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) "the Health Ministers" means the following Ministers, that is to say, **[**[F1]the Secretary of State concerned with health in England**]** and the Minister of Health and Social Services for Northern Ireland, and, in the case of anything falling to be done by the Health Ministers, means those Ministers acting jointly;

(b) "the Agriculture Ministers" means the following Ministers, that is to say, the **[**[F2]Secretary of State for Environment, Food and Rural Affairs**]**, [F3]. . . and the Minister of Agriculture for Northern Ireland, and, in the case of anything falling to be done by the Agriculture Ministers, means those Ministers acting jointly,

and "the Ministers" means [F4]. . . the Ministers **[**[F5]for Northern Ireland**]**specified in paragraphs (a) and (b) of this subsection **[**[F6]and the Secretary of State**]**, and, in the case of anything falling to be done by the Ministers, means all those Ministers acting jointly.

(2) In this Act, except where the contrary is expressly provided, "the appropriate Ministers"—

(a) for the purpose of performing any function under this Act (whether by the making of any regulations or order or otherwise) where the function is performed exclusively in relation to matters other than veterinary drugs and the treatment of diseases of animals, means the Health Ministers; and

(b) in any other case, means the Ministers.

Textual Amendments

F1 Words in s. 1(1)(a) substituted (27.12.1999) by S.I. 1999/3142, art. 5, **Sch. para. 1(1)** (with art. 4)

F2 S. 1(1): words in definition of "the Agricultural Ministers"substituted (27.3.2002) by S.I. 2002/794, art. 5(1), **Sch. 1 para. 15(1)(2)** (with arts. 5(3), 6)

F3 Words in s. 1(1)(b) repealed (27.12.1999) by S.I. 1999/3142, art. 5, **Sch. para. 1(2)** (with art. 4)

F4 Word in s. 1(1) repealed (27.3.2002) by S.I. 2002/794, art. 5(2), **Sch. 2** (with art. 6)

F5 S. 1(1): words in definition of "the Ministers"inserted (27.3.2002) by S.I. 2002/794, art. 5(1), **Sch. 1 para. 15(1)(3)(a)** (with arts. 5(3), 6)

F6 S. 1(1): words in definition of "the Ministers"inserted (27.3.2002) by S.I. 2002/794, art. 5(1), **Sch. 1 para. 15(1)(3)(b)** (with arts. 5(3), 6)

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

2 Establishment of Medicines Commission.

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

(2) The members of the Commission, of whom there shall be not less than eight, shall be appointed by the Ministers after consultation with such organisations as they consider appropriate, and, in relation to each of the activities specified in the next following subsection, shall include at least one person appearing to the Ministers to have wide and recent experience of, and to have shown capacity in, that activity.

(3) The activities referred to in subsection (2) of this section are—

(a) the practice of medicine (other than veterinary medicine);

(b) the practice of veterinary medicine;

(c) the practice of pharmacy;

(d) chemistry other than pharmaceutical chemistry;

(e) the pharmaceutical industry.

(4) The Ministers shall appoint one of the members of the Commission to be chairman of the Commission.

(5) The Medicines Commission shall by that name be a body corporate having perpetual succession and a common seal.

(6) F7

Textual Amendments

F7 S. 2(6) repealed by House of Commons Disqualification Act 1975 (c. 24), **Sch. 3** and Northern Ireland Assembly Disqualification Act 1975 (c. 25), **Sch. 3 Pt. I**

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**

C6 S. 2(2)(4) amended (S.) (1.7.1999) by S.I. 1999/1750, art. 4, **Sch. 3** (with art. 7)

3 General functions of Commission.

(1) The Commission shall give to any one or more of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act **[**F8advice on matters—

(a) relating to the execution of this Act,

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

(c) relating to the execution of 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**[**F9or the Clinical Trials Regulations**]**, it shall be the duty of the Commission—

(a) to make recommendations to the Ministers with regard to the number of committees to be established under section 4 of this Act and with regard to the functions to be assigned to each such committee;

(b) in relation to any such committee, to recommend to any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act such persons (whether members of the Commission or other persons) as the Commission consider well qualified to serve as members of that committee;

(c) from time to time (where either the Commission consider it expedient, or they are requested by the Ministers, to do so) to review the committees established under section 4 of this Act and to make recommendations to the Ministers with regard to any changes in their number or functions which the Commission consider appropriate;

[F10(d) to advise the licensing authority in cases where the authority—

(i) are required by the provisions of Part II of this Act, or by the provisions of the Clinical Trial 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.**]**

(e) to undertake the functions specified in subsection (3) of section 4 of this Act, in so far as those functions relate to medicinal products and are not for the time being assigned to a committee established under that section, and to undertake the functions mentioned in subsection (4) of that section in so far as those functions are not for the time being assigned to such a committee.

Textual Amendments

F8 Words in s. 3(1) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 1(2)**

F9 Words in s. 3(2) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 1(3)**

F10 S. 3(2)(d) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 1(4)**

Modifications etc. (not altering text)

C7 Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**

C8 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)**

4 Establishment of committees.

(1) The Ministers, the Health Ministers or the Agriculture Ministers, having regard to any recommendations made by the Commission under section 3(2) of this Act, and after consultation with such organisations as the Ministers concerned consider appropriate, 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, **[**[F11]connected with—

(a) the execution of this Act 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.

(5) The Ministers by whom a committee is established under this section shall appoint the members of the committee, and shall appoint one of those members to be chairman of the committee.

[[F12](5A) Where a committee is established under this section for purposes including the consideration of veterinary products as defined in section 29(2) of the Food Standards Act 1999, one member of the committee shall be appointed by the Ministers establishing the committee on the nomination of the Food Standards Agency.**]**

(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 such committee established under this section for purposes which consist of or include any of those specified in subsection (3) of this section as the authority performing that function considers appropriate in the circumstances.

Textual Amendments

F11 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**

F12 S. 4(5A) inserted (1.4.2000) by 1999 c. 28, s. 18, **Sch. 3 Pt III**, para. 15(2) (with s. 38); S.I. 2000/1066, **art. 2**

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

C12 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)**

C13 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 Schedule 1 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.

(2) The Commission shall, at such time in each year as the Ministers may direct, send to the Ministers **[**F13specified in paragraphs (a) and (b) of section 1(1) of this Act**]** a report with respect to the performance of their functions and of the functions of any committee appointed by them; and **[**F14the Secretary of State**]**. . .shall F15. . . lay before Parliament a copy of every such report.

(3) Each committee established under section 4 of this Act shall, at such time in each year as the Commission may direct, send to the Commission and to the Ministers **[**F13specified in paragraphs (a) and (b) of section 1(1) of this Act**]** a report with respect to the performance of their functions; and any report of the Commission under this section may include such information relating to the performance of the functions of any such committee as the Commission consider appropriate.

(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 Schedule 1 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

F13 Words in s. 5(2)(3) inserted (27.3.2002) by S.I. 2002/794, art. 5(1), **Sch. 1 para. 16** (with arts. 5(3), 6)

F14 Words in s. 5(2) substituted (27.12.1999) by S.I. 1999/3142, art. 5, **Sch. para. 1(3)** (with art. 4)

F15 Words in s. 5(2) repealed (27.3.2002) by S.I. 2002/794, art. 5(2), **Sch. 2** (with art. 6)

Modifications etc. (not altering text)

C14 Pt. I (ss. 1–5) extended by S.I. 1984/187, **art. 2**

Status:
Point in time view as at 01/05/2004.

Changes to legislation:
Medicines Act 1968, Part I is up to date with all changes known to be in force on or before 10 July 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.