purposes connected with medicinal products or related matters, or

(c) terminate any function conferred on the Commission by or under this Act, or

(d) vary any such function, so however as not to confer on the Commission any new function which could not be conferred on them in accordance with paragraph (b) of this subsection.

(5) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

Textual Amendments

F22 Words in s. 5(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(2)**

F23 S. 5(2) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(3)**

F24 Words in s. 5(2) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 5(a)** (with regs. 2(4), 3)

F25 S. 5(3) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(4)**

F26 Words in s. 5(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 5(b)** (with regs. 2(4), 3)

F27 Words in s. 5(4)(a) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(5)**

Modifications etc. (not altering text)

C15 Pt. I (ss. 1–5) extended by S.I. 1984/187, **art. 2**

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

Changes to legislation:
Medicines Act 1968, Part I is up to date with all changes known to be in force on or before 09 August 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.