



# Medicines Act 1968

## 1968 CHAPTER 67

An Act to make new provision with respect to medicinal products and related matters,  
and for purposes connected therewith. [25th October 1968]

### Modifications etc. (not altering text)

- C1** References to Ministers of Northern Ireland to be construed as references to heads of Northern Ireland departments: [Northern Ireland Constitution Act 1973 \(c. 36\)](#), [Sch. 5 para. 7](#)
- C2** Functions of Ministry of Home Affairs for Northern Ireland transferred to Department of Health and Social Services for Northern Ireland by S.R. & O. (N.I.) 1973 No. 504, [art. 5](#), [Sch. 2 Pt. I](#)
- C3** Functions exercisable by Ministers jointly under this Act (except s. 108(4)(7) now exercisable by those Ministers and Secretary of State for Wales jointly: [S.I. 1978/272](#), [art. 2\(3\)](#), [Sch. 1](#); references to Minister of Agriculture, Fisheries and Food amended (W.): *ibid.*, [art. 11\(6\)](#)
- C4** Act restricted by [S.I. 1985/273](#), [reg. 3\(3\)](#)
- C5** Act amended (N.I.) (1.4.1992) by [S.I. 1991/194 \(N.I. 1\)](#), [art. 7\(2\)](#), [Sch. 2 para. 5\(1\)](#); S.R. 1991/131, [art. 2\(e\)](#), [Sch. Pt. III](#)
- C6** Certain provisions of the Act extended and modified (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)
- C7** Act excluded in part (6.5.1998) by [S.I. 1998/1046](#), [reg. 43](#)  
Act excluded in part (6.5.1998) by [S.I. 1998/1047](#), [reg. 74](#)  
Act excluded in part (2.8.1999) by [S.I. 1999/1871](#), [reg. 92\(1\)](#)
- C8** Act: functions transferred (27.12.1999) by [S.I. 1999/3142](#), [art. 2\(1\)\(2\)](#) (with [art. 4](#))  
Act: functions transferred (27.3.2002) by [S.I. 2002/794](#), [art. 3\(1\)\(c\)\(2\)\(7\)](#) (with [art. 6](#))
- C9** Act excluded (30.10.2005) by [The Veterinary Medicines Regulations 2005 \(S.I. 2005/2745\)](#), [reg. 44\(1\)](#)

## PART I

### ADMINISTRATION

### Modifications etc. (not altering text)

- C10** Pt. I (ss. 1-5) modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\)](#), 3

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 1 Ministers responsible for administration of Act.

(1) In this Act—

- (a) “the Health Ministers” means the following Ministers, that is to say, [<sup>F1</sup>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 [<sup>F2</sup>Secretary of State for Environment, Food and Rural Affairs], <sup>F3</sup>. . . 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 <sup>F4</sup>. . . the Ministers [<sup>F5</sup>for Northern Ireland]specified in paragraphs (a) and (b) of this subsection [<sup>F6</sup>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)

- C11** Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**
- C12** S. 1 extended (3.4.1992) by S.I. 1992/605, **regs. 2(4), 3**

## <sup>F7</sup>2 Establishment of Medicines Commission.

### Textual Amendments

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

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### Modifications etc. (not altering text)

- C13** Pt. I (ss. 1–5) extended by [S.I. 1984/187, art. 2](#)
- C14** S. 2: Certain functions made exercisable (S.) (30.6.1999) by virtue of [S.I. 1999/1748, art. 3, Sch. 1 para. 3](#)

### [<sup>F8</sup>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

- F8** S. 2A inserted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\), regs. 1\(1\), 3](#)

### [<sup>F9</sup>3 Functions of the 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 advice on matters—
  - (a) relating to the execution of this Act,
  - (b) relating to the exercise of any power conferred by this Act,
  - (c) [<sup>F10</sup>relating 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, [<sup>F11</sup>the 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

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (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 [<sup>F12</sup>the 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

- F9** S. 3 substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), 4
- 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)

- C15** Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**
- C16** 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)**
- C17** 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, the Health Ministers or the Agriculture Ministers<sup>F13</sup>... 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, [<sup>F14</sup>connected with—
  - (a) the execution of this Act [<sup>F15</sup>, the Marketing Authorisation Regulations][<sup>F16</sup>, 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.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

(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.

[<sup>F17</sup>(4A) A committee established under this section shall have at least eight members.]

(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.

[<sup>F18</sup>(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.]

[<sup>F19</sup>(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 (30.10.2005) by virtue of [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), regs. 1(1), **5(2)**
- F14** 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**
- F15** 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)**
- F16** 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**
- F17** S. 4(4A) inserted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), regs. 1(1), **5(4)**
- F18** 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**
- F19** 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)

- C18** Pt. I(ss. 1–5) extended by S.I. 1984/187, **art. 2**
- C19** 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)**
- C20** 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)**
- C21** S. 4(1)(5): Certain functions made exercisable (S.) (30.6.1999) by S.I. 1999/1748, art. 3, **Sch. 1 para. 3**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- C22** 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)**
- C23** 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 [<sup>F20</sup>Schedule 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.
- [<sup>F21</sup>(2) The Commission shall, at such time in each year as the Ministers may direct, send to the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act 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.]
- [<sup>F22</sup>(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 specified in paragraphs (a) and (b) of section 1(1) of this Act 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 [<sup>F23</sup>Schedule 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

- F20** Words in s. 5(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(2)**
- F21** S. 5(2) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), regs. 1(1), **6(3)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**F22** S. 5(3) substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), regs. 1(1), **6(4)**

**F23** 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)**

**C24** Pt. I (ss. 1–5) extended by [S.I. 1984/187](#), **art. 2**

## PART II

### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

#### *General provisions and exemptions*

#### **6 The licensing authority.**

- (1) For the purposes of this Part of this Act the authority responsible for the grant, renewal, variation, suspension and revocation of licences and certificates shall be a body of Ministers consisting of all the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act.
- (2) Any function conferred on the licensing authority by or under this Act may be performed by any one of those Ministers acting alone or by any two or more of them acting jointly.
- (3) In accordance with the preceding provisions of this section, in this Act “the licensing authority” means any one or more of those Ministers, and, in the case of anything falling to be done by the licensing authority, means any one or more of those Ministers acting as mentioned in subsection (2) of this section.

**Modifications etc. (not altering text)**

**C25** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

**C26** S. 6 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch. S. 6 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19**, **Sch. 4**

**C27** S. 6 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(2)**

#### **7 General provisions as to dealing with medicinal products.**

- (1) The following provisions of this section shall have effect subject to—
  - (a) any exemption conferred by or under this Part of this Act;
  - (b) the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals; and
  - (c) the provisions of section 48 of this Act.
- (2) Except in accordance with a licence granted for the purposes of this section (in this Act referred to as a “product licence”) no person shall, in the course of a business carried on by him, and in circumstances to which this subsection applies,—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) sell, supply or export any medicinal product, or
- (b) procure the sale, supply or exportation of any medicinal product, or
- (c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

<sup>F24</sup>(2A) .....

<sup>F24</sup>(2B) .....

(3) No person shall import any medicinal product except in accordance with a product licence.

[<sup>F25</sup>(3A) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the Clinical Trials Regulations.]

[<sup>F26</sup>(3B) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is a homoeopathic medicinal product to which the 2001 Directive applies and which fulfils the conditions laid down in Article 14(1) of that Directive.]

(4) In relation to an imported medicinal product, subsection (2) of this section applies to circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product, has himself imported the product or procured its importation.

(5) In relation to any medicinal product which has not been imported, subsection (2) of this section applies to any circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product,

- [<sup>F27</sup>(a) is responsible for the composition of the product, or
- [ if that product is a proprietary medicinal product [<sup>F29</sup>, a ready-made veterinary drug or an industrially produced medicinal product other than a veterinary drug], is responsible for the placing of the product on the market in the United Kingdom.]]

(6) For the purposes of subsection (5) of this section a person shall be taken to be responsible for the composition of a medicinal product if (but only if) in the course of a business carried on by him—

- (a) he procures the manufacture of the product to his order by another person, where the order specifies, or incorporates by reference to some other document, particulars of the composition of the product ordered, whether those particulars amount to a complete specification or not, or
- (b) he manufactures the product otherwise than in pursuance of an order which fulfils the conditions specified in the preceding paragraph.

[<sup>F30</sup>(6A) Where the product which a person is responsible for placing on the market in the United Kingdom is not a veterinary drug, subsection (5)(b) of this section shall not apply if the product is—

- <sup>F31</sup>(a) .....
- (b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, <sup>F32</sup> . . .



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

<sup>F32</sup>(c) . . .

(6B) Where the product which a person is responsible for placing on the market in the United Kingdom is a veterinary drug, subsection (5)(b) of this section shall not apply if the product is—

- (a) a vaccine, toxin or serum,
- (b) a product based on radioactive isotopes,
- (c) a product specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under his care,
- (d) a homoeopathic medicinal product, or
- (e) an additive for animal feeding stuffs to which the provisions of Council Directive [70/524/EEC](#) apply. ]

<sup>F33</sup>(7) <sup>F34</sup>In this section—

<sup>F35</sup><sup>F36</sup> ...

“homoeopathic medicinal product” means any medicinal product (which may contain a number of principles) prepared from <sup>F37</sup> ..., substances <sup>F37</sup> ... called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State; ]

“proprietary medicinal product” means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack;

“radiopharmaceutical” means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose; and]

“ ready-made veterinary drug ” means a ready-prepared veterinary drug placed on the market in the United Kingdom in a pharmaceutical form in which it may be used without further processing, not being a drug placed on the market under a special name and in a special pack; <sup>F38</sup> . . . ]

#### Textual Amendments

- F24** S. 7(2A)(2B) repealed (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005](#) (S.I. 2005/2753), reg. 1(1), **Sch. para. 1(2)**
- F25** S. 7(3A) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004](#) (S.I. 2004/1031), reg. 1, **Sch. 10 para. 3**
- F26** S. 7(3B) inserted (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005](#) (S.I. 2005/2753), reg. 1(1), **Sch. para. 1(3)**
- F27** Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 2(2)** and (N.I.) S.R. 1977 No. 170, **reg. 3**
- F28** S. 7(5)(b) substituted by S.I. 1983/1724, **art. 2(2)**
- F29** Words in S. 7(5)(b) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(2), 4**
- F30** S. 7(6A)(6B) inserted (3.4.1992) by S.I. 1992/604, **regs. 2(3), 4**
- F31** S. 7(6A)(a) omitted (8.11.2005) by virtue of [The Blood Safety and Quality Regulations 2005](#) (S.I. 2005/50), **regs. 1(2), 25(1)(a)** (with reg. 2(2)-(4))
- F32** In s. 7(6A) para.(c) and word “or” omitted (13.2.1994) by S.I.1994/276, **reg.3(3)(b)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
- F33** S. 7(7) substituted by S.I. 1983/1724, **art. 2(3)**
- F34** Words in s. 7(7) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(4), 4**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- F35** Words in s. 7 repealed (30.10.2005) by Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005 (S.I. 2005/2753), reg. 1(1), **Sch. para. 1(4)(a)**
- F36** Definitions in s. 7(7) inserted (13.2.1994) by S.I. 1994/276, **reg. 3(4)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
- F37** Words in s. 7 repealed (30.10.2005) by Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005 (S.I. 2005/2753), reg. 1(1), **Sch. para. 1(4)(b)**
- F38** Words in s. 7(7) repealed (3.4.1992) by S.I. 1992/604, **regs. 2(5), 4**

#### **Modifications etc. (not altering text)**

- C28** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C29** S. 7 excluded by S.I. 1989/2325, **art. 2(1)**
- C30** S. 7 excluded (11.12.1992) by S.I. 1992/2844, **art. 2**  
S. 7 excluded (31.12.1994) by S.I. 1994/2986, **reg.3(1)**  
S. 7 excluded (1.1.1995) by S.I. 1994/3142, **reg. 18(1)**  
S. 7 excluded (1.1.1995) by S.I. 1994/3144, **reg.9(2)**
- C31** S.7 excluded by S.I. 1981/164, **art. 3**
- C32** S. 7 excluded (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), **regs. 1(a), 10(1)** (with Sch. 6)
- C33** S. 7 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)**
- C34** S. 7(1)(a)(2)(4)(5)(6) applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2), Sch.**

## **8 Provisions as to manufacture and wholesale dealing.**

- (1) The following provisions of this section shall have effect without prejudice to the operation of section 7 of this Act, but subject to the exemptions and provisions referred to in paragraphs (a) to (c) of subsection (1) of that section.
- (2) [<sup>F39</sup>Subject to [<sup>F40</sup>subsections (2A) and (2C)] of this section]No person shall, in the course of a business carried on by him, [<sup>F41</sup>manufacture, assemble or import from a third country] any medicinal product except in accordance with a licence granted for the purposes of this subsection (in this Act referred to as a “manufacturer’s licence”).
- [<sup>F42</sup>(2A) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) of this section only apply—
- (a) if the product has a product licence or marketing authorization, and
  - (b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that licence or authorization.]

[<sup>F42</sup>(2B) In subsection (2A) of this section—

“investigational medicinal product” has the meaning given by the Clinical Trials Regulations; and

“marketing authorization” means—

    - (a) a marketing authorization issued by a competent authority in accordance with Directive 2001/83/EC, or
    - (c) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93 . ]

[<sup>F43</sup>(2C) The prohibition in subsection (2) does not apply to a person who, in connection with the importation of a medicinal product from a third country—

      - (a) provides facilities solely for transporting the product, or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) in the course of a business carried on by him as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.]
- [<sup>F43</sup>(2D) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—
  - (a) with which the holder of a manufacturer's licence must comply, and
  - (b) which are to have effect as if they were provisions of the licence.]
- [<sup>F44</sup>( 3 ) [<sup>F45</sup>Subject to [<sup>F46</sup>subsections (3C) and (3D)] of this section,] no person shall, in the course of a business carried on by him—
  - (a) sell, or offer for sale, any medicinal product by way of wholesale dealing, or
  - ( b ) distribute, otherwise than by way of sale, any proprietary medicinal product [<sup>F47</sup>, ready-made veterinary drug or industrially produced medicinal product other than a veterinary drug] which has been imported, but was not consigned from a member State,  
except in accordance with a [<sup>F48</sup>wholesale dealer's licence].]
- [<sup>F49</sup>(3A) Without prejudice to the generality of subsection (3) of this section but subject to [<sup>F50</sup>subsections (3C) and (3D)], no person shall, in the course of a business carried on by him, distribute by way of wholesale dealing a product to which [<sup>F51</sup>the 2001 Directive applies] apply except in accordance with a wholesale dealer's licence.
  - (3B) Distribution of such a product by way of wholesale dealing shall not be taken to be in accordance with a wholesale dealer's licence unless, in particular, it occurs in the course of a business which is carried on at a place or places specified in the licence.
  - (3C) The restrictions imposed by subsections (3) and (3A) of this section do not apply to anything done in relation to a product to which [<sup>F51</sup>the 2001 Directive applies] apply by the holder of a manufacturer's licence in respect of it.]
- [<sup>F52</sup>(3D) The restrictions imposed by subsections (3) and (3A) of this section do not apply where the product concerned is an investigational medicinal product within the meaning given by the Clinical Trials Regulations.]
- [<sup>F53</sup>(3E) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—
  - (a) with which the holder of a wholesale dealer's licence must comply, and
  - (b) which are to have effect as if they were provisions of the licence.]
- [<sup>F54</sup>(4) Where the product which a person distributes is not a veterinary drug, subsection (3) (b) of this section shall not apply if the product is—
  - <sup>F55</sup>(a) .....
  - (b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, [<sup>F56</sup>...]
  - <sup>F56</sup>( c ) ...
- (5) Where the product which a person distributes is a veterinary drug, subsection (3)(b) of this section shall not apply if the product is—
  - (a) a vaccine, toxin or serum,
  - (b) a product based on radioactive isotopes,
  - (c) a product specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under his care,

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (d) a homoeopathic medicinal product, or
  - (e) an additive for animal feeding stuffs to which the provisions of Council Directive [70/524/ EEC](#) apply.
- (6) In this section, [<sup>F57</sup>homoeopathic medicinal product,]“proprietary medicinal product”, “radiopharmaceutical” and “ready-made veterinary drug” have the same meanings as in section 7 of this Act.]
- [<sup>F58</sup>(7) In this section any reference to distribution of a product by way of wholesale dealing is a reference to—
- (a) selling or supplying it, or
  - (b) procuring, holding or exporting it for the purposes of sale or supply, to a person who receives it for the purposes of—
    - (i) selling or supplying it, or
    - (ii) administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person.
- (8) In this Act any reference to a wholesale dealer’s licence is a reference to a licence granted for the purposes of subsection (3) or (3A) of this section.]

#### Textual Amendments

- F39** Words in s. 8(2) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 4\(2\)](#)
- F40** Words in s. 8(2) substituted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), [reg. 1\(1\)](#), [Sch. 5 para. 1\(2\)\(a\)](#) (with [Sch. 6](#))
- F41** Words in s. 8(2) substituted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), [reg. 1\(1\)](#), [Sch. 5 para. 1\(2\)\(b\)](#) (with [Sch. 6](#))
- F42** S. 8(2A)(2B) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 4\(3\)](#)
- F43** S. 8(2C)(2D) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), [reg. 1\(1\)](#), [Sch. 5 para. 1\(3\)](#) (with [Sch. 6](#))
- F44** S. 8(3)(4) substituted for s. 8(3) by (E.W.)(S.) [S.I. 1977/1050](#), [art. 3\(2\)](#) and (N.I.) [S.R. 1977 No. 170](#), [reg. 4](#)
- F45** Words in s. 8(3) inserted (14.4.1993) by [S.I. 1993/834](#), [reg. 2\(2\)](#)
- F46** Words in s. 8(3) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 4\(4\)](#)
- F47** Words in s. 8(3)(b) substituted (3.4.1992) by virtue of [S.I.1992/604](#), [regs. 3\(2\)](#), 4
- F48** Words in s. 8(3) substituted (14.4.1993) by [S.I. 1993/834](#), [reg. 2\(3\)](#)
- F49** S. 8(3A)-(3C) inserted (14.4.1993) by [S.I. 1993/834](#), [reg. 2\(4\)](#)
- F50** Words in s. 8(3A) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 4\(4\)](#)
- F51** Words in s. 8(3A)(3C) substituted (28.2.2002) by [S.I. 2002/236](#), [reg. 2\(a\)\(i\)](#)
- F52** S. 8(3D) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 4\(5\)](#)
- F53** S. 8(3E) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), [reg. 1\(1\)](#), [Sch. 5 para. 1\(4\)](#) (with [Sch. 6](#))
- F54** S. 8(4)(5)(6) substituted (3.4.1992) for s. 8(4) by virtue of [S.I. 1992/604](#), [regs. 3\(3\)](#), 4

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- F55** S. 8(4)(a) omitted (8.11.2005) by virtue of [The Blood Safety and Quality Regulations 2005 \(S.I. 2005/50\)](#), [regs. 1\(2\)](#), [25\(1\)\(b\)](#) (with [reg. 2\(2\)-\(4\)](#))
- F56** In S. 8(4) paragraph (c) and words immediately preceding it omitted (13.2.1994) by virtue of [S.I. 1994/276](#), [reg. 4\(2\)\(b\)](#) (which S.I. revoked and replaced defective [S.I. 1994/101](#) before the latter S.I. came into force)
- F57** Words in s.8(6) inserted (13.2.1994) by [S.I. 1994/276](#), [reg. 4\(3\)](#) (which S.I. revoked and replaced defective [S.I. 1994/101](#) before the latter S.I. came into force)
- F58** S. 8(7)(8) added (14.4.1993) by [S.I. 1993/834](#), [reg. 2\(5\)](#)

**Modifications etc. (not altering text)**

- C35** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)
- C36** S. 8 excluded by [S.I. 1989/2325](#), [art. 2\(3\)](#)
- C37** S. 8(2) excluded by [S.I. 1979/1114](#), [arts. 2, 4](#) and by [S.I. 1979/1585](#), [arts. 2, 3](#)
- C38** S. 8(3) excluded by [S.I. 1989/2322](#), [art. 2\(1\)](#)
- C39** S. 8(3) excluded by [S.I. 1990/566](#), [art. 2\(1\)](#)
- C40** S. 8(3)(b) excluded by [S.I. 1989/2322](#), [art. 2\(3\)](#)
- C41** S. 8(3)(b) excluded by [S.I. 1990/566](#), [art. 2\(3\)](#)

**9 Exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners.**

- (1) The restrictions imposed by sections 7 and 8 of this Act do not apply to anything done by a doctor or dentist which—
- (a) relates to a medicinal product specially prepared, or specially imported by him or to his order, for administration to a particular patient of his, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to that patient or to a person under whose care that patient is, or
  - (b) relates to a medicinal product specially prepared at the request of another doctor or dentist, or specially imported by him or to his order at the request of another doctor or dentist, for administration to a particular patient of that other doctor or dentist, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to that other doctor or dentist or to that patient or to a person under whose care that patient is.
- (2) Subject to subsection (3) of this section, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything done by a veterinary surgeon or veterinary practitioner which—
- (a) relates to a medicinal product specially prepared for administration to a particular animal or herd which is under his care, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to a person having the possession or control of that animal or herd, or
  - (b) relates to a medicinal product specially prepared at the request of another veterinary surgeon or veterinary practitioner for administration to a particular animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to that other veterinary surgeon or veterinary practitioner or to a person having the possession or control of that animal or herd.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) The last preceding subsection shall not have effect so as to exempt from the restrictions imposed by sections 7 and 8 of this Act anything done by a veterinary surgeon or veterinary practitioner—
- (a) in relation to a vaccine specially prepared for administration to poultry, or
  - (b) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived, or
  - (c) in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived [<sup>F59</sup>or
  - (d) in relation to a ready-made veterinary medicinal product as defined in Article 1.2 of the 1981 Directive.]

#### Textual Amendments

**F59** S. 9(3)(d) and preceding word inserted (31.12.1994) by S.I. 1994/2987, reg. 10(2)

#### Modifications etc. (not altering text)

**C42** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

**C43** S. 9(2) restricted by S.I. 1987/2217, art. 3

## 10 Exemptions for pharmacists.

- (1) Subject to the next following subsection, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy, a hospital [<sup>F60</sup>, a care home service] or a health centre and is done there by or under the supervision of a pharmacist and consists of—
- (a) preparing or dispensing a medicinal product in accordance with a prescription given by a practitioner, or
  - (b) assembling a medicinal product [<sup>F61</sup>provided that where the assembling takes place in a registered pharmacy—
    - (i) it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail pharmacy business, and
    - (ii) the medicinal product has not been the subject of an advertisement]; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, or of procuring the assembly of a medicinal product.
- (2) The exemption conferred by the preceding subsection does not apply to a vaccine specially prepared for administration to poultry, and does not apply to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless—
- (a) in the case of a vaccine, it is specially prepared for administration to the animal from which it is derived, or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) in the case of plasma or a serum, it is specially prepared for administration to one or more animals in the herd from which it is derived,  
and (in either case) it is so prepared in accordance with a prescription given by a veterinary surgeon or veterinary practitioner.
- (3) Those restrictions do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist in accordance with a specification furnished by the person to whom the product is or is to be sold or supplied, where—
- (a) the product is prepared or dispensed for administration to that person or to a person under his care, or
- (b) the product, not being a vaccine, plasma or serum, is prepared or dispensed for administration to an animal or herd which is in the possession or under the control of that person.
- (4) Without prejudice to the preceding subsections, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of—
- (a) preparing or dispensing a medicinal product for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist's own judgment as to the treatment required, and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed, or
- (b) preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1)(a) or subsection (3) of this section or in paragraph (a) of this subsection [<sup>F62</sup>provided that such stock is prepared with a view to retail sale or to supply in circumstances corresponding to retail sale and the preparation is done with a view to such sale or supply either at that registered pharmacy or at any other registered pharmacy forming part of the same retail pharmacy business];
- and those restrictions do not apply to anything which is done in a hospital or a health centre by or under the supervision of a pharmacist and consists of preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1) (a) of this section.
- [<sup>F63</sup>(5) Without prejudice to the preceding subsections, the restrictions imposed by section 7 of this Act do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist where—
- (a) the medicinal product is prepared or dispensed otherwise than in pursuance of an order from any other person, and
- (b) the medicinal product is prepared with a view to retail sale or supply in circumstances corresponding to retail sale at the registered pharmacy at which it is prepared, and
- (c) the medicinal product has not been the subject of an advertisement.
- (6) Without prejudice to the preceding subsections, the restrictions imposed by section 8(2) of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of preparing a medicinal product with a view to retail sale or to supply in circumstances corresponding to retail sale at that registered pharmacy.
- [ The preceding provisions of this section shall not have effect so as to exempt from  
<sup>F64</sup>(6A) the restrictions imposed by sections 7 and 8 of this Act anything done in a registered

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

pharmacy by or under the supervision of a pharmacist in relation to a ready-made veterinary medicinal product as defined in Article 1.2 of the 1981 Directive.]

- (7) Without prejudice to the preceding subsections, the restrictions imposed by section 8(3) [<sup>F65</sup>or (3A)] of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than an inconsiderable part of the business carried on by the pharmacist at that pharmacy.
- (8) For the purposes of this section “advertisement” shall have the meaning assigned to it by section 92 of this Act, except that it shall not include words inscribed on the medicinal product, or on its container or package.]
- [<sup>F66</sup>(9) In subsection (1) of this section, “care home service” has the meaning given by section 2(3) of the Regulation of Care (Scotland) Act 2001 (asp 8).]

#### Textual Amendments

- F60** Words in s. 10(1) inserted (S.) (1.4.2002) by 2001 asp 8, s. 79, **Sch. 3 para. 5(a)**; S.S.I. 2002/162, **art. 2(h)** (subject to arts. 3-13)
- F61** Words added by S.I. 1971/1445, **art. 3(a)**
- F62** Words added by S.I. 1971/1445, **art. 3(b)**
- F63** S. 10(5)–(8) added by S.I. 1971/1445, **art. 3(c)**
- F64** S. 10(6A) inserted (31.12.1994) by S.I. 1994/2987, **reg. 11(2)**
- F65** Words in s. 10(7) inserted (14.4.1993) by S.I. 1993/834, **reg. 3**
- F66** S. 10(9) added (S.) (1.4.2002) by 2001 asp 8, ss. 79, **Sch. 3 para. 5(b)**; S.S.I. 2002/162, **art. 2(h)** (subject to arts. 3-13)

#### Modifications etc. (not altering text)

- C44** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C45** S. 10 amended (E.W.S.) (*prosp*) by 1954 c. 61, **s. 131(1)(b)** (as inserted (*prosp.*) by 1997 c. 19, ss. 1, 2(1), **Sch. para. 2**)

## 11 Exemption for nurses and midwives.

- (1) The restrictions imposed by section 8 of this Act do not apply to the assembly of any medicinal products by a person in the course of that person’s profession as [<sup>F67</sup>a registered <sup>F68</sup>... nurse or a registered midwife] . . . <sup>F69</sup>
- (2) . . . . . <sup>F70</sup>

#### Textual Amendments

- F67** Words substituted by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 7 para. 14(a)**
- F68** Words in s. 11(1) omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 10(a)**
- F69** Words repealed by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 8**
- F70** S. 11(2) repealed by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 8**

#### Modifications etc. (not altering text)

- C46** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 12 Exemptions in respect of herbal remedies.

- (1) The restrictions imposed by sections 7 and 8 of this Act do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where—
  - (a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public, and
  - (b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.
- (2) Those restrictions also do not apply to the sale, supply, manufacture or assembly of any herbal remedy where the process to which the plant or plants are subjected in producing the remedy consists only of drying, crushing or comminuting, and the remedy is, or is to be, sold or supplied—
  - (a) under a designation which only specifies the plant or plants and the process and does not apply any other name to the remedy, and
  - (b) without any written recommendation (whether by means of a labelled container or package or a leaflet or in any other way) as to the use of the remedy.

### Modifications etc. (not altering text)

C47 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

## 13 Exemptions for imports.

- (1) The restriction imposed by section 7(3) of this Act does not apply to the importation of a medicinal product by any person for administration to himself or to any person or persons who are members of his household, and does not apply to the importation of a medicinal product where it is specially imported by or to the order of a doctor or dentist for administration to a particular patient of his.
- (2) Without prejudice to the preceding subsection, the restriction imposed by section 7(3) of this Act shall not apply to the importation of a medicinal product in such circumstances as may be specified in an order made by the Ministers for the purposes of this section.
- (3) Any exemption conferred by an order under this section may be conferred either in relation to medicinal products generally or in relation to a class of medicinal products specified in the order, and (in either case) may be so conferred subject to such conditions or limitations as may be so specified.

### Modifications etc. (not altering text)

C48 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 14 Exemption for re-exports.

- <sup>F71</sup>(1) [<sup>F72</sup>Subject to subsection (2) of this section,] the restrictions imposed by sections 7 and 8 of this Act do not apply to the exportation, or the sale or offer for sale for the purposes of exportation, of any imported medicinal product if it is, or is to be, exported—
- (a) in the form in which it was imported, and
  - (b) without being assembled in a way different from the way in which it was assembled on being imported.

<sup>F73</sup>[(2) Section 8(3A) of this Act applies to the exportation, or the sale for exportation, of any product to which [<sup>F74</sup>the 2001 Directive applies] apply if it is, or is to be exported to [<sup>F75</sup>an EEA State.]]

### Textual Amendments

- F71** S. 14 renumbered as s. 14(1) (14.4.1993) by [S.I. 1993/834, reg. 4\(a\)](#)
- F72** Words in s. 14(1) inserted (14.4.1993) by [S.I. 1993/834, reg. 4\(a\)](#)
- F73** S. 14(2) inserted (14.4.1993) by [S.I. 1993/834, reg. 4\(b\)](#)
- F74** Words in s. 14(2) substituted (28.2.2002) by [S.I. 2002/236, reg. 2\(a\)\(ii\)](#)
- F75** Words in s. 14(2) substituted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\), reg. 1\(1\), Sch. 5 para. 2 \(with Sch. 6\)](#)

### Modifications etc. (not altering text)

- C49** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403, art. 3\(1\)](#)
- C50** S. 14 applied (with modifications)(3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\), Sch.](#)

## 15 Provision for extending or modifying exemptions.

- (1) The appropriate Ministers may by order provide that sections 7 and 8 of this Act shall have effect subject to such exemptions (other than those for the time being having effect by virtue of sections 9 to 14 of this Act) as may be specified in the order.
- (2) Any exemption conferred by an order under the preceding subsection may be conferred subject to such conditions or limitations as may be specified in the order.
- (3) The appropriate Ministers may by order provide that any of the provisions of sections 9 to 14 of this Act specified in the order shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be so specified.
- (4) No order shall be made under subsection (3) of this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

### Modifications etc. (not altering text)

- C51** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403, art. 3\(1\)](#)

## 16 Transitional exemptions.

- (1) The restrictions imposed by sections 7 and 8 of this Act do not apply to anything done before such day as the Ministers may by order appoint for the purposes of

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

this subsection (in this Act referred to as “the first appointed day”); and, except as otherwise provided by any order made under section 17 of this Act, the following provisions of this section shall have effect in relation to things done on or after that day.

- (2) Section 7(2) of this Act shall not have effect in relation to a person in respect of his selling or supplying, or procuring the sale, supply, manufacture or assembly of, medicinal products of any description if, in the course of a business carried on by him, any medicinal products of that description were sold or supplied, or procured to be sold, supplied, manufactured or assembled, at any time before the first appointed day and medicinal products of that description were effectively on the market in the United Kingdom immediately before the first appointed day, and either—
- (a) information with regard to the composition of medicinal products of that description, and as to their being available for sale or supply in the United Kingdom, had before that day been made known generally to doctors, or to any particular class of doctors, or to dentists or pharmacists, or to veterinary surgeons and veterinary practitioners, in the United Kingdom, or
  - (b) information that the products were available for sale or supply in the United Kingdom had before that day been made known generally to the public in the United Kingdom.
- (3) Section 7(3) of this Act shall not have effect in relation to a person in respect of his importing medicinal products of any description in the course of a business carried on by him if, in the course of that business, medicinal products of that description were imported within the period of twenty-four months ending with the first appointed day.
- (4) Section 8(2) of this Act shall not have effect in relation to a person in respect of his manufacturing or assembling medicinal products of any description in the course of a business carried on by him if in the course of that business—
- (a) medicinal products of that description were manufactured or assembled within the period of twelve months ending with the first appointed day, or
  - (b) medicinal products of that description were manufactured or assembled before the beginning of that period and further supplies of such products could, if required, have been manufactured or assembled within that period:
- Provided that this subsection shall not have effect in relation to any particular operations carried out in the course of a business on or after the first appointed day unless the manufacture or assembly of the products as mentioned in paragraph (a) or paragraph (b) of this subsection, as the case may be, included those operations.
- (5) Section 8(3) of this Act shall not have effect in relation to a person in respect of his selling or offering for sale any medicinal products by way of wholesale dealing in the course of a business carried on by him if, in the course of that business, medicinal products were being sold or offered for sale by way of wholesale dealing within the period of twelve months ending with the first appointed day.

**Modifications etc. (not altering text)**

**C52** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C53** S. 16(1) modified by S.I. 1985/1403, **art. 3(2)** and S.I. 1985/1539, **art. 1**

**C54** S. 16(2)–(5) excluded by S.I. 1981/1690, **art. 2**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 17 Termination of transitional exemptions.

For the purposes of subsections (2) to (5) of the last preceding section, the Ministers may by one or more orders under this section appoint one or more days, subsequent to the first appointed day, and may by any such order provide that such one or more of those subsections as may be specified in that order shall cease to have effect either—

- (a) generally in relation to anything done on or after the day appointed by that order, or
- (b) in relation to anything done on or after that day in so far as it consists of operations or activities, or relates to medicinal products of any such class, as may be so specified.

### Modifications etc. (not altering text)

**C55** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

### *Applications for, and grant and renewal of, licences*

### Modifications etc. (not altering text)

**C56** Definitions in ss. 18-22 applied (N.I.) (1.4.1992) by S.I. 1991/194 (N.I. 1), **art. 7(2)**, **Sch. 2 para. 5(4)**; S.R. 1991/131, **art. 2(e)**, **Sch. Pt.III**

## 18 Application for licence.

- (1) Any application for the grant of a licence under this Part of this Act shall be made to the licensing authority and shall be made in such form and manner, and shall contain, or be accompanied by, such information, documents, samples and other material, as may be prescribed.
- (2) Any such application shall indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.
- <sup>[F76]</sup>(3) Where documents that constitute a dossier for the purposes of <sup>[F77]</sup>Article 28 of the 2001 Directive] are forwarded to the licensing authority under and in accordance with the said Article, or documents are forwarded to that authority under and in accordance with Article 17 of Council Directive <sup>M1</sup>81/851/EEC of 28 September 1981, such forwarding shall be deemed to be an application for the grant of a product licence under this Part of this Act.]

### Textual Amendments

**F76** S. 18(3) substituted by S.I. 1983/1724, **art. 4**

**F77** Words in s. 18(3) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(b)**

### Modifications etc. (not altering text)

**C57** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C58** S. 18 applied (with modifications)(11.3.1992) by S.I. 1992/605, **reg. 2(1)(2)**, **Sch.**

**C59** Definitions in ss. 18-22 applied (N.I.)(1.4.1992) by S.I. 1991/194 (N.I. 1), **art. 7(2)**, **Sch. 2 para. 5(4)**; S.R. 1991/131, **art. 2(e)**, **Sch. Pt. III**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### **Marginal Citations**

**M1** OJ No. L 317. 6.11.81, p. 1.

### **19 Factors relevant to determination of application for licence.**

- (1) Subject to the following provisions of this Part of this Act, in dealing with an application for a product licence the licensing authority shall in particular take into consideration—
  - (a) the safety of medicinal products of each description to which the application relates;
  - (b) the efficacy of medicinal products of each such description for the purposes for which the products are proposed to be administered; and
  - (c) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality.
- (2) In taking into consideration the efficacy for a particular purpose of medicinal products of a description to which such an application relates, the licensing authority shall leave out of account any question whether medicinal products of another description would or might be equally or more efficacious for that purpose:  
Provided that nothing in this subsection shall be construed as requiring the licensing authority, in considering the safety of medicinal products of a particular description, in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.
- (3) Where any such application indicates that the purposes for which the licence is required relate (wholly or partly) to medicinal products which have been or are to be imported, then in dealing with the application, in so far as it relates to such products, the licensing authority shall also take into consideration in particular the methods, standards and conditions of manufacture of those products and may, if they think fit, require the production by the applicant of any one or more of the following, that is to say—
  - (a) an undertaking, given by the manufacturer of any such products, to permit the premises where they are or are to be manufactured, and the operations carried on or to be carried on in the course of manufacturing them, to be inspected by or on behalf of the licensing authority;
  - (b) an undertaking, given by or on behalf of the manufacturer of any such products, to comply with any prescribed conditions or any conditions attached to the licence by the licensing authority;
  - (c) a declaration, given by or on behalf of the manufacturer of any such products, that, in relation to the manufacture of those products, any requirements imposed by or under the law of the country in which they are or are to be manufactured have been or will be complied with.
- (4) Where any such application indicates that the purposes for which the license is required relate exclusively to the exportation of medicinal products, the licensing authority shall leave out of account considerations of safety and efficacy (as mentioned in paragraphs (a) and (b) of subsection (1) of this section) if satisfied that in the circumstances it is reasonable to do so.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (5) In dealing with an application for a manufacturer's licence the licensing authority shall in particular take into consideration—
- (a) the operations proposed to be carried out in pursuance of the licence;
  - (b) the premises in which those operations are to be carried out;
  - (c) the equipment which is or will be available on those premises for carrying out those operations;
  - (d) the qualifications of the persons under whose supervision those operations will be carried out; and
  - (e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.
- (6) In dealing with an application for a wholesale dealer's licence the licensing authority shall in particular take into consideration—
- (a) the premises on which medicinal products of the descriptions to which the application relates will be stored;
  - (b) the equipment which is or will be available for storing medicinal products on those premises;
  - (c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and
  - (d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.
- (7) The preceding provisions of this section shall have effect subject to the provisions of this Part of this Act relating to licences of right.

**Modifications etc. (not altering text)**

**C60** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403, art. 3\(1\)](#)

**C61** Definitions in ss. 18-22 applied (N.I) (1.4.1992) by [S.I. 1991/194, \(N.I. 1\), art. 7\(2\), Sch. 2 para. 5\(4\); S.R. 1991/194, art. 2\(e\), Sch. Pt. III](#)

**C62** S. 19 (1)(2)(3) applied (with modifications) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.

**20 Grant or refusal of licence.**

- (1) Subject to [<sup>F78</sup>sections 8(2E) and (3E) and 19,], and to the following provisions of this Act, on any application to the licensing authority for a licence under this Part of this Act the licensing authority—
- (a) may grant a licence containing such provisions as they consider appropriate, or
  - (b) if, having regard to the provisions of this Act [<sup>F79</sup>and any Community obligation], they consider it necessary or expedient to do so, may refuse to grant a licence.

[<sup>F80</sup>(1A) The licensing authority must either grant or refuse any application for a licence under this Part, before the end of a period of 90 days from the date upon which they receive the application.]

[<sup>F80</sup>(2B) If there are requirements in force under section 18 that apply to the application, subsection (1A) applies only if the requirements have been met]

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- [<sup>F80</sup>(2C) If a notice under section 44 requires the applicant to provide the licensing authority with information, the period specified in subsection (1) stops running when the notice is given, and does not start running again until—
- (a) the licensing authority receives the information; or
  - (b) the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it.]
- (2) The licensing authority shall not refuse to grant such a licence on any grounds relating to the price of any product, and shall not insert in any such licence any provisions as to the price at which any product may be sold, supplied, imported or exported.
- (3) The licensing authority shall not refuse to grant such a licence on any grounds relating to the safety, quality or efficacy of medicinal products of any description, except after consultation with the appropriate committee <sup>F81</sup>....
- <sup>F82</sup>(4) .....
- (5) Where on an application for a licence under this Part of this Act—
- (a) the licensing authority refuse to grant a licence, or
  - (b) the licensing authority grant a licence otherwise than in accordance with the application, and the applicant requests the licensing authority to state their reasons,
- the licensing authority shall serve on the applicant a notice stating the reasons for their decision.

#### Textual Amendments

- F78** Words in s. 20(1) substituted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 3\(a\)](#) (with [Sch. 6](#))
- F79** Words inserted by (E.W.) [S.I. 1977/1050](#), [art. 4\(3\)](#) and (N.I.) [S.R. 1977 No. 170](#), [reg. 5\(3\)](#)
- F80** S. 20(1A)(2B)(2C) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 3\(b\)](#) (with [Sch. 6](#))
- F81** Words in s. 20(3) omitted (30.10.2005) by virtue of [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 1\(a\)](#)
- F82** S. 20(4) omitted (30.10.2005) by virtue of [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 1\(b\)](#)

#### Modifications etc. (not altering text)

- C63** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)
- C64** Ss. 20–22 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), [Sch.](#)
- C65** Definitions in ss. 18–22 applied (N.I.) (1.4.1992) by [S.I. 1991/194](#), (N.I. 1), art. 7(2), [Sch. 2 para. 5\(4\)](#); [S.R. 1991/131](#), [art. 2\(e\)](#), [Sch. Pt.III](#)

#### [<sup>F83</sup>21 Procedure on reference to appropriate committee

- (1) Where the appropriate committee are consulted under section 20(3) of this Act and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they—
- (a) may be unable to advise the licensing authority to grant the licence; or

---

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

---

- (b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application, they shall notify the applicant accordingly.
- (2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.
- (3) The appropriate committee shall give the applicant an opportunity to make such representations in accordance with subsections (4) to (7) of this section.
- (4) Subject to subsection (5) of this section, the applicant shall provide the appropriate committee with—
- (a) his written representations or a written summary of the oral representations he intends to make; and
  - (b) any documents on which he wishes to rely in support of those representations, before the end of the period of six months beginning with the date of the notice referred to in subsection (2) of this section, or within such shorter period as the appropriate committee may specify in the notification under subsection (1).
- (5) If the applicant so requests, the appropriate committee may extend the time limit referred to in subsection (4) of this section, up to a maximum period of twelve months beginning with the date of the notice referred to in subsection (2) of this section.
- (6) The applicant may not submit any additional written representations or documents once the time limit referred to in subsections (4) and (5) of this section has expired, except with the permission of the appropriate committee.
- (7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with subsection (4) of this section, arrange for the applicant to make such representations at a hearing before the committee.
- (8) The appropriate committee shall—
- (a) take into account such representations as are made in accordance with this section; and
  - (b) report their findings and advice to the licensing authority, together with the reasons for their advice.
- (9) After receiving the report of the appropriate committee, the licensing authority shall—
- (a) decide whether to grant or refuse the application, or to grant it otherwise than in accordance with the application; and
  - (b) take the report into account when making their decision.
- (10) The licensing authority shall notify the applicant of—
- (a) the decision made pursuant to subsection (9) of this section; and
  - (b) the advice given to them by the appropriate committee and the reasons for that advice.
- (11) If—
- (a) the applicant has made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application; or



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) the applicant has not made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application, on grounds which differ from those relied on in the advice of the appropriate committee,

the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

- (12) In this Part of the Act, "the time allowed" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.]

#### Textual Amendments

**F83** S. 21 substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 2**

#### Modifications etc. (not altering text)

**C66** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

**C67** Ss. 20–22 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.

**C68** Definitions in ss. 18–22 applied (N.I.) (1.4.1992) by [S.I. 1991/194](#), (N.I. 1), art. 7(2), Sch. 2 para. 5(4); [S.R. 1991/131](#), **art. 2(e)**, **Sch. Pt. III**

**C69** S. 21 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19**, **Sch. 4**

**C70** S. 21 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(2)**

**C71** S. 21 applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), **reg. 1(2)(b)**, **Sch. 5 para. 11(3)**

**C72** S. 21 applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), **reg. 1(2)(b)**, **Sch. 5 para. 6(3)**

**C73** S. 21(11)(a)(b) applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), **reg. 1(2)(b)**, **Sch. 5 para. 2(4)**

#### <sup>F84</sup> 22 Procedure in other cases.

- (1) This section applies when—
- an application is made for the grant of a licence under this Part of this Act; and
  - the appropriate committee—
    - is not consulted under subsection (3) of section 20, or
    - is consulted under that subsection but does not give a provisional opinion in accordance with section 21(1).
- (2) If the licensing authority propose—
- to refuse to grant the licence, or
  - to grant it otherwise than in accordance with the application,
- they shall notify the applicant of their proposals and the reasons for them.
- (3) If the applicant is so notified, he may, within the time allowed—
- notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the proposal; or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.
- (4) If the applicant makes written representations in accordance with subsection (3)(b) of this section, the licensing authority shall take those representations into account before determining the application.

#### Textual Amendments

**F84** Ss. 22, 22A substituted for s. 22 (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 3**

#### Modifications etc. (not altering text)

**C74** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C75** Ss. 20-22 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, Sch.

**C76** Definitions in ss. 18-22 applied (N.I.) (1.4.1992) by S.I. 1991/194 (N.I. 1), art. 7(2), **Sch. 2 para. 5(4)**; S.R. 1991/131, art. 2(e), **Sch. Pt.III**

**C77** s. 22 extended (with modifications) (14.2.1994) by S.I. 1994/105, **reg. 19, Sch.4**

**C78** S. 22 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005 (S.I. 2005/2753), regs. 1(1), **19(2)**

### 22A . Hearing before person appointed

- (1) If the applicant gives notice under section 21(11) or section 22(3) of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—
- (a) make that appointment; and
  - (b) arrange for the applicant to have an opportunity of appearing before that person.
- (2) The person appointed—
- (a) shall not be, or at any time have been, a member of—
    - (i) the Commission on Human Medicines or any of its Expert Advisory Groups,
    - (ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or
    - (iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and
  - (b) shall not be an officer or servant of any Minister of the Crown.
- (3) Subject to subsection (4) of this section, the applicant shall provide the person appointed with—
- (a) a written summary of the oral representations he intends to make; and
  - (b) any documents on which he wishes to rely in support of those representations, before the end of the period of three months beginning with the date of the notice referred to in subsection (1) of this section.
- (4) If the applicant so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in subsection (3) of this section, up to a

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

maximum period of six months beginning with the date of the notice referred to in subsection (1) of this section.

- (5) If the applicant fails to comply with the time limit in subsection (3) of this section, or where he has been granted an extended time limit under subsection (4) of this section, that time limit—
  - (a) he may not appear before or be heard by the person appointed, and
  - (b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.
- (6) The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.
- (7) At the hearing before the person appointed, both the applicant and the licensing authority may make representations.
- (8) If the applicant so requests the hearing shall be in public.
- (9) After the hearing—
  - (a) the person appointed shall provide a report to the licensing authority; and
  - (b) the licensing authority shall take the report into account and decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, or to confirm or alter their decision, as the case may be.
- (10) The licensing authority shall then—
  - (a) notify the applicant of their decision;
  - (b) if the applicant so requests, provide the applicant with a copy of the report of the person appointed.]

#### Textual Amendments

**F84** Ss. 22, 22A substituted for s. 22 (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 3**

#### Modifications etc. (not altering text)

- C79** S. 22A applied by SI 1992/605 Sch. (as amended) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 4 para. 6(a)**
- C80** S. 22A excluded (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 5 para. 19(3)(a)(i)**
- C81** S. 22A(10)(b) applied by SI 1978/1006 reg. 7(3) (as substituted (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 4 para. 3(b)**)
- C82** Ss. 22A(2)-(9) applied by SI 1978/1006 reg. 7(3) (as substituted (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 4 para. 3(b)**)

## 23 Special provisions as to effect of manufacturer's licence.

- (1) Subject to the provisions of this Part of this Act relating to <sup>F85</sup>... medicinal tests on animals and to the following provisions of this section, a manufacturer's licence shall not have effect so as to authorise the manufacture or assembly of medicinal products of any description for sale or supply to any other person, or for exportation, unless either—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) the holder of the licence is also the holder of a product licence which is applicable to medicinal products of that description, or
- [<sup>F86</sup>(b) the products are manufactured or assembled to the order of—
- (i) a person who is the holder of such a product licence, or
- (ii) if the products are to be used for the purposes of a clinical trial, the sponsor of that trial,]
- and (in either case) the products are manufactured or assembled in accordance with that product licence.
- (2) Subject to the next following subsection, the preceding subsection shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a practitioner, where the practitioner—
- (a) being a doctor or dentist, states that the product is required for administration to a patient of his or is required, at the request of another doctor or dentist, for administration to a patient of that other doctor or dentist, or
- (b) being a veterinary surgeon or veterinary practitioner, states that the product is required for administration to an animal or herd which is under his care or is required, at the request of another veterinary surgeon or veterinary practitioner, for administration to an animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner,
- and shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a pharmacist in accordance with a prescription given by a practitioner.
- (3) The exemption conferred by the last preceding subsection—
- (a) in a case falling within paragraph (b) of that subsection, or
- (b) in so far as it relates to the manufacture or assembly of a medicinal product to the order of a pharmacist,
- does not apply to a vaccine specially prepared for administration to poultry.
- (4) If by virtue of an order made under section 15 of this Act an exemption is conferred in respect of the restrictions imposed by section 7 of this Act, but no corresponding exemption is conferred in respect of the restrictions imposed by section 8(2) of this Act, the order may provide that subsection (1) of this section shall have effect subject to such exceptions or modifications as the Ministers consider appropriate in the circumstances.
- (5) Where subsection (1) of this section has effect in relation to medicinal products of any description, and the conditions specified in that subsection are not fulfilled, the manufacture or assembly of medicinal products of that description for sale or supply to another person, or for exportation, notwithstanding that it complies with the provisions contained in the manufacturer’s licence, shall for the purposes of this Act be deemed to be not in accordance with that licence.
- [<sup>F87</sup>(6) In this section, “clinical trial” and “sponsor”, in relation to a clinical trial, have the meaning given by Clinical Trials Regulations.]

#### Textual Amendments

**F85** Words in s. 23(1) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, [Sch. 10 para. 5\(2\)\(a\)](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**F86** S. 23(1)(b) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 5(2)(b)**

**F87** S. 23(6) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 5(3)**

**Modifications etc. (not altering text)**

**C83** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C84** S.23 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

S. 23 modified (1.1.1995) by S.I. 1994/3144, **reg.9(3)**

S. 23 applied (1.1.1995) by S. I. 1994/3142, **reg. 18(2)**

S. 23 amended (E.W.S.) (*prosp.*) by 1954 c. 61, **s. 13I para. 1(b)** (as inserted (*prosp.*) by 1997 c. 19, **ss. 1,2**, Sch. para.2)

**C85** S. 23 modified (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), regs. 1(a), **10(2)** (with Sch. 6)

**C86** S. 23 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)**

**24 Duration and renewal of licence.**

[<sup>F88</sup>(1) A licence granted under this Part expires—

- (a) in accordance with the provisions of the licence, or
- (b) if there is no such provision, at the end of the period of five years beginning with the date on which the licence was granted, or if it has been renewed the date on which it was last renewed.

(1AA) But so far as the licence relates to a medicinal product to which the 2001 Directive applies, it remains in force until—

- (a) revoked by the licensing authority; or
- (b) surrendered by the holder.]

(2) Any [<sup>F89</sup>licence granted under this Part of this Act], if it has not been revoked, may, on the application of the holder of the licence, be renewed by the licensing authority for a further period of five years from the date on which it would otherwise expire or such shorter period from that date as the licensing authority may determine.

[<sup>F90</sup>(2A) Subsection (2) does not apply to a licence insofar as it relates to a medicinal product to which the 2001 Directive applies.]

(3) On an application to the licensing authority for the renewal of a licence under this Part of this Act, the licensing authority—

- (a) may renew the licence, with or without modifications, for such a further period as is mentioned in subsection (2) of this section, or
- (b) may grant to the applicant a new licence containing such provisions as the licensing authority consider appropriate, or
- (c) if, having regard to the provisions of this Act [<sup>F91</sup>and any Community obligation under [<sup>F92</sup>the 2001 Directive other than Titles VI, VII and VIII of that Directive]], they consider it necessary or expedient to do so, may refuse to renew the licence or to grant a new licence.

[<sup>F93</sup>(3A) References to a licence in subsection (3) are to be read as references to a licence only insofar as that licence relates to a medicinal product to which the 2001 Directive does not apply.]

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) In relation to any such application the provisions of sections 18 and 19, subsections (2) to (5) of section 20 and sections [F9421 to 22A] of this Act shall have effect as if in those provisions any reference to refusing a licence included a reference to refusing to renew a licence and any reference to granting a licence included a reference to renewing it.
- (5) Every application for the grant or renewal of a licence under this Part of this Act shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the licence for the full period of five years mentioned in subsection (1) or subsection (2) of this section, as the case may be; and in this Part of this Act any reference (including a reference implied by virtue of the last preceding subsection) to the grant or renewal of a licence otherwise than in accordance with the application shall be construed accordingly.
- [F95(5A) Subsection (5) does not apply to a licence insofar as it relates to a medicinal product to which the 2001 Directive applies.]
- (6) Where an application for the renewal of a licence under this Act has been duly made—
- (a) the licence shall not cease to be in force by virtue of the preceding provisions of this section before the licensing authority have determined the application, and
  - (b) if by an interim order made under section 107(3)(a) of this Act the operation of the decision of the licensing authority on the application is suspended, the licence shall not cease to be in force by virtue of those provisions so long as the operation of the decision continues to be suspended by the order.

F96(7) . . .

#### Textual Amendments

- F88** S. 24(1)(1AA) substituted for s. 24(1) (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 4\(2\)](#) (with [Sch. 6](#))
- F89** Words substituted by (E.W.)(S.) [S.I. 1977/1050](#), [art. 4\(4\)](#) and (N.I.) S.R. 1977 No. 170, [reg. 5\(4\)](#)
- F90** S. 24(2A) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 4\(3\)](#) (with [Sch. 6](#))
- F91** Words in s. 24(3)(c) inserted (13.2.1994) by [S.I. 1994/276](#), [reg. 5\(b\)](#) (which S.I. revoked and replaced defective [S.I. 1994/101](#) before the latter S.I. came into force)
- F92** Words in “s. 24(3)(C)” substituted (28.2.2002) by virtue of [S.I. 2002/236](#), [reg. 2\(c\)\(ii\)](#)
- F93** S. 24(3A) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 4\(4\)](#) (with [Sch. 6](#))
- F94** Words in s. 24(4) substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 4](#)
- F95** S. 24(5A) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 4\(5\)](#) (with [Sch. 6](#))
- F96** S. 24(7) deleted (28.2.2002) by virtue of [S.I. 2002/236](#), [reg. 2\(c\)\(ii\)](#)

#### Modifications etc. (not altering text)

- C87** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)
- C88** S. 24 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), [Sch.](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## *Licences of right*

### **25 Entitlement to licence of right.**

<sup>F97</sup>(1) .....

<sup>F97</sup>(2) .....

<sup>F97</sup>(3) .....

- (4) In this Act “licence of right” means a licence to which a person is entitled by virtue of this section, including such a licence which has been renewed (with or without modifications) but not a licence granted instead of the renewal of such a licence.

#### **Textual Amendments**

**F97** S. 25(1)-(3) repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), Sch. 1 Pt. 17 Group 7

#### **Modifications etc. (not altering text)**

**C89** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

### <sup>F98</sup>**26 Scope of licence of right in different cases.**

.....

#### **Textual Amendments**

**F98** S. 26 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), Sch. 1 Pt. 17 Group 7

#### **Modifications etc. (not altering text)**

**C90** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

### **27 Proceedings on application for licence of right.**

- (1) Sections 19 to [<sup>F99</sup>22A] of this Act shall not have effect in relation to any application for a licence of right.
- (2) If on any such application the licensing authority—
- (a) propose to refuse to grant a licence on that application, on the grounds that none of the provisions of subsections (2) to (5) of section 16 of this Act has been proved to have effect in relation to the applicant, or
  - (b) propose to grant a licence which will not extend to some of the matters specified in the application.

the licensing authority shall, before the end of the period of three months from the date on which the application is received by them, serve on the applicant a notice stating their proposals and the reasons for them and, in a case falling within paragraph (b) of this subsection, the matters specified in the application to which it is proposed that the licence should not extend.

- (3) If, within the time allowed after the service of a notice under subsection (2) of this section, the applicant gives notice to the licensing authority of his desire to be heard under this subsection or makes representations in writing to the licensing authority

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

with respect to their proposals, then, before determining the application, the licensing authority shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or shall take those representations into account, as the case may be.

(4) Where the applicant avails himself of the opportunity afforded to him in pursuance of subsection (3) of this section or makes representations in writing as mentioned in that subsection, then if—

- (a) the licensing authority refuse to grant a licence on the application, or
- (b) grant a licence otherwise than in accordance with the application, and the applicant requests the licensing authority to state their reasons.

the licensing authority shall serve on the applicant a notice stating the reasons for their decision.

(5) If, in a case where the licensing authority have served a notice under subsection (2) of this section, the application is not finally disposed of before the date which, in relation to any matters specified in the application, is the relevant date, then on and after that date, and until the application has been finally disposed of, the provisions of this Act shall have effect in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.

(6) Where, on an application for a licence of right, the licensing authority do not serve a notice under subsection (2) of this section before the end of the period mentioned in that subsection, the licensing authority shall be required to grant a licence in accordance with sections 25 and 26 of this Act as if all the matters specified in the application had been proved; and if such a licence has not been granted before the date which, in relation to any of those matters, is the relevant date, the provisions of this Act shall have effect on and after that date in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.

(7) For the purposes of this section the relevant date, in relation to any matters specified in an application, is the date on which, in accordance with one or more orders made under section 17 of this Act, that subsection of section 16 of this Act which has effect in relation to those matters ceases to have effect in relation to them; and an application shall for the purposes of this section be taken to be finally disposed of on (but not before) the occurrence of whichever of the following events last occurs, that is to say—

- (a) the licensing authority make a decision determining the application;
- (b) the time within which an application under section 107 of this Act with respect to that decision can be made expires without its having been made;
- (c) if such an application under section 107 of this Act is made, the proceedings on the application under that section are finally determined or abandoned or otherwise disposed of;
- (d) if there is an appeal against the decision in any such proceedings as are mentioned in paragraph (c) of this subsection, or an appeal against the decision on such an appeal, the proceedings on that appeal are finally determined or abandoned or otherwise disposed of;
- (e) the time for bringing any such appeal as is mentioned in paragraph (d) of this subsection expires without its having been brought.

[<sup>F100</sup>(8) Subsections (2), (8) and (10)(b) of section 22A of this Act shall have effect in relation to a person appointed under subsection (3) of this section and to proceedings before him and his report as they have effect for the purposes of that section.]



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### Textual Amendments

**F99** Word in s. 27(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), Sch. 1 para. 5(a)

**F100** S. 27(8) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), Sch. 1 para. 5(b)

#### Modifications etc. (not altering text)

**C91** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

**C92** Power to exclude s. 27(5)(6) conferred by Medicines Act 1971 (c. 69), s. 1(2)(a)

### *Suspension, revocation and variation of licences*

## **28 General power to suspend, revoke or vary licences.**

- (1) Subject to the following provisions of this Part of this Act, the licensing authority may suspend a licence under this Part of this Act for such period as the authority may determine, or may revoke, or vary the provisions of, any such licence.
- (2) The suspension or revocation of a licence under this section may be total or may be limited to medicinal products of one or more descriptions or to medicinal products manufactured, assembled or stored on any particular premises or in a particular part of any premises.
- (3) <sup>F101</sup>Subject to subsection (3A) of this section]the powers conferred by this section shall not be exercisable by the licensing authority in relation to a product licence except on one or more of the following grounds, that is to say—
  - (a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;
  - (b) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products of a description to which the licence relates;
  - (c) that medicinal products of any such description, as sold, supplied, exported, imported, manufactured or assembled in pursuance of the licence, fail to a material extent to correspond to the characteristics by reference to which the licence was granted;
  - (d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of any such description;
  - (e) that any premises on which, or in part of which, medicinal products of any such description are manufactured, assembled or stored by or on behalf of the holder of the licence are unsuitable;
  - (f) in the case of a licence other than a licence of right, that the holder of the licence has not, within two years after the grant of the licence, notified to the licensing authority, in relation to each description of medicinal products to which the licence relates, a date on which medicinal products of that description were effectively on the market in the United Kingdom;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (g) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes;
- (h) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory.
- [<sup>F102</sup>(i) that any of the provisions of the licence, insofar as they relate to the incorporation in animal feeding stuffs of any medicinal product . . . <sup>F103</sup> are not in accordance with any Community obligation.]
- [<sup>F104</sup>(j) that, in relation to medicinal products of any description to which the licence relates [<sup>F105</sup>(other than products to which [<sup>F106</sup>the 2001 Directive applies] )] any of the provisions contained in regulations which—
  - (i) are made under section 85 of this Act (labelling and marking of containers and packages), and
  - (ii) impose requirements which give effect to Community obligations,
 has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble such medicinal products.]
- [<sup>F107</sup>(3A) Where a product licence relates to a product to which [<sup>F106</sup>the 2001 Directive applies], the power conferred by this section to suspend a licence shall be exercisable in relation to the licence on the ground that—
  - (a) any of the provisions contained in regulations made under section 85 (labelling and marking of containers and packages) or 86 (leaflets) of this Act, or
  - (b) section 86(4),
 has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product.]
- (4) Subject to the following provisions of this section, the powers conferred by this section shall not be exercisable in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the following grounds, that is to say—
  - (a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;
  - (b) that a material change of circumstances has occurred in relation to any of those matters;
  - (c) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence;
  - (d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of a description to which the licence relates.
- (5) In relation to a manufacturer's licence, the powers conferred by this section shall be exercisable on either of the following grounds, in addition to those specified in subsection (4) of this section, that is to say—
  - (a) that the holder of the manufacturer's licence has carried out processes of manufacture or assembly to the order of another person who is the holder of a product licence, and has habitually failed to comply with the provisions of that product licence;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) that the holder of the manufacturer's licence does not have the requisite facilities for carrying out properly processes of manufacture or assembly authorised by the licence.
- (6) In relation to a wholesale dealer's licence, the powers conferred by this section shall be exercisable on the following grounds, in addition to those specified in subsection (4) of this section, that is to say, that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related.
- (7) The preceding provisions of this section shall have effect subject to the next following section.

#### Textual Amendments

- F101** Words in s. 28(3) inserted (13.2.1994) by S.I. 1994/276, **reg. 6(2)(a)** (with **reg. 6(4)**) (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
- F102** S. 28(3)(i) added by (E.W.)(S.) S.I. 1975/1169 (N.I.), S.R. & O (N.I.) 1975/197
- F103** Words repealed by **Animal Health and Welfare Act 1984** (c. 40, SIF 2:8), s. 16, Sch. 1 para. 3(2), **Sch. 2**
- F104** S. 28(3)(j) inserted by (E.W.)(S.) S.I. 1977/1050, **art. 4(5)** and (N.I.) S.R. 1977 No. 170, **reg. 5(5)**
- F105** Words in s. 28(3)(j) inserted (13.2.1994) by S.I. 1994/276, **reg. 6(2)(b)** (with **reg. 6(4)**) (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
- F106** Words in s. 28(3)(j)(3A) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(iii)**
- F107** S. 28(3A) inserted (13.2.1994) by S.I. 1994/276, **reg. 6(3)** (with **reg. 6(4)**) (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)

#### Modifications etc. (not altering text)

- C93** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C94** S. 28 (1)(2)(3)(7) applied (with modifications)(3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, **Sch.**

## 29 Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28.

- (1) The provisions of Schedule 2 to this Act shall have effect where the licensing authority propose to exercise any power conferred by section 28 of this Act.
- (2) Without prejudice to any requirement of that Schedule as to the service of notices, where in the exercise of any such power the licensing authority suspend, revoke or vary a licence, they shall serve on the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for their decision to suspend, revoke or vary the licence.

#### Modifications etc. (not altering text)

- C95** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C96** S. 29 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, **Sch.**  
s. 29 extended (with modifications) (14.2.1994) by S.I. 1994/105, **reg. 19**, **Sch.4**
- C97** S. 29 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by **Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005** (S.I. 2005/2753), **regs. 1(1)**, **19(2)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**[<sup>F108</sup>30 Variation of licence on application of holder.**

- (1) This section applies if the holder of a licence under this Part applies to the licensing authority for the licence to be varied.
- (2) The application must—
  - (a) be in writing,
  - (b) specify the required variation,
  - (c) be signed by or on behalf of the applicant,
  - (d) be accompanied by such information as is reasonably required to enable the licensing authority to consider the application, and
  - (e) if there is a requirement in force under section 1(1)(a) of the Medicines Act 1971 to pay a fee in respect of the application, be accompanied by the required fee.
- (3) The licensing authority must consider any application properly made under this section.
- (4) If subsection (5) applies, they must either vary the licence or refuse to vary it before the end of the period allowed for considering the application.
- (5) This subsection applies to a variation which would have the effect of altering—
  - (a) the types of medicinal product,
  - (b) any operation carried out under the licence,
  - (c) any premises, or
  - (d) any equipment or facilities,
 in respect of which the licence was granted.
- (6) If the licensing authority considers that it is necessary for them to conduct an inspection of any premises to which the application relates, the period allowed is 90 days beginning with the date on which they receive the application.
- (7) Otherwise, the period allowed is 90 days beginning with that date.
- (8) The licensing authority may give the applicant written notice requiring him to give them such further information in connection with the application as they consider reasonable.
- (9) The period allowed for consideration stops running when a notice is given under paragraph (8) and does not start running again until—
  - (a) the licensing authority receives the information; or
  - (b) the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it
- (10) Nothing in this section affects the powers conferred by section 28.]

**Textual Amendments**

**F108** S. 30 substituted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), **Sch. 5 para. 5** (with Sch. 6)

**Modifications etc. (not altering text)**

**C98** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C99** S. 30 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), Sch.

### *Clinical trials and medicinal tests on animals*

#### **F109** 31 **Clinical trials.**

.....

##### **Textual Amendments**

**F109** S. 31 omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004](#) ([S.I. 2004/1031](#)), [reg. 1](#), [Sch. 10 para. 6](#)

##### **Modifications etc. (not altering text)**

**C100** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)

#### **32 Medicinal tests on animals.**

- (1) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him,—
  - (a) sell or supply any medicinal product for the purposes of a medicinal test on animals, or
  - (b) procure the sale or supply of any medicinal product for the purposes of such a test, or
  - (c) procure the manufacture or assembly of any medicinal product for sale or supply for the purposes of such a test,unless one or other of the conditions specified in the next following subsection is fulfilled.
- (2) Those conditions, in relation to a person doing any of the things specified in the preceding subsection, are—
  - (a) that he is the holder of a product licence which authorises the test in question, or he does it to the order of the holder of such a licence, and (in either case) he does it in accordance with that licence;
  - (b) that a certificate for the purposes of this section (in this Act referred to as an “animal test certificate”) has been issued certifying that, subject to the provisions of the certificate, the licensing authority have consented to the test in question and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.
- (3) Subject to the following provisions of this Act, no person shall import any medicinal product for the purposes of a medicinal test on animals unless either—
  - (a) he is the holder of a product licence which authorises that test, or imports the product to the order of the holder of such a licence, and (in either case) he imports it in accordance with that licence, or
  - (b) an animal test certificate has been issued certifying as mentioned in subsection (2)(b) of this section and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him, administer any substance or article to an animal by way of a medicinal test on animals, or procure any substance or article to be so administered, unless either—
- (a) in the case of a medicinal product, there is in force a product licence (whether held by him or by another person) which authorises that test and the product is administered in accordance with that licence or in accordance with any instructions required by the licence to be communicated to the person carrying out the test, or
  - (b) whether the substance or article is a medicinal product or not, an animal test certificate has been issued certifying as mentioned in subsection (2)(b) of this section and that certificate is for the time being in force and the substance or article is administered in accordance with that certificate.
- (5) For the purposes of this section a product licence shall be taken to be a licence which authorises a particular medicinal test on animals if—
- (a) the substance or article to be administered in the test is a medicinal product of a description to which the licence relates, and
  - (b) the uses of medicinal products of that description which are referred to in the licence are such as to include their use for the purposes of that test.
- (6) In this Act “medicinal test on animals” means an investigation or series of investigations consisting of any of the following, that is to say—
- (a) the administration of a medicinal product of a particular description to one or more animals, where there is evidence that medicinal products of that description have effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals, and the product is administered for the purpose of ascertaining whether, or to what extent, it has those or any other effects, whether advantageous or otherwise;
  - (b) the administration of a medicinal product to one or more animals in circumstances where there is no such evidence as is mentioned in the preceding paragraph, and the product is administered for the purpose of ascertaining whether, or to what extent, it has any effects relevant to a medicinal purpose;
  - (c) the administration of any substance or article, other than a medicinal product, to one or more animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose, whether there is evidence that it has effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals or not.

**Modifications etc. (not altering text)**

**C101** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C102** Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

**C103** S. 32 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

**33 Exemptions in respect of medicinal tests on animals.**

- (1) The restrictions imposed by subsections (1) and (4) of section 32 of this Act do not apply to anything done in relation to a substance or article for the purposes or by way of a medicinal test on animals if—

---

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

---

- (a) the test is, or is to be, carried out in circumstances where there is no evidence that the substance or article has effects which may be beneficial to, or otherwise advantageous in relation to, the animal or animals to which it is, or is to be, administered, and
  - (b) the arrangements for the test are such as to secure that no animal to which the substance or article is administered in the course of the test, and no carcase or part of the carcase or produce of any such animal, will be sold or supplied for human consumption.
- (2) Subject to the next following subsection, the restrictions imposed by subsections (1) and (4) of that section do not apply to a veterinary surgeon or veterinary practitioner in respect of his—
  - (a) selling or supplying, or procuring the sale or supply of, a medicinal product for the purpose of its being administered to one or more animals which are under his care, or
  - (b) procuring the manufacture or assembly of a medicinal product where the product is specially prepared to his order for the purpose of its being administered to one or more such animals, or
  - (c) administering a substance or article to an animal which is under his care, or procuring a substance or article to be so administered.
- (3) Subsection (2) of this section shall not have effect in relation to a veterinary surgeon or veterinary practitioner where the medicinal test in question is to be carried out under arrangements made by, or at the request of, another person, and (where the arrangements are made by the veterinary surgeon or veterinary practitioner and not at the request of any other person) shall not have effect so as to exempt from the restrictions in question anything done—
  - (a) in relation to a vaccine specially prepared for administration to poultry, or
  - (b) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived, or
  - (c) in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived.
- (4) Subject to subsection (6) of this section, the restrictions imposed by subsection (1) of that section do not apply to anything which is done in a registered pharmacy and is done there by or under the supervision of a pharmacist and consists of dispensing a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner or of procuring the assembly of a medicinal product.
- (5) Subject to subsection (6) of this section, the restrictions imposed by subsection (1) of that section also do not apply to anything done in relation to a medicinal product where—
  - (a) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a veterinary surgeon or veterinary practitioner who has stated that it is required for administration to an animal or herd which is under his care, or is required, at the request of another veterinary surgeon or veterinary practitioner, for administration to

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- an animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner, or
- (b) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a pharmacist in accordance with a prescription given by a practitioner, or
  - (c) it consists of selling the product by way of wholesale dealing where it has been manufactured or assembled in the circumstances specified in paragraph (a) or paragraph (b) of this subsection.
- (6) The exemptions conferred by subsections (4) and (5) of this section do not apply to a vaccine specially prepared for administration to poultry, and do not apply to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless—
- (a) in the case of a vaccine, it is specially prepared for administration to the animal from which it is derived, or
  - (b) in the case of plasma or a serum, it has been specially prepared for administration to one or more animals in the herd from which it is derived.

**Modifications etc. (not altering text)**

**C104** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C105** Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

**C106** S. 33 amended (E.W.S.) (*prosp.*) by 1954 c. 61, **s. 13I(1)(b)** (as inserted (*prosp.*) by 1997 c. 19, ss. 1, 2, **Sch. para.2**)

**C107** S. 33 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

**34 Restrictions as to animals on which medicinal tests have been carried out.**

- (1) Subject to the following provisions of this Act, no person shall in the course of a business carried on by him sell or supply for human consumption an animal to which in the course of that business a substance or article has been administered by way of a test to which this section applies, or the carcase or any part of the carcase or any produce of such an animal, unless—
- (a) at the time when the substance or article was so administered there was in force an animal test certificate issued in respect of that test, and
  - (b) all the provisions of that certificate relating to the carrying out of the test and the disposal of the animal or its carcase or produce are, and have at all material times been, complied with.
- (2) This section applies to any medicinal test on animals which is carried out in the course of the business of the person who has manufactured the substance or article administered in the test, or is carried out on his behalf in the course of the business of a laboratory or research establishment carried on by another person, and (in either case) is so carried out on one or more animals kept in the course of the business of the person carrying out the test.

**Modifications etc. (not altering text)**

**C108** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C109** Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

**C110** S. 34 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### **35 Supplementary provisions as to clinical trials and medicinal tests on animals.**

- (1) The restrictions imposed by section 7 of this Act do not apply to anything done in accordance with <sup>F110</sup>... an animal test certificate.
- (2) The restrictions imposed by section 8(2) of this Act—
  - <sup>F111</sup>(a) .....
  - (b) do not apply to the manufacture or assembly of any medicinal product for the sole purpose of its being administered by way of a medicinal test on animals, or of its being sold, supplied or exported for the sole purpose of its being so administered, unless the product falls within a class of medicinal products specified in an order made for the purposes of this paragraph by the Agriculture Ministers.
- (3) No class of medicinal products shall be specified in an order for the purposes of paragraph (b) of subsection (2) of this section unless it appears to the Agriculture Ministers to be requisite to do so for securing that the exemption conferred by that paragraph does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.
- (4) <sup>F112</sup>... neither the restrictions imposed by section 7 of this Act nor those imposed by section 32(1) of this Act apply to anything done in relation to a medicinal product for the purposes of a medicinal test on animals which is to be carried out wholly outside the United Kingdom, unless the product falls within a class specified in an order made for the purposes of subsection (2)(b) of this section.
- (5) Where the holder of a manufacturer's licence manufactures or assembles any medicinal product for sale or supply for the purposes of <sup>F113</sup>... a medicinal test on animals, and—
  - <sup>F114</sup>(a) an animal test certificate has been issued and is for the time being in force in respect of that test, and the test is to be carried out in accordance with that certificate, and;
  - (b) the product is so manufactured or assembled as to comply with any requirements of the certificate relating to the products to be administered in the <sup>F115</sup>... test,then, if the conditions specified in subsection (1) of section 23 of this Act are not fulfilled in relation to the product, that section shall have effect in relation to it as if those conditions were fulfilled.
- (6) Without prejudice to subsection (5) of this section, section 23(1) of this Act shall not have effect in relation to the manufacture or assembly of any medicinal product for sale or supply for the purposes of a medicinal test on animals, where the product falls within a class specified in an order made for the purposes of subsection (2)(b) of this section.
- (7) For the purposes of [<sup>F116</sup>section 32] of this Act a person shall not be treated as doing anything, or procuring anything to be done, for the purposes <sup>F117</sup>... of a medicinal test on animals if—
  - (a) the <sup>F118</sup>... test is, or is to be, carried out under arrangements to which he is not a party, and
  - (b) he has not been informed of those arrangements.
- (8) The appropriate Ministers may by order provide—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- <sup>F119</sup>(a) .....
- (b) that section 32 of this Act shall have effect subject to such exemptions (other than those for the time being having effect by virtue of section 33 of this Act and subsection (4) of this section) as may be so specified.
- (9) Any exemption conferred by an order under subsection (8) of this section may be conferred subject to such conditions or limitations as may be specified in the order.
- (10) The appropriate Ministers may by order provide that <sup>F120</sup>... any of the provisions of section 33 of this Act, or subsection (4) of this section, shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.
- (11) No order shall be made under subsection (10) of 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

- F110** Words in s. 35(1) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(2)**
- F111** S. 35(2)(a) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(3)**
- F112** Words in s. 35(4) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(4)**
- F113** Words in s. 35(5) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(5)(a)**
- F114** S. 35(5)(a) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(5)(b)**
- F115** Words in s. 35(5)(b) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(5)(c)**
- F116** Words in s. 35(7) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(6)(a)**
- F117** Words in s. 35(7) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(6)(b)**
- F118** Words in s. 35(7)(a) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(6)(c)**
- F119** S. 35(8)(a) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(7)**
- F120** Words in s. 35(10) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 7(8)**

#### Modifications etc. (not altering text)

- C111** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C112** S. 35 (other than subsection (8)(a)) applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

### 36 Application for, and issue of, certificate.

- (1) Any application for <sup>F121</sup>... an animal test certificate shall be made to the licensing authority and shall be made in such form and manner, and shall contain, or be

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

accompanied by, such information, documents, samples and other material, as may be prescribed.

- (2) In dealing with any such application, the licensing authority shall have regard in particular to any evidence available to them as to any risks involved in the proposed <sup>F122</sup> ... medicinal test on animals.
- (3) Subject to the next following section, the provisions of sections 20 to [<sup>F123</sup>22A] of this Act shall have effect in relation to applications for <sup>F124</sup> ... animal test certificates, as if in those sections any reference to a licence under this Part of this Act were a reference to such a certificate.

#### Textual Amendments

- F121** Words in s. 36(1) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 8(a)**
- F122** Words in s. 36(2) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 8(b)**
- F123** Word in s. 36(3) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 6**
- F124** Words in s. 36(3) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 8(c)**

#### Modifications etc. (not altering text)

- C113** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C114** Ss. 32–39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**
- C115** S. 36 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

### <sup>F125</sup>37 Transitional provisions as to clinical trials and medicinal tests on animals.

.....

#### Textual Amendments

- F125** S. 37 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), **Sch. 1 Pt. 17** Group 7

#### Modifications etc. (not altering text)

- C116** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C117** Ss. 32–39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

### 38 Duration and renewal of certificate.

- (1) Subject to the following provisions of this section, every <sup>F126</sup> ... animal test certificate, unless previously renewed or revoked, shall expire at the end of the period of two years from the date on which it was issued or the date as from which it was last renewed, as the case may be, or at the end of such shorter period from that date as may be specified in the certificate as issued or last renewed.
- (2) Any such certificate, if it has not been revoked, may, on the application of the holder of the certificate, be renewed by the licensing authority for a further period of two years from the date on which it would otherwise expire or such shorter period from that date as the licensing authority may determine.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) Subsections (1) and (2) of section 36 of this Act shall have effect in relation to applications for the renewal of such certificates as they have effect in relation to applications for the issue of such certificates.
- (4) On an application for the renewal of such a certificate the licensing authority—
- (a) may renew the certificate, with or without modifications, for such a further period as is mentioned in subsection (2) of this section, or
  - (b) may issue to the applicant a new <sup>F127</sup>... animal test certificate containing such provisions as the licensing authority consider appropriate, or
  - (c) if, having regard to the provisions of this Act, they consider it necessary or expedient to do so, may refuse to renew the certificate or to issue a new certificate.
- (5) In relation to any such application the provisions of subsections (2) to (5) of section 20, and of sections [<sup>F128</sup>21 to 22A], of this Act shall have effect as if in those provisions any reference to refusing a licence under this Part of this Act included a reference to refusing to renew [<sup>F129</sup>an animal test certificate] and any reference to granting such a licence included a reference to renewing such a certificate.
- (6) Every application for the grant or renewal of [<sup>F130</sup>an animal test certificate] shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the certificate for the full period of two years mentioned in subsection (1) or subsection (2) of this section, as the case may be; and in any provisions of [<sup>F131</sup>section 21, 22 or 22A] of this Act as applied by the last preceding subsection any reference to the grant or renewal of a certificate otherwise than in accordance with the application shall be construed accordingly.
- (7) Where an application for the renewal of such a certificate has been duly made—
- (a) the certificate shall not cease to be in force by virtue of the preceding provisions of this section before the licensing authority have determined the application, and
  - (b) if by an interim order made under section 107(3)(a) of this Act the operation of the decision of the licensing authority on the application is suspended, the certificate shall not cease to be in force by virtue of those provisions so long as the operation of the decision continues to be suspended by the order.

#### Textual Amendments

- F126** Words in s. 38(1) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 10(a)**
- F127** Words in s. 38(4) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 10(a)**
- F128** Words in s. 38(5) substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 7(a)**
- F129** Words in s. 38(5) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 10(b)**
- F130** Words in s. 38(6) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 10(b)**
- F131** Words in s. 38(6) substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 7(b)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### **Modifications etc. (not altering text)**

**C118** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)

**C119** Ss. 32-39 modified (1.1.1995) by S.I. 1994, reg. 18(4)

**C120** S. 38 applied (with modifications) (2.8.1999) by [S.I. 1999/1871](#), [art. 92\(3\)](#)

### **39 Suspension, revocation or variation of certificate.**

- (1) Subject to the following provisions of this section, the licensing authority may suspend, for such period as the authority may determine, [<sup>F132</sup>an animal test certificate], or may revoke, or vary the provisions of, any such certificate.
- (2) The powers conferred by this section shall not be exercisable by the licensing authority except on one or more of the following grounds, that is to say—
  - (a) that the matters stated in the application on which the certificate was issued were false or incomplete in a material particular;
  - (b) that any of the provisions of the certificate has to a material extent been contravened;
  - (c) that medicinal products of any description to which the certificate relates, as sold, supplied, exported, imported, manufactured or assembled for the purposes of the <sup>F133</sup>... medicinal test on animals to which it relates, fail to a material extent to correspond to the characteristics by reference to which the certificate was issued;
  - (d) that the holder of the certificate has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to any substances or articles to which the certificate relates;
  - (e) that any such substances or articles can no longer be regarded as substances or articles which can safely be administered for the purposes of the <sup>F134</sup>... medicinal test on animals to which the certificate relates;
  - (f) that the specification and standards to which any such substances or articles are manufactured can no longer be regarded as satisfactory.
- (3) The provisions of section 29 of, and Schedule 2 to, this Act shall have effect in relation to [<sup>F135</sup>an animal test certificate] as they have effect in relation to a product licence, as if in paragraph 1 of that Schedule the reference to paragraph (g) or paragraph (h) of section 28(3) of this Act were a reference to paragraph (e) or paragraph (f) of subsection (2) of this section.
- (4) Without prejudice to any power exercisable by virtue of the preceding provisions of this section, the licensing authority may, on the application of the holder of [<sup>F136</sup>an animal test certificate], vary the provisions of the certificate in accordance with any proposals contained in the application, if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the certificate relates.

#### **Textual Amendments**

**F132** Words in s. 39(1) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, [Sch. 10 para. 11\(a\)](#)

**F133** Words in s. 39(2)(c) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, [Sch. 10 para. 11\(b\)](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- F134** Words in s. 39(2)(e) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 11(b)**
- F135** Words in s. 39(3) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 11(a)**
- F136** Words in s. 39(4) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 11(a)**

**Modifications etc. (not altering text)**

- C121** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C122** Ss. 32–39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**
- C123** S. 39 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

*Medicated animal feeding stuffs*

[<sup>F137</sup>40] **Medicated animal feeding stuffs.**

- (1) The Agriculture Ministers may by regulations prohibit the incorporation by any person, in the course of a business carried on by him, of a medicinal product of any description in an animal feeding stuff unless such of the conditions mentioned in subsection (2) of this section as may be specified in the regulations are satisfied.
- (2) The conditions referred to in subsection (1) of this section are—
  - (a) that it is incorporated in accordance with provisions relating to the incorporation of the medicinal product in animal feeding stuffs contained in a product licence or animal test certificate (whether held by him or by another person);
  - (b) that it is incorporated in accordance with a written direction given by a veterinary surgeon or veterinary practitioner, being a written direction complying with such requirements as may be specified in the regulations;
  - (c) that the person concerned is for the time being entered in a register kept for the purposes of the regulations by the registrar or the Northern Ireland enforcement authority.
- (3) A condition imposed by virtue of subsection (2)(a) of this section shall be taken to be satisfied if the person incorporating the medicinal product in the animal feeding stuff—
  - (a) is not the holder of a product licence or animal test certificate containing such provisions as are mentioned in that paragraph, but
  - (b) believes, on reasonable grounds, that another person is the holder of such a licence or certificate containing such provisions and that the medicinal product is incorporated in accordance with those provisions.
- (4) The Agriculture Ministers may by regulations prohibit—
  - (a) the sale, offer for sale, supply or export by any person in the course of a business carried on by him of any animal feeding stuff in which a medicinal product has been incorporated, or
  - (b) the importation by any person of any animal feeding stuff in which a medicinal product has been incorporated,
 unless such of the conditions mentioned in subsection (5) of this section as may be specified in the regulations are satisfied.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (5) The conditions referred to in subsection (4) of this section are—
- (a) that the medicinal product was not incorporated in the animal feeding stuff in contravention of any prohibition imposed by virtue of subsection (1) of this section;
  - (b) that the feeding stuff is sold, offered for sale, supplied, exported or imported (as the case may be) in accordance with a written direction given by a veterinary surgeon or veterinary practitioner, being a written direction complying with such requirements as may be specified in the regulations;
  - (c) that the person concerned is for the time being entered in a register kept for the purposes of the regulations by the registrar or the Northern Ireland enforcement authority.
- (6) A condition imposed by virtue of subsection (5)(a) of this section shall be taken to be satisfied if the person selling, offering for sale, supplying, exporting or importing the animal feeding stuff—
- (a) did not incorporate the medicinal product in it, and
  - (b) had no reasonable grounds to believe that it was incorporated in contravention of any prohibition imposed by virtue of subsection (1) of this section.
- (7) Regulations under this section may impose such conditions as the Agriculture Ministers think fit in respect of the inclusion or retention of persons in a register kept for the purposes of the regulations, including conditions requiring the payment to the registrar or the Northern Ireland enforcement authority of fees of such amounts as the Agriculture Ministers may with the consent of the Treasury determine.
- (8) In determining any such fees, the Agriculture Ministers may have regard to—
- (a) any costs incurred or to be incurred by the Pharmaceutical Society or the Northern Ireland enforcement authority in connection with any duty to enforce any provision of regulations under this section, and
  - (b) any costs incurred or to be incurred by any other person for the purpose of maintaining or improving standards among those engaged in the activities referred to in subsections (1) and (4) of this section.
- (9) Any fees received by virtue of this section for the inclusion or retention of any person in a register kept for the purposes of the regulations shall, if the Agriculture Ministers so determine, be applied to such extent and in such manner as they may determine towards meeting any costs falling within subsection (8)(b) of this section; subject to that, any such fees received by the registrar shall be applicable for the purposes of the Pharmaceutical Society.
- (10) A person contravenes this section if he contravenes any prohibition imposed by virtue of subsection (1) or (4) of this section.
- (11) References in this Act to the incorporation of a medicinal product in an animal feeding stuff do not include a reference to it being so incorporated in the course of making a medicinal product; but, subject to that, they include a reference to the incorporation—
- (a) for a medicinal purpose of a substance or article other than a medicinal product, or
  - (b) of a substance in which a medicinal product has been incorporated, in an animal feeding stuff.
- (12) In this section— “the Northern Ireland enforcement authority” means any Northern Ireland Department having a duty to enforce any provision of this section or of

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

regulations under it; and “the registrar” means any person appointed under section 1 of the Pharmacy Act <sup>M2</sup>1954 as registrar for the purposes of that Act.]

**Textual Amendments**

**F137** S. 40 substituted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 13(1)

**Modifications etc. (not altering text)**

**C124** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), art. 3(1)

**C125** S. 40 applied (1.1.1995) by [S.I. 1994/3142](#), reg. 18(2)

**C126** S. 40(11) applied (1.7.1992) by [S.I. 1992/1520](#), reg. 2(2)

**Marginal Citations**

**M2** [1954 c.61](#) (83:1).

**41–42** ..... **F138**

**Textual Amendments**

**F138** Ss. 41, 42 repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, Sch. 1 para. 3(3), Sch. 2

*Supplementary provisions*

**43 Extension of s. 7 to certain special circumstances.**

- (1) Where in the course of a business carried on by him a person sells, supplies or exports a substance or article for use wholly or mainly in either or both of the ways specified in section 130(1) of this Act, and the substance or article, not having been—
  - (a) manufactured or imported for such use, or
  - (b) previously sold or supplied for such use,
 does not constitute a medicinal product before that person so sells, supplies or exports it, then (subject to subsection (2) of this section) subsection (2) of section 7 of this Act, if apart from this subsection it would not so have effect, shall have effect in relation to the sale, supply or exportation of the substance or article as if he were selling, supplying or exporting it in circumstances to which that subsection applies.
- (2) Subsection (1) of this section shall not have effect in relation to a transaction whereby a person, in the course of a business carried on by him, sells a substance or article by retail or supplies a substance or article in circumstances corresponding to retail sale unless in the course of that business the substance or article has been assembled for the purpose of being sold or supplied by him.
- (3) In any reference in this Part of this Act to the provisions of, or the restrictions imposed by, section 7 of this Act, the reference to that section shall be construed as including a reference to subsection (2) of that section as extended by the preceding subsections.
- (4) Where in the course of a business carried on by him a person proposes to sell, supply or export a substance or article for use as mentioned in subsection (1) of this section, where the substance or article will not constitute a medicinal product before he so



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

sells, supplies or exports it and he will not be selling, supplying or exporting it in circumstances to which section 7(2) of this Act applies, he may, if he so desires, apply for a product licence in respect of that substance or article, and the licensing authority (subject to the provisions of sections 19 to [F139]22A] of this Act) may grant to him a product licence in respect of it, as if he were proposing to sell, supply or export it in circumstances to which section 7(2) of this Act applies; and a product licence so granted may be renewed, suspended, revoked or varied accordingly.

- (5) In subsection (2) of this section the reference to assembling a substance or article in the course of a business carried on by a person is a reference to doing in the course of that business anything which (in accordance with section 132(1) of this Act) would constitute assembling if it had been a medicinal product when sold or supplied to him.

#### Textual Amendments

**F139** Word in s. 43(4) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), Sch. 1 para. 8

#### Modifications etc. (not altering text)

**C127** Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, art. 3(1)

## 44 Provision of information to licensing authority.

- (1) Where an application has been made to the licensing authority for a licence under this Part of this Act (including a licence of right) or for [F140]an animal test certificate] (including a certificate to which a person is entitled by virtue of section 37(4) of this Act) the licensing authority, before determining the application, may request the applicant to furnish to the licensing authority such information relating to the application as the licensing authority may consider requisite; and, where any such request has been made, the licensing authority shall not be required to determine the application until either—
- the information requested has been furnished to them, or
  - it has been shown to their reasonable satisfaction that the applicant is unable to furnish the information.
- (2) The licensing authority may serve on the holder of a licence under this Part of this Act, or of [F141]an animal test certificate], a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority information of any description specified in the notice in accordance with the following provisions of this section.
- (3) Except as provided by subsection (4) of this section, a notice under subsection (2) of this section shall not be served unless it appears to the licensing authority, or it is represented to them <sup>F142</sup>... by the appropriate committee, that circumstances exist by reason of which it is necessary to consider whether the licence or certificate should be varied, suspended or revoked; and the information required by such a notice shall be such as appears to the licensing authority, or is represented to them <sup>F142</sup>... by the committee, to be requisite for considering that question.
- (4) Subsection (3) of this section shall not have effect in the case of a licence of right, or of a certificate issued in pursuance of section 37(4) of this Act, whether the licence or certificate has been renewed or not; and, in the case of such a licence or certificate, a

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

notice under this section may be served at any time and may require any information which, in the opinion of the licensing authority, would be relevant if—

- (a) sections 25 and 37(4) of this Act had not been enacted, and
  - (b) the licensing authority were then dealing with an application, by the person who is the holder of the licence or certificate, for the grant or issue of a licence or certificate containing the same provisions as those contained in the licence or certificate in question.
- (5) Before the end of the period of two years from the date on which a product licence, other than a licence of right, is granted, the holder of the licence shall, in respect of each description of medicinal products to which the licence relates which is effectively on the market in the United Kingdom within that period, notify to the licensing authority a date on which medicinal products of that description were effectively on that market.

#### Textual Amendments

**F140** Words in s. 44(1) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 12**

**F141** Words in s. 44(2) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 12**

**F142** Words in s. 44(3) omitted (30.10.2005) by virtue of [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 9**

#### Modifications etc. (not altering text)

**C128** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

**C129** S. 44 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch.4**

**C130** S. 44 amendment to earlier affecting provision [SI 1994/105 Sch. 4 \(30.10.2005\)](#) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(3)**

**C131** S. 44(1)(2)(3) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.

## 45 Offences under Part II.

- (1) Subject to the next following section, any person who contravenes any of the provisions of section 7, section 8, <sup>F143</sup>... section 32, section 34 or section 40 of this Act, or who is in possession of any medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those sections, shall be guilty of an offence.
- (2) Where any medicinal product or animal feeding stuff is imported in contravention of section 7, <sup>F144</sup>... section 32 or section 40 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the product or feeding stuff knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.
- (3) Any person who, being the holder of a product licence or of [<sup>F145</sup>an animal test certificate], procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence or certificate relates, and—
  - (a) does not communicate to that person the provisions of the licence or certificate which are applicable to medicinal products of that description, or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) in a case where any of those provisions has been varied by a decision of the licensing authority, does not communicate the variation to that person within fourteen days after notice of the decision has been served on him, shall be guilty of an offence.
- (4) Any person who, being the holder of a product licence or of an animal test certificate, sells or supplies a substance or article to which the licence or certificate relates to another person for the purpose of its being incorporated in any animal feeding stuff, and does not communicate to that person any provisions of the licence or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.
- (5) Where any such provisions of a product licence or animal test certificate as are mentioned in subsection (4) of this section are varied by the licensing authority, and on varying those provisions the licensing authority serve on the holder of the licence or certificate a notice requiring him, within such time (not being less than fourteen days from the date of service of the notice) as may be specified in the notice, to take such steps as may be so specified for making the variation known, either generally or to persons or classes of persons specified in the notice, then if the holder of the licence or certificate does not comply with the requirements of that notice he shall be guilty of an offence.
- (6) Any person who, in giving any information which he is required to give under section 44 of this Act, makes a statement which he knows to be false in a material particular shall be guilty of an offence.
- (7) Any person who without reasonable excuse fails to comply with a requirement imposed on him by a notice under section 44(2) of this Act shall be guilty of an offence.
- (8) Any person guilty of an offence under any of subsections (1) to (6) of this section shall be liable—
- (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (9) Any person guilty of an offence under subsection (7) of this section shall be liable on summary conviction to a fine not exceeding [<sup>F146</sup>level 3 on the standard scale]

#### Textual Amendments

- F143** Words in s. 45(1) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 13(a)**
- F144** Words in s. 45(2) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 13(a)**
- F145** Words in s. 45(3) substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 13(b)**
- F146** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c. 48, SIF 39:1\)](#), **ss. 38, 46**, (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **ss. 289F, 289G** and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), **arts. 5, 6**

#### Modifications etc. (not altering text)

- C132** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- C133** s. 45 extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)
- C134** S. 45 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(4)**
- C135** S. 45(1)(2)(6)(7)(8)(9) applied (with modifications) (3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.

#### 46 Special defences under s. 45.

- (1) Where the holder of a product licence or of [<sup>F147</sup>an animal test certificate] is charged with an offence under the last preceding section in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence or certificate which are applicable to it, it shall be a defence for him to prove—
- that he had communicated those provisions to that other person, and
  - that he did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with.
- (2) Where the holder of a manufacturer's licence is charged with an offence under the last preceding section in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a product licence or of [<sup>F147</sup>an animal test certificate] which is applicable to those products, but the products were manufactured or assembled to the order of another person, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing,—
- that the other person in question was the holder of a product licence applicable to those products, or of [<sup>F147</sup>an animal test certificate] applicable to them, and
  - that the products were manufactured or assembled in accordance with that product licence or certificate.
- (3) . . . . . <sup>F148</sup>

#### Textual Amendments

- F147** Words in s. 46 substituted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 14**
- F148** S. 46(3)(4) repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, Sch. 1 para. 3(3), **Sch. 2**

#### Modifications etc. (not altering text)

- C136** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403, art. 3\(1\)](#)
- C137** S. 46 extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)
- C138** S. 46 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(2)**
- C139** S. 46(1) applied (with modifications)(3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.

#### 47 Standard provisions for licences or certificates.

- (1) The Ministers may by regulations prescribe standard provisions for the purposes of this Part of this Act, either generally or in relation to any class of medicinal products specified in the regulations.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (2) Any standard provisions so prescribed may be incorporated by the licensing authority in any licence under this Part of this Act or any <sup>F149</sup>... animal test certificate granted or issued on or after the date on which the regulations come into operation, and may be so incorporated with or without modifications and either generally or in relation to medicinal products of any particular class.
- (3) The following provisions of this section shall have effect where—
- (a) standard provisions are prescribed by regulations made under this section, or
  - (b) after any such provisions have been so prescribed, they are amended by, or superseded by new standard provisions prescribed by, subsequent regulations so made;
- and in the following provisions of this section, in a case falling within paragraph (a) but not within paragraph (b) of this subsection, “the operative standard provisions” means the standard provisions prescribed by the regulations and “the relevant regulations” means those regulations, and, in any other case, “the operative standard provisions” means the standard provisions as amended by the subsequent regulations or the new standard provisions prescribed by those regulations, as the case may be, and “the relevant regulations” means the subsequent regulations.
- (4) Subject to the following provisions of this section, as from the end of the period of three months from the date on which the relevant regulations come into operation, the operative standard provisions shall be deemed to be incorporated in any licence under this Part of this Act, or any <sup>F150</sup>... animal test certificate, which is in force at the end of that period or, in the case of a suspended licence or certificate, would then be in force if it were not suspended, in so far as, in accordance with the relevant regulations, the operative standard provisions are applicable to medicinal products of any description to which that licence or certificate relates.
- (5) Notwithstanding anything in subsection (4) of this section, the operative standard provisions shall not by virtue of that subsection be deemed to be incorporated in any licence of right, or in any certificate issued in pursuance of section 37(4) of this Act, including any such licence or certificate which has been renewed, except in circumstances where, immediately before the first appointed day, the manufacture or importation of substances or articles to which the licence or certificate relates was authorised by a licence issued under Part I of the <sup>M3</sup>Therapeutic Substances Act 1956 or under Part II of the <sup>M4</sup>Diseases of Animals Act 1950, or of the <sup>M5</sup>Diseases of Animals Act (Northern Ireland) 1958, and, where those circumstances exist, shall be deemed to be so incorporated only in relation to substances or articles to which the licence so issued was applicable.
- (6) At any time after the relevant regulations are made and before the end of the period of three months from the date on which they come into operation, the holder of any licence or certificate may apply to the licensing authority to direct—
- (a) that the operative standard provisions shall not be deemed to be incorporated in that licence or certificate, or
  - (b) that the operative standard provisions shall be deemed to be so incorporated subject to such exceptions or modifications as may be specified in the application;

and if, on any such application, the licensing authority direct that the operative standard provisions shall not be deemed to be so incorporated, or shall be deemed to be so incorporated subject to exceptions and modifications specified in the direction, with or without provision postponing the date as from which they are to be deemed

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

to be so incorporated, that direction shall have effect notwithstanding anything in subsection (4) of this section.

- (7) Where an application is made to the licensing authority under subsection (6) of this section, then, if the licensing authority propose to refuse to give a direction in accordance with the application, the licensing authority, before determining the application, shall afford to the applicant an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to that proposal; and, if the licensing authority then determine to refuse to give a direction in accordance with the application, they shall serve on the applicant a notice stating the reasons for their decision.
- (8) Without prejudice to any direction given under subsection (6) of this section, where such an application is made—
- (a) the operative standard provisions shall not be deemed to be incorporated in the licence or certificate to which the application relates before the licensing authority have made a decision on that application, and
  - (b) if an application under section 107 of this Act is made with respect to that decision, those provisions shall not be deemed to have been or to be so incorporated before the application under subsection (6) of this section has been finally disposed of;

and so much of subsection (7) of section 27 of this Act as relates to the time when an application is to be taken to be finally disposed of shall have effect for the purposes of this subsection as it has effect for the purposes of that section.

- (9) The powers conferred on the licensing authority by the preceding provisions of this Part of this Act to vary the provisions of a licence or certificate shall be exercisable with respect to any provisions which, in accordance with this section, are incorporated or deemed to be incorporated in a licence or certificate.

#### Textual Amendments

- F149** Words in s. 47(2) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 15**
- F150** Words in s. 47(4) omitted (1.5.2004) by virtue of [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 15**

#### Modifications etc. (not altering text)

- C140** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**
- C141** S. 47(1)(2)(3)(4)(6)(7) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.
- C142** S. 47(4) excluded (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), Sch. 6 para. 1(2)(c) (i) Sch. 6 para. 3(2)(a) **Sch. 6 para. 3(3)(a)** (with Sch. 6)
- C143** S. 47(6) applied (with modifications) (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), Sch. 6 para. 1 Sch. 6 para. 3(2) **Sch. 6 para. 3(3)** (with Sch. 6)
- C144** S. 47(7) modified (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), Sch. 6 para. 1 Sch. 6 para. 3(2) **Sch. 6 para. 3(3)** (with Sch. 6)
- C145** S. 47(8) excluded (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), Sch. 6 para. 1 Sch. 6 para. 3(2) **Sch. 6 para. 3(3)** (with Sch. 6)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### Marginal Citations

- M3 1956 c. 25.
- M4 1950 c. 36.
- M5 1958 c. 13 (N.I.)

### 48 Postponement of restrictions in relation to exports.

- (1) Notwithstanding anything in sections 7 to 47 of this Act but subject to [F151sections 49 and 49A of this Act,] in relation to anything done before such day (subsequent to the first appointed day) as the Ministers may by order appoint for the purposes of this subsection (in this section referred to as “the special appointed day”) those sections shall have effect as if in them—
  - (a) every reference to exportation (in whatever form the reference occurs) were omitted;
  - (b) any reference to the sale or supply of a medicinal product did not include sale or supply which involves, or is for the purposes of, exporting the product; and
  - (c) any reference to offering a medicinal product for sale did not include an offer for sale where the prospective sale would involve, or would be for the purposes of, exporting the product.
- (2) The Ministers shall not make an order under the preceding subsection unless it appears to them to be necessary or expedient to do so for the purpose of giving effect to an agreement to which the United Kingdom or Her Majesty’s Government in the United Kingdom is a party or will be a party on the day appointed by the order.
- (3) The following provisions of this section shall have effect where an order is made under subsection (1) of this section; and for the purposes of those provisions the relevant transitional conditions shall be taken to be fulfilled by a person in relation to medicinal products of any description if, in the course of a business carried on by him,—
  - (a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending immediately before the special appointed day, and
  - (b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.
- (4) Unless the order expressly excludes the operation of this subsection,—
  - (a) subject to any order made by virtue of paragraph (b) of this subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting on or after the special appointed day, or procuring the exportation on or after that day of, medicinal products of any description in relation to which he fulfils the relevant transitional conditions;
  - (b) section 17 of this Act shall have effect in relation to paragraph (a) of this subsection as it has effect in relation to the subsections of section 16 of this Act mentioned in that section.
- (5) Where a product licence which is in force on the special appointed day authorises the holder of the licence to sell medicinal products of any description, or to procure the sale, or procure the manufacture or assembly for sale, of medicinal products of any description, that licence shall have effect on and after that day as if—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) it also authorised him to export medicinal products of that description, or (as the case may be) to procure the exportation, or procure the manufacture or assembly for exportation, of medicinal products of that description, and
- (b) it authorised him to do so subject to the like provisions as (apart from subsections (3) to (7) of section 47 of this Act) are specified in the licence in relation to selling or (as the case may be) procuring the sale, or procuring the manufacture or assembly for sale, of such products:

Provided that, if the operation of subsection (4) of this section is not excluded by the order, a product licence shall not have effect as mentioned in this subsection in relation to medicinal products of any description so long as paragraph (a) of that subsection has effect in relation to the holder of the licence in respect of his exporting, or procuring the exportation of, medicinal products of that description.

- (6) Where on an application for a product licence made before such date as may be appointed by the order for the purposes of this subsection, which states that it is an application made by virtue of this subsection, it is proved to the reasonable satisfaction of the licensing authority that the applicant fulfilled or will fulfil the relevant transitional conditions in relation to one or more descriptions of medicinal products, then (subject to the next following subsection) he shall be entitled to the grant of a product licence granted so as—
  - (a) to be limited to exportation, or procuring exportation, of medicinal products, and
  - (b) not to extend to medicinal products of any description other than those in respect of which it is so proved that the applicant fulfilled or will fulfil those conditions, and
  - (c) not to extend to medicinal products of any description in respect of which, at the time when the licence is granted, a product licence is already held by the applicant.
- (7) If a person would, on making an application under subsection (6) of this section, be entitled to the grant of a product licence under that subsection in respect of medicinal products of a particular description, and he would at the same time, on making an application as mentioned in section 25(1) of this Act, be entitled to the grant of a licence of right in respect of medicinal products of the same description, he may apply to the licensing authority for a single product licence for both purposes, and he shall be entitled to the grant of a product licence having the same effect as the two licences, if granted separately, would together have had.
- (8) Subsection (6) of section 26 of this Act shall have effect for the purposes of subsections (6) and (7) of this section as it has effect for the purposes of that section.
- (9) An order made under subsection (1) of this section may contain such provisions relating to proceedings on an application made under subsection (6) or subsection (7) of this section (whether by way of applying with modifications any of the provisions of section 27 of this Act or otherwise) as the Ministers may consider appropriate.
- (10) 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

**F151** Words in s. 48(1) substituted (14.4.1993) by [S.I. 1993/834](#), [reg. 5](#)



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

C146 Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)

**49 Special provisions in respect of exporting certain products.**

- (1) Nothing in subsection (1) of section 48 of this Act shall affect the operation of any of the provisions of sections 7 to 47 of this Act in relation to any medicinal product falling within a class specified in an order made under this section by the Health Ministers or the Agriculture Ministers.
- (2) No class of medicinal products shall be specified in an order made by the Health Ministers or the Agriculture Ministers under this section unless it appears to the Ministers making the order to be requisite to do so for securing that any exemption conferred by section 48(1) of this Act does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.
- (3) Subsections (3) to (7) of section 48 of this Act shall not have effect in relation to medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the day appointed for the purposes of subsection (1) of that section.
- (4) Subject to the next following subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting, or procuring the exportation of, medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the first appointed day if, in the course of a business carried on by that person,—
  - (a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending with the first appointed day, and
  - (b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.
- (5) Sections 17 and 25 of this Act shall have effect in relation to subsection (4) of this section as they have effect in relation to subsections (2) to (5) of section 16 of this Act.
- (6) Where a person is entitled to the grant of a licence of right by reason that subsection (4) of this section has effect in relation to him, he shall be entitled to the grant of a product licence; but, subject to the next following subsection, the licence shall be granted so as not to extend to medicinal products of any description other than those in respect of which the conditions specified in that subsection are proved to the reasonable satisfaction of the licensing authority to have been fulfilled, and shall be limited to exporting, or procuring the exportation of, medicinal products.
- (7) Subsection (5) of section 26 of this Act (with the omission of paragraph (b) of that subsection) and subsection (6) of that section shall have effect in relation to the grant of a licence of right in accordance with subsection (6) of this section as those subsections have effect in relation to the grant of such a licence in accordance with subsection (1) of that section.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (8) In relation to any application for a licence of right which is made by virtue of section 25 of this Act as applied by subsection (5) of this section, the provisions of section 27 of this Act shall have effect subject to such modifications as may be specified by order made by the Ministers for the purposes of this subsection.

**Modifications etc. (not altering text)**

C147 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**F152**      **Special provisions in respect of exporting certain products to member States**  
**49A**

**Textual Amendments**

**F152** S. 49A repealed (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), **Sch. 5 para. 6** (with Sch. 6)

**[<sup>F153</sup>49B. Special provisions in respect of exporting certain products to EEA States**

Nothing in section 48 of this Act affects the operation of section 8(3A) of this Act in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if —

- (a) it is a product to which the 2001 Directive applies; and
- (b) the exportation is, or is to be, to an EEA State.]

**Textual Amendments**

**F153** S. 49B inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), **Sch. 5 para. 7** (with Sch. 6)

**50**      **Certificates for exporters of medicinal products.**

On the application of any person who proposes to export medicinal products of any description, the licensing authority may issue to him a certificate containing any such statement relating to medicinal products of that description as the licensing authority may consider appropriate having regard—

- (a) to any requirements (whether having the force of law or not) which have effect in the country to which the products are to be exported, and
  - (b) to the provisions of this Act and to any licence granted or other thing done by virtue of this Act.
- [<sup>F154</sup>, and
- (c) to the provisions of the Clinical Trials Regulations and to any authorisation granted or other thing done by virtue of those regulations.]

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### Textual Amendments

**F154** S. 50(c) and word inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [reg. 1](#), [Sch. 10 para. 16](#)

#### Modifications etc. (not altering text)

**C148** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)

**C149** S. 50 applied (with modifications)(3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#),Sch.

## PART III

### FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

#### Modifications etc. (not altering text)

**C150** Part III (ss.51-68) modified (1.1.1995) by [S.I. 1994/3144](#), [reg. 9\(9\)](#)

**C151** Pt. III 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\(12\)](#)

#### *Provisions as to sale or supply of medicinal products*

### 51 General sale lists.

- (1) The appropriate Ministers may by order specify descriptions or classes of medicinal products, as being products which in their opinion can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.
- (2) In this Act any reference to a medicinal product on a general sale list is a reference to a medicinal product of a description, or falling within a class, specified in an order under this section which is for the time being in force.
- (3) An order under this section may designate any description or class of medicinal products specified in the order as being medicinal products which, in the opinion of the appropriate Ministers, can with reasonable safety be sold by means of automatic machines; and any reference in this Act to a medicinal product in the automatic machines section of a general sale list is a reference to a medicinal product of a description, or falling within a class, so designated by any such order which is for the time being in force.

#### Modifications etc. (not altering text)

**C152** S. 51 extended by [S.I. 1984/187](#), [art. 2](#)

[S. 51](#) applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)

[S. 51](#) applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)

### 52 Sale or supply of medicinal products not on general sale list.

Subject to any exemption conferred by or under this Part of this Act, on and after such day as the Ministers may by order appoint for the purposes of this section (in this

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

Part of this Act referred to as “the appointed day”) no person shall, in the course of a business carried on by him, sell by retail, offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product which is not a medicinal product on a general sale list, unless—

- (a) that person is, in respect of that business, a person lawfully conducting a retail pharmacy business;
- (b) the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy; and
- (c) that person, or, if the transaction is carried out on his behalf by another person, then that other person, is, or acts under the supervision of, a pharmacist.

#### Modifications etc. (not altering text)

- C153** S. 52 excluded by [S.I. 1978/1421](#)  
 S. 52 excluded by [S.I. 1989/2318](#), [arts. 3\(1\)\(3\)](#), [6\(1\)\(3\)](#), [9\(1\)\(3\)\(5\)](#), [11\(1\)](#), [13\(2\)](#), [14](#)  
 S. 52 excluded (12.10.1994) by [S.I. 1980/1924](#), [art. 2\(3\)](#) (as inserted by [S.I. 1994/2409](#), [art. 2](#)) (which S.I. was revoked (19.10.1998) by [S.I. 1998/2368](#), [art. 2\(b\)](#))  
 S. 52 excluded (19.10.1998) by [S.I. 1980/1924](#), [art. 6A](#) (as inserted by [S.I. 1998/2368](#), [art. 2\(c\)](#))  
 S. 52 excluded (9.8.2000) by [S.I. 1980/1924](#), [arts. 4A](#), [4B](#) (as inserted by [S.I. 2000/1919](#), [art. 2\(c\)](#))  
 S. 52 excluded (4.4.2003) by [S.I. 1980/1924](#), [arts. 4C](#), [4D](#) (as inserted by [S.I. 2003/697](#), [art. 3](#))  
 S. 52 excluded (31.1.2004) by [S.I. 1980/1924](#), [art. 4AA](#) (as inserted by [S.I. 2004/1](#), [art. 3](#))
- C154** S. 52 extended by [S.I. 1984/187](#), [art. 2](#)
- C155** S. 52 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
 S. 52 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)  
 S. 52 amended (E.W.S.) (*prosp.*) by [1954 c. 61](#), [s. 13I\(1\)\(b\)](#), (as inserted (*prosp.*) by [1997 c. 19](#) ss. 1,2, Sch. para. 2)
- C156** S. 52 excluded by [SI 1980/1924 art. 4AA](#) (as inserted (31.1.2004) by [Medicines \(Pharmacy and General Sale - Exemption\) Amendment Order 2004](#) ([S.I. 2004/1](#)), [arts. 1\(1\)](#), [3](#))
- C157** S. 52(c) excluded by [S.I. 1989/2318](#), [art. 13\(1\)](#)

### 53 Sale or supply of medicinal products on general sale list.

- (1) Subject to any exemption conferred by or under this Part of this Act, on and after the appointed day no person shall, in the course of a business carried on by him, sell by retail, or offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product on a general sale list elsewhere than at a registered pharmacy, unless the conditions specified in the following provisions of this section are fulfilled.
- (2) The place at which the medicinal product is sold, offered, exposed or supplied as mentioned in the preceding subsection must be premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, unless either—
  - (a) the product is sold, offered, exposed for sale or supplied by means of an automatic machine and the product is a medicinal product in the automatic machines section of a general sale list, or
  - (b) the product is a veterinary drug.
- (3) The medicinal product must have been made up for sale in a container elsewhere than at the place at which it is sold, offered, exposed for sale or supplied as mentioned in subsection (1) of this section and the container must not have been opened since the product was made up for sale in it.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) The business, so far as concerns the sale or supply of medicinal products, must be carried on in accordance with such conditions (if any) as may be prescribed for the purposes of this section.

**Modifications etc. (not altering text)**

- C158** S. 53 excluded by [S.I. 1978/1421](#)  
S. 53 excluded (19.10.1998) by [S.I. 1980/1924](#), [art. 6A](#) (as inserted by [S.I. 1998/2368](#), [art. 2\(c\)](#))  
S. 53 excluded (9.8.2000) by [S.I. 1980/1924](#), [arts. 4A, 4B](#) (as inserted by [S.I. 2000/1919](#), [art. 2\(c\)](#))  
S. 53 excluded (4.4.2003) by [S.I. 1980/1924](#), [arts. 4C, 4D](#) (as inserted by [S.I. 2003/697](#), [art. 3](#))  
S. 53 excluded (31.1.2004) by [S.I. 1980/1924](#), [art. 4AA](#) (as inserted by [S.I. 2004/1](#), [art. 3](#))  
**C159** S. 53 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 53 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)  
**C160** S. 53 excluded by [SI 1980/1924 art. 4AA](#) (as inserted (31.1.2004) by [Medicines \(Pharmacy and General Sale - Exemption\) Amendment Order 2004 \(S.I. 2004/1\)](#), [arts. 1\(1\), 3](#))

**54 Sale of medicinal products from automatic machines.**

- (1) On and after the appointed day no person shall sell, or offer or expose for sale, any medicinal product by means of an automatic machine unless it is a medicinal product in the automatic machines section of a general sale list.
- (2) The appropriate Ministers may by order provide that no person shall by means of an automatic machine sell, or offer or expose for sale, any medicinal product to which the order applies unless the container in which it is sold, or offered or exposed for sale, complies with such restrictions as to the quantity of the medicinal product, or the number of medicinal products, which it contains as may be specified in the order.
- (3) An order under subsection (2) of this section may be made either in respect of medicinal products generally or in respect of medicinal products of a particular description or falling within a particular class specified in the order.

**Modifications etc. (not altering text)**

- C161** S. 54 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 54 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)

*Exemptions from sections 52 and 53*

**55 Exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners.**

- (1) The restrictions imposed by sections 52 and 53 of this Act do not apply to the sale, offer for sale, or supply of a medicinal product—
- (a) by a doctor or dentist to a patient of his or to a person under whose care such a patient is, or
- (b) in the course of the business of a hospital or health centre, where the product is sold, offered for sale or supplied for the purpose of being administered (whether in the hospital or health centre or elsewhere) in accordance with the directions of a doctor or dentist.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (2) Those restrictions also do not apply—
- (a) to the sale or supply of a medicinal product of a description, or falling within a class, specified in an order made by the Health Ministers for the purposes of this paragraph, where the product is sold or supplied by a registered nurse in the course of her professional practice, or
  - (b) to the sale or supply of a medicinal product of a description, or falling within a class, specified in an order made by the Health Ministers for the purposes of this paragraph, where the product either is sold or supplied by a [<sup>F155</sup>registered midwife] in the course of her professional practice or is delivered or administered by such a midwife on being supplied in pursuance of arrangements made by [<sup>F156</sup>the Secretary of State or the Ministry of Health and Social Services for Northern Ireland].
- (3) The restrictions imposed by those sections do not apply to the sale, offer for sale, or supply of a medicinal product by a veterinary surgeon or veterinary practitioner for administration by him or under his direction to an animal or herd which is under his care.
- (4) Expressions to which a meaning is assigned by subsection (2) of section 11 of this Act have the same meanings in this section as in that section.

#### Textual Amendments

**F155** Words in s. 55(2)(b) substituted (1.8.2004) by [The Health Act 1999 \(Consequential Amendments\) \(Nursing and Midwifery\) Order 2004 \(S.I. 2004/1771\)](#), art. 1(1), **Sch. para. 10(b)**

**F156** Words substituted by [National Health Service Reorganisation Act 1973 \(c. 32\)](#), **Sch. 4 para. 128(1)**

#### Modifications etc. (not altering text)

**C162** S. 55 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**

S. 55 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch.5**

**C163** S. 55(1) extended by [S.I. 1984/187](#), **art. 2**

## 56 Exemptions in respect of herbal remedies.

- (1) Subject to the following provisions of this section, the restrictions imposed by sections 52 and 53 of this Act do not apply to anything done at premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, and which consists of the sale, or offer or exposure for sale, or the supply in circumstances corresponding to retail sale, of a herbal remedy where the processes to which the plant or plants are subjected consist of drying, crushing or comminuting, with or without any subsequent process of tableting, pill-making, compressing or diluting with water, but not any other process.
- (2) Without prejudice to the preceding subsection, but subject to subsection (3) of this section, those restrictions do not apply to the sale or supply of a herbal remedy where the person selling or supplying the remedy sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.
- (3) The appropriate Ministers may by order provide that subsections (1) and (2) of this section shall not have effect in relation to herbal remedies of a description, of falling within a class, specified in the order.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

- C164** S. 56 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 56 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)
- C165** S. 56 excluded (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\)](#), [10\(3\)](#) (with [Sch. 6](#))

**57 Power to extend or modify exemptions.**

- (1) The appropriate Ministers may by order provide that section 52 or section 53 of this Act, or both of those sections, shall have effect subject to such exemptions (other than those for the time being having effect by virtue of sections 55 and 56 of this Act) as may be specified in the order.
- (2) Any exemption conferred by an order under the preceding subsection may be conferred subject to such conditions or limitations as may be specified in the order.
- [<sup>F157</sup>(2A) Without prejudice to the generality of subsection (2) of this section, an order under subsection (1) of this section providing for the exemption from section 52 of this Act of the sale, or offer or exposure for sale, by retail or the supply in circumstances corresponding to retail sale of veterinary drugs by any persons—
- (a) may, as a condition of the exemption, require those persons to be entered for the time being in a register of merchants in veterinary drugs kept by the registrar or the Northern Ireland enforcement authority, and
  - (b) may impose such conditions as the appropriate Ministers think fit in respect of the inclusion or retention of persons in the register, including conditions requiring the payment to the registrar or the Northern Ireland enforcement authority of fees of such amounts as the appropriate Ministers may with the consent of the Treasury determine.
- (2B) In determining any such fees, the appropriate Ministers may have regard to—
- (a) any costs incurred or to be incurred by the Pharmaceutical Society or the Northern Ireland enforcement authority in connection with any power or duty to enforce any provisions of section 52 or of regulations under section 66 of this Act, so far as those powers or duties relate to veterinary drugs, and
  - (b) any costs incurred or to be incurred by any other person for the purpose of maintaining or improving standards among those engaged in the sale by retail of veterinary drugs or the supply of such drugs in circumstances corresponding to retail sale.
- (2C) Any fees received by virtue of this section for the inclusion or retention of any person in a register of merchants in veterinary drugs shall, if the appropriate Ministers so determine, be applied to such extent and in such manner as they may determine towards meeting any costs falling within subsection (2B)(b) of this section; subject to that, any such fees received by the registrar shall be applicable for the purposes of the Pharmaceutical Society.
- (2D) In the preceding provisions of this section— “the Northern Ireland enforcement authority” means any Northern Ireland department having a duty to enforce any of the provisions referred to in subsection (2B)(a) of this section, being a duty relating to veterinary drugs; and “the registrar” means the person appointed under section 1 of the Pharmacy Act <sup>M6</sup>1954 as registrar for the purposes of that Act.]

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) The appropriate Ministers may by order provide that subsection (1)(b) or subsection (2) of section 55 of this Act shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.
- (4) No order shall be made under subsection (3) of 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

**F157** S. 57(2A)–(2D) inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 14

#### Modifications etc. (not altering text)

**C166** Ss. 57, 58, 61 extended by [S.I. 1984/187](#), art. 2

**C167** S. 57 applied (1.1.1995) by [S.I. 1994/3142](#), reg. 18(2)

S. 57 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, Sch.5

#### Marginal Citations

**M6** [1954 c.61 \(83:1\)](#).

### *Additional provisions*

## 58 Medicinal products on prescription only.

- (1) The appropriate Ministers may by order specify descriptions or classes of medicinal products for the purposes of this section; and, in relation to any description or class so specified, the order shall state which of the following, that is to say—
- (a) doctors,
  - (b) dentists, and
  - (c) veterinary surgeons and veterinary practitioners, <sup>F158</sup>and
  - <sup>F159</sup>(d) [ registered nurses or midwives who are of such a description and comply with such conditions as may be specified in the order] <sup>F160</sup>, and
  - (e) other persons who are of such a description and comply with such conditions as may be specified in the order]
- <sup>F161</sup>(1A) The descriptions of persons which may be specified in an order by virtue of subsection (1)(e) are the following, or any sub-category of such a description—
- <sup>F162</sup>(a) persons who are registered in the register maintained under article 5 of the Health Professions Order 2001;]
  - (b) persons who are pharmacists;
  - (c) persons whose names are entered in a roll or record established by the General Dental Council by virtue of section 45 of the Dentists Act 1984 (c. 24) (dental auxiliaries);
  - (d) persons who are registered in either of the registers of ophthalmic opticians kept under section 7(a) of the Opticians Act 1989 (c. 44);
  - (e) persons who are registered osteopaths within the meaning of the Osteopaths Act 1993 (c. 21);
  - (f) persons who are registered chiropractors within the meaning of the Chiropractors Act 1994 (c. 17);



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (g) persons who are registered in any register established, continued or maintained under an Order in Council under section 60(1) of the Health Act 1999 (c. 8);
- (h) any other description of persons which appears to the appropriate Ministers to be a description of persons whose profession is regulated by or under a provision of, or made under, an Act of the Scottish Parliament or Northern Ireland legislation and which the appropriate Ministers consider it appropriate to specify.

<sup>F161</sup>(1B) Where an order under this section includes provision by virtue of subsection (1)(e), the order shall specify such conditions as are necessary to secure that any person who is an appropriate practitioner by virtue of the provision may prescribe, give directions or administer only in respect of human use.]

are to be appropriate practitioners for the purposes of this section.

(2) Subject to the following provisions of this section—

- (a) no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description, or falling within a class, specified in an order under this section except in accordance with a prescription given by an appropriate practitioner; and
- (b) no person shall administer (otherwise than to himself) any such medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner.

(3) Subsection (2)(a) of this section shall not apply—

- (a) to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner, or
- (b) to the sale or supply of a medicinal product, for administration to an animal or herd under his care, by a veterinary surgeon or veterinary practitioner who is an appropriate practitioner.

(4) Without prejudice to the last preceding subsection, any order made by the appropriate Ministers for the purposes of this section may provide—

- (a) that paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs, shall have effect subject to such exemptions as may be specified in the order [<sup>F163</sup>or, where the appropriate practitioner is [<sup>F164</sup>a registered nurse or midwife,]<sup>F165</sup>or is an appropriate practitioner by virtue of provision made under subsection (1)(e) of this section,]such modifications as may be so specified];
- (b) that, for the purpose of paragraph (a) of that subsection, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the order are fulfilled.

<sup>F166</sup>(4A) An order under this section may provide, in relation to a person who is an appropriate practitioner by virtue of subsection (1)(d) or (e), that such a person may—

- (a) give a prescription for a medicinal product falling within a description or class specified in the order;
- (b) administer any such medicinal product; or
- (c) give directions for the administration of any such medicinal product,

only where he complies with such conditions as may be specified in the order in respect of the cases or circumstances in which he may do so.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- <sup>F166</sup>( 4B ) An order under this section may provide, in relation to a condition specified by virtue of subsection (4A), for the condition to have effect subject to such exemptions as may be specified in the order.
- <sup>F166</sup>( 4C ) Where a condition is specified by virtue of subsection (4A), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the order by virtue of subsection (4)(a) of this section) given by an appropriate practitioner for the purposes of subsection (2)(a) or (b) of this section.]
- (5) Any exemption conferred [<sup>F167</sup>or modification made] by an order in accordance with subsection (4)(a) of this section may be conferred [<sup>F168</sup>or made] subject to such conditions or limitations as may be specified in the order.
- (6) Before making an order under this section the appropriate Ministers shall consult the appropriate committee<sup>F169</sup> ....

#### Textual Amendments

- F158** S. 58(1)(d) and preceding word inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), s. 1(1); S.I. 1994/2408, art. 2
- F159** S. 58(1)(d) substituted (27.6.2003) by S.I. 2002/253, arts. 1(2), 54, Sch. 5 para. 2(a); London Gazette: Issue number 567984
- F160** S. 58(4)(e) and preceding word inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, s. 63(2); S.I. 2002/1095, art. 2(1)
- F161** S. 58(1A)(1B) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, s. 63(3); S.I. 2002/1095, art. 2(1)
- F162** S. 58(1A)(a) substituted (9.7.2003) by Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 6
- F163** Words in s. 58(4)(a) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), s. 1(2); S.I. 1994/2408, art. 2
- F164** Words in s. 58(4)(a) substituted (27.6.2003) by S.I. 2002/253, arts. 1(2), 54, Sch. 5 para. 2(b); London Gazette: Issue number 567984
- F165** Words in s. 58(4)(a) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, s. 63(4); S.I. 2002/1095, art. 2(1)
- F166** S. 58(4A)-(4C) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, s. 63(5); S.I. 2002/1095, art. 2(1)
- F167** Words in s. 58(5) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), s. 1(3)(a); S.I. 1994/2408, art. 2
- F168** Words in s. 58(5) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), s. 1(3)(b); S.I. 1994/2408, art. 2
- F169** Words in s. 58(6) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), Sch. 1 para. 10

#### Modifications etc. (not altering text)

- C168** Ss. 57, 58, 61 extended by S.I. 1984/187, art. 2  
S. 58 applied (31.3.1997) by S.I. 1997/322, reg. 34, Sch. 5
- C169** S. 58 applied (1.1.1995) by S.I. 1994/3142, reg. 18(2)  
S. 58 modified (1.1.1995) by S.I. 1994/3144, reg. 9(10)
- C170** Ss. 58 58A 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)
- C171** S. 58(1) restricted (1.1.1995) by S.I. 1994/3144, reg. 8(4)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C172** S. 58(6) modified (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), Sch. 5 para. 1(2)

**[<sup>F170</sup>58A Requirement to specify certain products for human use as prescription-only products.**

- (1) The appropriate Ministers shall, subject to subsection (4) of this section, so exercise their powers under section 58(1) of this Act as to secure that every product—
  - (a) in respect of which a product licence is granted;
  - (b) to which [<sup>F171</sup>the 2001 Directive applies]; and
  - (c) to which subsection (2) of this section applies;falls within one of the descriptions or classes specified for the purposes of section 58.
- (2) This subsection applies to any product which—
  - (a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or
  - (b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or
  - (c) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation; or
  - (d) is normally prescribed by a doctor or dentist for parenteral administration.
- (3) In considering whether subsection (2) of this section applies to a product the appropriate Ministers shall take into account whether the product—
  - (a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or
  - (b) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention); or
  - (c) is likely, if incorrectly used—
    - (i) to present a substantial risk of medicinal abuse, or
    - (ii) to lead to addiction, or
    - (iii) to be used for illegal purposes; or
  - (d) contains a substance which, by reason of its novelty or properties, might fall within paragraph (c) above, but as to which there is insufficient information available to determine whether it does so fall; or
  - (e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital; or
  - (f) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or
  - (g) is intended for outpatients but may produce very serious sideeffects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.
- (4) Subsection (1) of this section shall not apply in relation to any product if the appropriate Ministers so determine having regard to—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) the maximum single dose;
- (b) the maximum daily dose;
- (c) the strength of the product;
- (d) its pharmaceutical form;
- (e) its packaging; or
- (f) such other circumstances relating to its use as may be specified in the determination.

(5) In this section and section 58B of this Act—

“the Narcotic Drugs Convention” means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30th March 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972 <sup>X1</sup>; and

“the Psychotropic Substances Convention” means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971 <sup>X2</sup>.]

#### Editorial Information

- X1 The Convention, as amended by the Protocol, is published as Cmnd. 7466.
- X2 Cmnd. 7330.

#### Textual Amendments

- F170 S. 58A inserted (1.1.1993) by S.I. 1992/3271 , **regs. 1(1) , 2**
- F171 Words in s. 58A(1)(b) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(v)**

#### Modifications etc. (not altering text)

- C170 Ss. 58 58A 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)**
- C173 S. 58A extended (with modifications) (14.2.1994) by S.I. 1994/105 , **reg. 19 , Sch. 4**
- C174 S. 58A modified (1.1.1995) by S.I. 1994/3144 , **reg. 9(4)(10)**  
S. 58A applied (1.1.1995) by 1994/3142, reg. 18

### <sup>F172</sup>58B Requirement to specify certain products for veterinary use as prescription-only products.

- (1) The appropriate Ministers shall so exercise their powers under section 58(1) of this Act as to secure that every product—
  - (a) in respect of which a product licence is granted;
  - (b) to which the 1981 Directive applies; and
  - (c) to which subsection (2) or (3) of this section applies;
 falls within one of the descriptions or classes specified for the purposes of section 58.
- (2) This subsection applies to any product which—
  - (a) is subject to restrictions on supply or use resulting from the Narcotic Drugs Convention, the Psychotropic Substances Convention or any Community obligation (other than an obligation under the 1981 Directive); or
  - (b) is likely to cause unnecessary risk to the target species, humans or the environment unless special precautions are taken by a veterinary surgeon or veterinary practitioner; or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (c) is intended for a treatment or condition which requires a precise prior diagnosis; or
  - (d) may cause effects which impede or interfere with subsequent diagnosis or treatment.
- (3) This subsection applies to any new product containing an active ingredient where a product licence for veterinary use was granted in respect of the ingredient less than five years prior to the relevant date in relation to the product unless, having regard to—
- (a) the information and particulars provided by the applicant for the licence; or
  - (b) experience acquired in the use of the product;
- the appropriate Ministers are satisfied that subsection (2) of this section does not apply to the product.
- (4) For the purposes of subsection (3) of this section the relevant date in relation to a product is the date on which it falls to be determined by the appropriate Ministers whether subsection (3) applies to the product.
- (5) Section 58A(5) of this Act applies for the purposes of this section.

#### Textual Amendments

F172 S. 58B inserted (1.1.1993) by S.I. 1992/3271, regs. 1(1),2

#### Modifications etc. (not altering text)

C175 S. 58B applied (1.1.1995) by S.I. 1994/3142, reg. 18

## 59 Special provisions in relation to new medicinal products.

- (1) The following provisions of this section shall have effect where an order under section 58 of this Act is made so as to apply to all medicinal products which fall within a class specified in the order and are of a description in respect of which the following conditions are fulfilled, that is to say, that—
- (a) medicinal products of that description were not effectively on the market in the United Kingdom immediately before the first appointed day;
  - (b) a product licence granted under Part II of this Act (whether before, on or after the date on which the order comes into operation) applies to medicinal products of that description (whether it also applies to medicinal products of any other description or not); and
  - (c) before the grant of that licence, no product licence had been granted which was applicable to medicinal products of that description.
- (2) Where such an order is made in accordance with the preceding subsection—
- (a) the restrictions imposed by section 58(2) of this Act shall not apply by virtue of the order to medicinal products of any description except during a period beginning with the date which, in relation to medicinal products of that description, is the relevant date and of such duration from that date as may be specified in the order;
  - (b) in section 58(4)(a) of this Act the reference to exemptions specified in the order shall, in relation to that order, be construed as including a reference to any exemption specified in a direction given by the appropriate Ministers

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

and relating to medicinal products of a particular description specified in that direction.

- (3) In subsection (2)(a) of this section “the relevant date”, in relation to medicinal products of any description to which an order made in accordance with subsection (1) of this section applies, means the date on which the order comes into operation, or the date on which the product licence applicable to medicinal products of that description (as mentioned in subsection (1)(b) of this section) comes into operation, whichever is the later.

**Modifications etc. (not altering text)**

- C176** S. 59 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**  
S. 59 modified (1.1.1995) by S.I. 1994/3144, **reg.9(5)**  
S. 59 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
S. 59 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**
- C177** S. 59 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)**

**60 Restricted sale, supply and administration of certain medicinal products.**

- (1) Subject to the following provisions of this section, regulations made by the appropriate Ministers may provide that no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description specified in the regulations, or falling within a class so specified, unless—
- (a) he is a practitioner holding a certificate issued for the purposes of this section by the appropriate Ministers in respect of medicinal products of that description or falling within that class, or a person acting in accordance with the directions of such a practitioner, and the product is so sold or supplied for the purpose of being administered in accordance with the directions of that practitioner, or
  - (b) he is a person lawfully conducting a retail pharmacy business and the product is so sold or supplied in accordance with a prescription given by such a practitioner.
- (2) Any regulations made under this section may provide that no person shall administer (otherwise than to himself) a medicinal product of a description specified in the regulations, or falling within a class so specified, unless he is such a practitioner as is mentioned in subsection (1)(a) of this section or a person acting in accordance with the directions of such a practitioner.
- (3) The powers conferred by the preceding subsections shall not be exercisable in respect of medicinal products of a particular description, or falling within a particular class, except where it appears to the appropriate Ministers that the sale by retail, or supply in circumstances corresponding to retail sale, or the administration, of such products requires specialised knowledge on the part of the practitioner by whom or under whose directions they are sold, supplied or administered.
- (4) Any regulations made under this section in respect of a particular description or class of medicinal products may specify the qualifications and experience which an applicant for a certificate in respect of that description or class of medicinal products must have, and may provide for the appointment of a committee to advise the appropriate Ministers, in such cases as may be prescribed by or determined in

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

accordance with the regulations, with respect to the grant, renewal, suspension and revocation of such certificates.

(5) Any such regulations shall include provision as to the grant, duration, renewal, suspension and revocation of certificates for the purposes of this section, including provision for affording—

- (a) to an applicant for the grant or renewal of such a certificate, where the appropriate Ministers propose to refuse to grant or renew it, and
- (b) to the holder of such a certificate, where the appropriate Ministers propose to suspend or revoke it,

an opportunity of appearing before, and being heard by, a person appointed for the purpose by the appropriate Ministers or of making representations in writing to those Ministers with respect to that proposal.

(6) Regulations made under this section may provide that, for the purposes of paragraph (b) of subsection (1) of this section, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription as mentioned in that paragraph unless such conditions as are prescribed by the regulations are fulfilled.

(7) Before making any regulations under this section the appropriate Ministers shall consult the appropriate committee<sup>F173</sup>....

#### Textual Amendments

**F173** Words in s. 60(7) omitted (30.10.2005) by virtue of [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), **Sch. 1 para. 11**

#### Modifications etc. (not altering text)

**C178** S. 60 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**

S. 60 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch.5**

**C179** S. 60 restricted (1.1.1995) by [S.I. 1994/3144](#), **reg. 8(4)**

S. 60 modified (1.1.1995) by [S.I. 1994/3144](#), **reg. 9(10)**

**C180** S. 60 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)**

**C181** S. 60(7) modified (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 5 para. 2(2)**

## 61 Special restrictions on persons to be supplied with medicinal products.

The appropriate Ministers may by regulations provide, either in respect of medicinal products generally or in respect of medicinal products of a description or falling within a class specified in the regulations, that, subject to such exceptions as may be so specified, no person—

- (a) being the holder of a product licence, or
- (b) in the course of business carried on by him and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell or supply any medicinal product to which the regulations apply to any person who does not fall within a class specified in the regulations.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

- C182** Ss. 57, 58, 61 extended by S.I. 1984/187, **art. 2**
- C183** S. 61 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
S. 61 modified (1.1.1995) by S.I. 1994/3144, **reg.9(6)**  
S. 61 applied (31.3.1997) by S.I. 1997/322, **reg. 54, Sch.5**
- C184** S. 61 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)**
- C185** S. 61 modified (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), **regs. 1(a), 10(4)** (with Sch. 6)

**62 Prohibition of sale or supply, or importation, of medicinal products of specified description, or of animal feeding stuffs incorporating such products.**

- (1) Subject to the following provisions of this section, the appropriate Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—
- (a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or (in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products;
  - (b) prohibit the sale or supply, or the importation, of animal feeding stuffs in which medicinal products of any description, or falling within any class, specified in the order have been incorporated, or (in such manner as may appear to them to be sufficient to identify the feeding stuffs in question) designate particular animal feeding stuffs in which medicinal products have been incorporated and prohibit the sale or supply, or the importation, of those particular feeding stuffs.
- (2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.
- (3) Before making an order under this section the appropriate Ministers, unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health, whether of human beings or of animals, shall consult the appropriate committee<sup>F174</sup>....
- (4) Where an order is made under this section without prior consultation with the appropriate committee<sup>F175</sup>... in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).
- (5) If any organisation consulted in pursuance of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the appropriate Ministers of their desire to be heard under this subsection, or have made representations in writing to those Ministers with respect to that proposal, then before making the order—
- (a) if the organisation have given notice of their desire to be heard, the appropriate Ministers shall arrange for them to have an opportunity of appearing before, and being heard by, the [<sup>F176</sup>appropriate committee], or



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) if they have made representations in writing, the appropriate Ministers shall refer those representations to the [<sup>F176</sup>appropriate committee],  
and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the [<sup>F176</sup>appropriate committee] shall report their findings and conclusions to the appropriate Ministers and those Ministers shall take that report into account in determining whether to make the order.
- (6) Subsection (5) of this section shall not have effect where in the opinion of the appropriate Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

[<sup>F177</sup>(7) If an order is made under this section and either—

- (a) the appropriate committee have not considered the proposal to make the order,  
or  
(b) the order is made contrary to the advice of the appropriate committee,  
the order shall include a statement of the fact that it has been so made.]

#### Textual Amendments

- F174** Words in s. 62(3) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(2)**
- F175** Words in s. 62(4) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(3)**
- F176** Words in s. 62(5) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(4)**
- F177** S. 62(7) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(5)**

#### Modifications etc. (not altering text)

- C186** S. 62 extended by S.I. 1984/187, **art. 2**
- C187** S. 62 extended with modifications by S.I. 1985/1403, **art. 3(1)**  
S. 62 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
- C188** S. 62 (1)(a), (2)–(7) extended by S.I.s 1982/425, art. 3, 1984/187, art. 2 and extended with modifications by S.I. 1985/1403, **art. 3(1)**
- C189** S. 62(3) modified (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 3(2)**

## 63 Adulteration of medicinal products.

No person shall—

- (a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state, or
- (b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

#### Modifications etc. (not altering text)

- C190** Ss. 63–65 extended by S.I. 1984/187, **art. 2**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C191** S. 63 applied (1.1.1995) by S.I 1994/3142, reg. 18(2)

## **64 Protection of purchasers of medicinal products.**

- (1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.
- (2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.
- (3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.
- (4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—
  - (a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and
  - (b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.
- (5) Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner, the preceding provisions of this section shall have effect as if—
  - (a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and
  - (b) in subsection (1) of this section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”.

### **Modifications etc. (not altering text)**

**C192** Ss. 63–65 extended by [S.I. 1984/187](#), [art. 2](#)

## **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

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

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 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

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (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 [<sup>F178</sup>Commission] as a synonym for that name.

#### **Textual Amendments**

**F178** Word in s. 65(8) substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 13](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

C193 Ss. 63–65 extended by S.I. 1984/187, art. 2

**66 Further powers to regulate dealings with medicinal products.**

- (1) The appropriate Ministers may by regulations prescribe such requirements as they may consider necessary or expedient with respect to any of the following matters, that is to say—
- (a) the manner in which, or persons under whose supervision, medicinal products may be prepared or may be dispensed;
  - (b) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons;
  - (c) the amount of space to be provided in any premises for the sale or supply of medicinal products;
  - (d) the accommodation (including the amount of space) to be provided in any premises for members of the public to whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled;
  - (e) the amount of space to be provided in any premises for the storage of medicinal products;
  - (f) the safekeeping of medicinal products;
  - (g) the disposal of medicinal products which have become unusable or otherwise unwanted;
  - (h) precautions to be observed before medicinal products are sold or supplied;
  - (i) the keeping of records relating to the sale or supply of medicinal products;
  - (j) the supply of medicinal products distributed as samples;
  - (k) sanitation, cleanliness, temperature, humidity or other factors relating to the risks of deterioration or contamination in connection with the manufacture, storage, transportation, sale or supply of medicinal products;
  - (l) the construction, location and use of automatic machines for the sale of medicinal products.
- (2) Without prejudice to the generality of the preceding subsection, regulations made under subsection (1) of this section may prescribe requirements in respect of—
- (a) the construction, lay-out, drainage, equipment, maintenance, ventilation, lighting and water supply of premises at or from which medicinal products are manufactured, stored, transported, sold or supplied;
  - (b) the disposal of refuse at or from any such premises; and
  - (c) any apparatus, equipment, furnishings or utensils used at any such premises.

**Modifications etc. (not altering text)**

C194 S. 67 extended by S.I.s 1982/425, art. 3, 1984/187, art. 2 and extended with modifications by S.I. 1985/1403, art. 3(1)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### *Offences, and provision for disqualification*

#### **67 Offences under Part III.**

- (1) The following provisions of this section shall have effect subject to sections 121 and 122 of this Act.
- <sup>F179</sup>(1A) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an order under section 58 of this Act by virtue of subsection (4A) of that section shall be guilty of an offence.
- (1B) Any person who—
- (a) is an appropriate practitioner by virtue of provision made under section 58(1) of this Act; and
  - (b) gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner,
- shall be guilty of an offence.]
- (2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections 52, 58, 63, 64 and 65, or who contravenes any regulations made under section 60 or section 61 or any order made under section 62 of this Act, shall be guilty of an offence.
- (3) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 62 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.
- <sup>F180</sup>(3A) A person who has in his possession a medicinal product to which paragraph (a) of section 58(2) applies, with the intention of supplying it otherwise than in accordance with the requirements of that paragraph, is guilty of an offence.]
- (4) Any person guilty of an offence under <sup>F181</sup>subsection (1A), (1B), (2), (3) or (3A)] of this section shall be liable—
- (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (5) Any person who contravenes section 53 or section 54(1) or an order made under section 54(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding <sup>F182</sup>level 3 on the standard scale].
- (6) Any regulations made under section 66 of this Act may provide that any person who contravenes the regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding <sup>F183</sup>level 5 on the standard scale] or such lesser sum as may be specified in the regulations.

#### **Textual Amendments**

**F179** S. 67(1A)(1B) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, s. 63(7) (a) (with ss. 64(9), 65(4)); S.I. 2002/1095, art. 2(1) (with transitional provisions in art. 3)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- F180** S. 67(3A) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), **Sch. 5 para. 8(a)** (with Sch. 6)
- F181** Words in s. 67(4) substituted (30.10.2005) by virtue of [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), **Sch. 5 para. 8(b)** (with Sch. 6)
- F182** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), **ss. 38, 46**, (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **ss. 289F, 289G** and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), **arts. 5, 6**
- F183** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), **s. 46**, (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **s. 289G** and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), **arts. 5, 6**

**Modifications etc. (not altering text)**

- C195** S. 67 extended by [S.I.s 1982/425](#), art. 3, [1984/187](#), art. 2 and extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**
- S. 67 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**
- S. 67 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**

**68 Disqualification on conviction of certain offences.**

- (1) Where in proceedings brought by an enforcement authority a person is convicted of an offence under section 67(6) of this Act in respect of any premises used for carrying on a retail pharmacy business, then on the application of that authority the court by or before which he was convicted may (subject to the following provisions of this section) make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order.
- (2) The court shall not make an order under this section disqualifying a person in respect of any premises unless the court thinks it expedient to do so having regard—
  - (a) to the gravity of the offence of which he has been convicted as mentioned in the preceding subsection, or
  - (b) to the unsatisfactory nature of the premises, or
  - (c) to any offences under section 67(6) of this Act of which he has previously been convicted.
- (3) No order under this section shall be made against a person on the application of an enforcement authority unless the authority have, not less than fourteen days before the date of the hearing, given him notice in writing of their intention to apply for such an order to be made against him.
- (4) If, while an order under this section disqualifying a person in respect of any premises is in force, the premises are used for the purposes of a retail pharmacy business carried on by him, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F184</sup>level 5 on the standard scale].
- (5) Subject to the next following subsection, at any time after the end of the period of six months from the date on which an order under this section comes into force, the person to whom the order relates may apply to the court by which the order was made to revoke the order or to vary it by reducing the period of disqualification.
- (6) On any application made under subsection (5) of this section the court may revoke or vary the order as mentioned in that subsection if it thinks it proper to do so having

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

regard to all the circumstances of the case, including in particular the conduct of the applicant and any improvement in the state of the premises to which the order relates; but, if on any such application the court refuses to revoke or vary the order, no further application made by the applicant under that subsection shall be entertained if it is made within three months from the date of the refusal.

- (7) The court to which an application under subsection (5) of this section is made shall have power to order the applicant to pay the whole or any part of the costs of the application.
- (8) In the application of this section to Scotland, for references to an enforcement authority and to costs there shall be substituted respectively references to the procurator fiscal and to expenses.

#### Textual Amendments

**F184** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), **ss. 38, 46**, (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), **ss. 289F, 289G** and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), **arts. 5, 6**

#### Modifications etc. (not altering text)

**C196** S. 68 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**

## PART IV

### PHARMACIES

#### Modifications etc. (not altering text)

**C197** Pt. IV: Power to amend conferred (N.I.) (2.4.2001) by [2001 c. 3 \(N.I.\)](#), s. 60, **Sch. 4 para. 2(2)**; [S.R. 2001/128](#), art. 2(4), **Sch.**

**C198** Pt. IV 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)**

**C199** Pt. IV (except ss. 80-83): Power to amend conferred (15.3.2000) by [1999 c. 8](#), ss. 60(1)(2)(4), 67(1), **Sch. 3 para. 2(3)(b)**; [S.I. 2000/779](#), **art. 2**

#### *Persons lawfully conducting retail pharmacy business*

### 69 General provisions.

- (1) Subject to the provisions of any order made under section 73 of this Act, a person carrying on a retail pharmacy business shall be taken to be a person lawfully conducting such a business if, not being disqualified by virtue of section 80 of this Act,—
- (a) that person (or, if the business is carried on by a partnership, each, or, in Scotland, one or more, of the partners) is a pharmacist and the conditions specified in section 70 of this Act are fulfilled in relation to the business, or
  - (b) that person is a body corporate and the conditions specified in section 71 of this Act are fulfilled in relation to the business, or



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (c) that person is a representative of a pharmacist (as defined by section 72 of this Act) and the conditions specified in subsection (2) of that section are fulfilled in relation to him and in relation to the business and the period applicable in accordance with subsection (3) of that section has not expired.
- (2) For the purposes of the application of this Part of this Act to a business which—
- (a) is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be also carried on elsewhere or not, or
- (b) so far as concerns the retail sale of medicinal products, or the supply of such products in circumstances corresponding to retail sale, is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be carried on elsewhere or not,
- each such part of that building shall be taken to be separate premises.

- (3) In this Part of this Act—

<sup>F185</sup>

“the board”, in relation to a body corporate, means the body of persons controlling the body corporate, by whatever name called;

“the Council” means the Council of the Pharmaceutical Society;

“the registrar” in relation to Great Britain means the person appointed under section 1 of the <sup>M7</sup>Pharmacy Act 1954 as registrar for the purposes of that Act, and in relation to Northern Ireland means the person appointed under [<sup>F186</sup>Article 9(1) of the <sup>M8</sup>Pharmacy (Northern Ireland) Order 1976] as registrar for the purposes of that Act;

“the Statutory Committee” in relation to Great Britain means the committee appointed under section 7 of the Pharmacy Act 1954, and in relation to Northern Ireland means the committee appointed under [<sup>F187</sup>Article 19 of the Pharmacy (Northern Ireland) Order 1976].

#### Textual Amendments

**F185** Definition in s. 69(3) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt.XII**

**F186** Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 2(2)** and (N.I.) S.R. 1977 No. 170, **reg. 3**

**F187** Words substituted by S.I. 1976/1213 (N.I. 22), **Sch. 5 para. 4**

#### Marginal Citations

**M7** 1954 c. 61.

**M8** S.I. 1976/1213 (N.I. 22)

## 70 Business carried on by individual pharmacist or by partners.

- (1) Subject to the next following subsection, the conditions referred to in section 69(1) (a) of this Act are that, at all premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail—
- (a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not), or the supply at those premises of such products in circumstances corresponding to retail sale, is under the personal control of the person carrying on the business or that of another pharmacist, and

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) his name and certificate of registration or those of the other pharmacist, as the case may be, are conspicuously exhibited,
- [<sup>F188</sup>and that it is the personal control of persons none of whom is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (qualification by European diploma), [<sup>F189</sup>or Article 8(2)(c) of the Pharmacy (Northern Ireland) Order 1976], which fulfils the condition imposed by virtue of paragraph (a) above in relation to such of those premises . . . <sup>F190</sup>as have been registered pharmacies for less than three years.]
- (2) In relation to a business carried on by a partnership the preceding subsection shall have effect as if—
- (a) in paragraph (a) of that subsection, for the word “person”, there were substituted the words “one or more of the partners”, and
- (b) in paragraph (b) of that subsection, for the words “his name and certificate of registration”, there were substituted the words “the name and certificate of registration of the partner (or, if more than one, of each partner) exercising personal control at those premises as mentioned in the preceding paragraph”.

In the application of this subsection to Scotland, for paragraph (a) there shall be substituted the following paragraph—

- “(a) in paragraph (a) of that subsection, for the words “the person carrying on the business” there were substituted the words “one or more of the partners who are pharmacists”, and”

- (3) In this section and in sections 71 and 72 of this Act “certificate of registration” in relation to Great Britain means a certificate of registration under the <sup>M9</sup>Pharmacy Act 1954, and in relation to Northern Ireland means a certificate of registration within the meaning of [<sup>F191</sup>the <sup>M10</sup>Pharmacy (Northern Ireland) Order 1976].

#### Textual Amendments

**F188** Words inserted by [S.I. 1987/2202, art. 3\(1\)](#)

**F189** Words substituted by [S.R. 1987/457, reg. 3\(a\)](#)

**F190** Words repealed by [S.R. 1987/457 reg. 3\(b\)](#)

**F191** Words substituted by [S.I. 1976/1213 \(N.I. 22\), Sch. 5 para. 5](#)

#### Marginal Citations

**M9** [1954 c. 61.](#)

**M10** [S.I. 1976/1213 \(N.I. 22\)](#)

## 71 Bodies corporate.

- (1) The conditions referred to in section 69(1)(b) of this Act are that the business, so far as concerns the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of a superintendent in respect of whom the requirements specified in subsection (2) of this section are fulfilled, . . . <sup>F192</sup>that, at all premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail—
- (a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not) or the supply at those premises of such products in circumstances corresponding to retail sale, if it is not under the personal control of the superintendent, is

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- carried on, subject to the directions of the superintendent, under the personal control of a manager or assistant who is a pharmacist, and
- (b) the name and certificate of registration of the person under whose personal control the business is carried on at those premises as mentioned in the preceding paragraph (whether he is the superintendent or some other person) are conspicuously exhibited, <sup>F193</sup>and that it is the personal control of persons none of whom (whether the superintendent or a manager or assistant) is a pharmacist by virtue of section 4A of the Pharmacy Act 1954, <sup>F194</sup>or Article 8(2)(c) of the Pharmacy (Northern Ireland) Order 1976], which fulfils the condition imposed by virtue of paragraph (a) above in relation to such of those premises . . . <sup>F195</sup> as have been registered pharmacies for less than three years.]
- (2) The requirements referred to in the preceding subsection in relation to a superintendent are that—
- (a) the superintendent is a pharmacist;
- (b) a statement in writing signed by him, and signed on behalf of the body corporate, specifying his name and stating whether he is a member of the board of that body or not, has been sent to the registrar; and
- (c) he does not act in a similar capacity for any other body corporate.

#### Textual Amendments

**F192** Word repealed by S.I. 1987/2202, art. 3(2)(a)

**F193** Words inserted by S.I. 1987/2202, art. 3(2)(b)

**F194** Words substituted by S.R. 1987/457, reg. 3(a)

**F195** Words repealed by S.R. 1987/457, reg. 3(b)

## 72 Representative of pharmacist in case of death or disability.

- (1) The provisions of this section shall have effect where a pharmacist carries on a retail pharmacy business and—
- (a) he dies, or
- (b) he is adjudged bankrupt or enters into a composition or scheme or deed of arrangement with his creditors, or, in Scotland, sequestration of his estate is awarded or he makes a trust deed for behoof of his creditors or a composition contract, or
- (c) a receiver is appointed for him under Part VIII of the <sup>M11</sup>Mental Health Act 1959, or, in Scotland, a <sup>F196</sup>guardian] or judicial factor is appointed for him on the ground that he suffers from mental disorder, or, in Northern Ireland, a committee, receiver or guardian is appointed in his case under the <sup>M12</sup>Lunacy Regulation (Ireland) Act 1871,
- and a representative of his thereafter carries on his business.
- (2) The conditions referred to in section 69(1)(c) of this Act are that the name and address of the representative, and the name of the pharmacist whose representative he is, have been notified to the registrar and that, at all premises at which the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail,—
- (a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not) or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- the supply at those premises of such products in circumstances corresponding to retail sale, is under the personal control of a pharmacist, and
- (b) his name and certificate of registration are conspicuously exhibited.
- (3) The period referred to in section 69(1)(c) of this Act—
- (a) in the case of the death of a pharmacist, is a period of five years from the date of his death;
- (b) in the case of the bankruptcy or sequestration of the estate of a pharmacist, is a period of three years from the date on which he is adjudged bankrupt or the date of the award of sequestration, as the case may be;
- (c) in the case of a composition or scheme or deed of arrangement, or of a trust deed or composition contract, is a period of three years from the date on which the trustee appointed thereunder becomes entitled to carry on the business; and
- (d) in a case falling within subsection (1)(c) of this section, is a period of three years from the date of the appointment of the receiver, [<sup>F197</sup>curator bonis,] judicial factor, committee or guardian,
- or, in any such case, is such longer period as, on the application of the representative, the Statutory Committee, having regard to all the circumstances of the case, may direct.
- (4) In this section “representative”—
- (a) in relation to a pharmacist who has died, means his executor or administrator and, in respect of a period of three months from the date of his death, if he has died leaving no executor who is entitled and willing to carry on the business, includes any person beneficially interested in his estate;
- (b) in a case falling within paragraph (b) of subsection (1) of this section, means the trustee in bankruptcy or the trustee in the sequestration or any trustee appointed under the composition scheme, deed of arrangement, trust deed or composition contract; and
- (c) in a case falling within paragraph (c) of that subsection, means the receiver, [<sup>F197</sup>curator bonis,] judicial factor, committee or guardian [<sup>F198</sup>; and in paragraph (b) above the reference to a trustee appointed under a composition, scheme or deed of arrangement includes a reference to the supervisor of a [<sup>F199</sup>voluntary arrangement proposed for the purposes of, and approved under, Part VIII of the Insolvency Act 1986][<sup>F200</sup>or Chapter II of Part VIII of the Insolvency (Northern Ireland) Order 1989].]

#### Textual Amendments

- F196** Words in s. 72(1) substituted (S.) (1.4.2002) by 2000 asp 4, s. 88(2), **Sch. 5 para. 12(a)**; S.S.I. 2001/81, art. 3, **Sch. 2**
- F197** Words in s. 72(3)(d)(4)(c) repealed (S.) (1.4.2002) by 2000 asp 4, s. 88(2)(3), **Sch. 5 para. 12(b)**, **Sch. 6**; S.S.I. 2001/81, art. 3, **Sch. 2**
- F198** Words inserted by **Insolvency Act 1985** (c. 65, SIF 66), s. 235, Sch. 8 para. 15, **Sch. 9 para. 11(2)**
- F199** Words substituted by **Insolvency Act 1986** (c. 45, SIF 66), s. 439(2), **Sch. 14**
- F200** Words in s. 72(4) added (N.I.) (1.10.1991) by S.I. 1989/2405 (N.I. 19), art. 381, **Sch. 9 Pt. II para. 24**; S.R. 1991/411, art. 2

#### Marginal Citations

- M11** 1959 c. 72.
- M12** 1871 c. 22.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### 73 Power to extend or modify conditions.

- (1) The Health Ministers may by order add to, revoke or vary any of the provisions of sections 70 to 72 of this Act, so as either—
  - (a) to modify, or provide new conditions in substitution for, the conditions referred to in any of the paragraphs of section 69(1) of this Act, or
  - (b) for the purposes of any of those paragraphs, to provide alternative conditions compliance with which is to have the like effect as compliance with the conditions referred to in that paragraph.
- (2) Any provision made by an order in accordance with subsection (1) of this section may be made either generally or in relation to any particular circumstances specified in the order.
- (3) Any order made under this section may direct that subsection (1) or subsection (2) of section 69 of this Act shall have effect subject to such exceptions or modifications as appear to the Health Ministers to be necessary or expedient in consequence of the provision made by the order in accordance with subsection (1) of this section.
- (4) Where an order under this section is for the time being in force, any reference to section 69 of this Act in any other enactment as amended by this Act shall be construed as a reference to that section as modified by the order.
- (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.

#### *Registration of pharmacies*

### 74 Meaning of “registered pharmacy”.

- (1) <sup>F201</sup> . . . In this Act “registered pharmacy” means premises for the time being entered in the register required to be kept under section 75 of this Act.
- <sup>F202</sup>(2) . . . . .
- (3) In this section and in section 76 of this Act “year” means a period of twelve months beginning on such date as the Council may from time to time determine.
- <sup>F202</sup>(4) . . . . .

#### **Textual Amendments**

**F201** Words in s. 74(1) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt. XII**

**F202** S. 74(2)(4) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt. XII**

### 75 Registration of premises.

- (1) It shall be the duty of the registrar to keep a register for the purposes of this section (in this Part of this Act referred to as “the register”) and, subject to the following provisions of this section, on payment of the prescribed fee to enter in the register any premises in respect of which an application is made under this section.

---

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

---

- (2) Any application for the registration of premises under this section shall be made in the prescribed manner and shall specify the premises to which the application relates and shall contain such other particulars as may be prescribed.
- (3) On the making of any such application the registrar shall notify the appropriate Minister, specifying the premises to which the application relates and the date on which the application was made, and shall not enter those premises in the register before the end of the period of two months from that date, unless before the end of that period the appropriate Minister consents to his doing so.
- (4) If it appears to the appropriate Minister that in a material respect the premises do not comply with the requirements of regulations made under section 66 of this Act which are for the time being in force, and accordingly he proposes to certify that the premises are unsuitable for registration under this section, he shall, before the end of the period referred to in subsection (3) of this section, serve on the applicant a notice stating his proposals and the reasons for them, and shall serve a copy of that notice on the registrar; and, where a copy of such a notice is served on him, the registrar shall not enter the premises in the register except where required to do so in accordance with the following provisions of this section.
- (5) If, within the time allowed after the service on him of a notice under subsection (4) of this section, the applicant gives notice to the appropriate Minister of his desire to be heard with respect to the proposals, or makes representations in writing to the appropriate Minister with respect to the proposals, then, before determining whether to issue a certificate under this section in respect of the premises,—
  - (a) if the applicant has given notice of his desire to be heard, the appropriate Minister shall afford to him an opportunity of appearing before, and being heard by, a person appointed by that Minister for the purpose, or
  - (b) if he has made representations in writing, that Minister shall consider those representations.
- (6) Where the appropriate Minister has served a notice under subsection (4) of this section, then—
  - (a) if he determines not to issue a certificate certifying that the premises are unsuitable for registration under this section, he shall notify the applicant and the registrar of his decision and (subject to subsection (7) of this section) the registrar shall forthwith enter the premises in the register;
  - (b) if the appropriate Minister issues such a certificate, he shall transmit the certificate to the registrar and shall notify the applicant that he has done so, and, if so required by the applicant, shall inform him of the reasons for his decision to issue such a certificate.
- (7) Notwithstanding anything in the preceding provisions of this section, the registrar shall not enter any premises in the register in pursuance of an application under this section unless it is shown to his reasonable satisfaction either—
  - (a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or
  - (b) that, if the premises are entered in the register, and the applicant begins to carry on a retail pharmacy business at those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business.
- (8) In this section “the appropriate Minister”—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) in relation to premises in England or Wales, means [<sup>F203</sup>the Secretary of State];
- (b) in relation to premises in Scotland, means the Secretary of State; and
- (c) in relation to premises in Northern Ireland, means the Minister of Health and Social Services for Northern Ireland,

and “the time allowed” means the period of twenty-eight days or such extended period as the appropriate Minister may in any particular case allow.

**Textual Amendments**

**F203** Words substituted by virtue of S.I. 1968/1699, arts. 2, 5(4)(a)

**Modifications etc. (not altering text)**

**C200** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: S.I. 1969/388, art. 2(1)

**76 Supplementary provisions as to registration of premises.**

- (1) Where any premises have been entered in the register, then, in respect of each year subsequent to the year in which the premises were so entered, a further fee (in this section referred to as a “retention fee”) of the prescribed amount shall be payable by the person carrying on a retail pharmacy business at those premises.
- (2) If, on demand being made to him in the prescribed manner, the person carrying on a retail pharmacy business at any premises entered in the register fails to pay a retention fee in respect of those premises within two months from the date on which the demand is made, the Council may direct the registrar to remove the premises from the register; but if, before the end of the year in respect of which the retention fee is payable or such longer period as in any particular case the Council may allow, the person carrying on the business pays to the registrar the retention fee in respect of that year, together with such additional sum (if any) by way of penalty as may be prescribed,—
  - (a) the registrar shall restore the premises to the register, and
  - (b) if the Council so direct, the restoration shall be deemed to have had effect as from the date on which the premises were removed from the register.
- (3) Where a change occurs in the ownership of a retail pharmacy business carried on at any premises registered under section 75 of this Act, the registration of the premises under that section—
  - (a) if the change occurs on the death of the person carrying on the business, or, in the case of a partnership, on the death of one of the partners, shall become void at the end of the period of three months from the date of the death, and
  - (b) in any other case, shall become void at the end of the period of twenty-eight days from the date on which the change occurs.

<sup>F204</sup>(4) .....

- (5) Where the registration of any premises under section 75 of this Act in respect of a business becomes void by virtue of subsection (3) of this section, an application for the premises to be restored to the register may be made by the person who, in consequence of the change of ownership, has become the owner of the business; and where such an application is made, and it is shown to the reasonable satisfaction of the registrar either—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or
  - (b) that, if the premises are restored to the register, and the applicant thereafter carries on a retail pharmacy business at those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business,
- and (in a case where, if the registration had not become void, a retention fee would have become payable) a fee equal to a retention fee has been paid, the registrar shall restore the premises to the register.
- (6) Any regulations prescribing anything for the purposes of section 75 of this Act or this section shall be made by the Health Ministers.
  - (7) A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises were, or were not, entered in the register shall be admissible in any proceedings as evidence (and, in Scotland, shall be sufficient evidence) that those premises were, or were not, entered in the register on that date.
  - (8) Any fees received by the registrar by virtue of the last preceding section or this section shall be applicable for the purposes of the Pharmaceutical Society.
  - (9) In the application of this section to Northern Ireland, any reference to the Council shall be construed as a reference to the Minister of Health and Social Services for Northern Ireland, the reference to subsection (2) of section 74 of this Act shall be construed as a reference to that subsection as modified by subsection (4) of that section, and subsection (8) shall be omitted.

#### Textual Amendments

**F204** S. 76(4) repealed (5.11.1993) by 1993 c. 50, s. 1(1), Sch. 1Pt. XII

#### 77 Annual return of premises to registrar.

Every person who carried on a retail pharmacy business shall, in the month of January in each year, send to the registrar—

- (a) a list of all premises at which his business, so far as it consists of the retail sale of medicinal products, is carried on, and
- (b) in the case of any premises where medicinal products, other than medicinal products on a general sale list, are sold by retail, or are supplied in circumstances corresponding to retail sale, the name of the pharmacist under whose personal control the business, so far as concerns the retail sale or supply of medicinal products at those premises, is carried on.

*Provisions as to use of certain titles, descriptions and emblems*

#### 78 Restrictions on use of titles, descriptions and emblems.

- (1) The provisions of this section shall have effect subject to section 79 of this Act.
- (2) <sup>F205</sup> . . . No person shall—
  - (a) take or use any of the following titles, that is to say, chemist and druggist, druggist, dispensing chemist, and dispensing druggist, or



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (b) take or use the title of chemist in connection with the sale of any goods by retail or the supply of any goods in circumstances corresponding to retail sale, unless the conditions specified in the next following subsection are fulfilled.
- (3) Those conditions are—
- (a) in the case of an individual, that he is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership) and that he does not take or use the title in question in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and
- (b) in the case of a body corporate, that the body is a person lawfully conducting a retail pharmacy business and that the title in question is not taken or used by that body in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and that the pharmacist who, in relation to that business, is such a superintendent as is referred to in section 71(1) of this Act is a member of the board of the body corporate.
- (4) <sup>F205</sup> . . . No person shall, in connection with a business carried on by him which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, use the description “pharmacy” except in respect of a registered pharmacy or in respect of the pharmaceutical department of a hospital or a health centre.
- (5) <sup>F205</sup> . . . —
- (a) no person who is not a pharmacist shall take or use any of the following titles, that is to say, pharmaceutical chemist, pharmaceutist, pharmacist, member of the Pharmaceutical Society, and Fellow of the Pharmaceutical Society, and
- (b) without prejudice to the preceding paragraph, no person shall take or use any of those titles in connection with a business carried on (whether by him or by some other person) at any premises which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, unless those premises are a registered pharmacy or a hospital or health centre.
- (6) <sup>F205</sup> . . . No person shall, in connection with any business, use any title, description or emblem likely to suggest—
- (a) that he possesses any qualification with respect to the sale, manufacture or assembly of medicinal products which he does not in fact possess, or
- (b) that any person employed in the business possesses any such qualification which that person does not in fact possess.
- (7) For the purposes of the last preceding subsection the use of the description “pharmacy”, in connection with a business carried on at any premises, shall be taken to be likely to suggest that the person carrying on the business (where that person is not a body corporate) is a pharmacist and that any other person, under whose personal control the business (so far as concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale) is carried on at those premises, is also a pharmacist.
- (8) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in section 69(1)(c) of

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

this Act, subsections (5) to (7) of this section shall not have effect so as to prevent the representative from taking or using, in connection with that business, any title, description or emblem which the pharmacist himself could have used in accordance with those subsections.

#### Textual Amendments

**F205** Words in s. 78 repealed (5.11.1993) by 1993 c. 50, s. 1(1), Sch. 1 Pt. XII

### 79 Provision for modifying or extending restrictions under s. 78.

- (1) The Health Ministers may by order provide that any of the restrictions imposed by section 78 of this Act shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the order.
- (2) Without prejudice to the preceding subsection, regulations made by the Health Ministers may (in addition to the restrictions for the time being having effect by virtue of section 78 of this Act) impose such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified in the regulations.
- (3) Without prejudice to the application of section 129(6) of this Act, before making any order or regulations under this section the Health Ministers shall consult the Council.
- (4) Regulations made under this section shall be of no effect unless a draft of the regulations has been laid before Parliament and approved by a resolution of each House of Parliament.

#### *Disqualification, and removal of premises from register*

### 80 Power for Statutory Committee to disqualify and direct removal from register.

- (1) Where a body corporate carries on a retail pharmacy business and—
  - (a) that body is convicted of an offence under any of the relevant Acts, or
  - (b) any member of the board or any officer of or person employed by that body is convicted of an offence, or has been guilty of misconduct, and the offence or misconduct is such as in the opinion of the Statutory Committee renders him, or would if he were a pharmacist render him, unfit to be a pharmacist,
 then, subject to the following provisions of this Part of this Act, the Statutory Committee, after inquiring into the case, may direct that the body corporate shall be disqualified for the purposes of this Part of this Act.
- (2) In any case falling within the preceding subsection—
  - (a) if the Statutory Committee give a direction under that subsection, they shall direct the registrar to remove from the register all premises entered in the register as being premises at which the body corporate carries on a retail pharmacy business;
  - (b) if the Statutory Committee do not give a direction under the preceding subsection, they may, if they think fit, direct the registrar to remove from the register all those premises, or such of them as may be specified in the direction under this paragraph.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) Directions under subsection (1) of this section and under paragraph (a) of the last preceding subsection, and any direction under paragraph (b) of the last preceding subsection, may, if the Statutory Committee think fit, be given so as to have effect for a limited period; and in that case the registrar, at the end of that period, shall restore to the register any premises removed from it in compliance with the direction given under paragraph (a) or paragraph (b) of the last preceding subsection.
- (4) Where, in any such case as is mentioned in subsection (1) of section 72 of this Act, a representative, or a person employed by a representative in the business referred to in that subsection,—
- (a) is convicted of an offence, or
  - (b) has been guilty of misconduct,
- and the offence or misconduct is such as in the opinion of the Statutory Committee renders him, or would if he were a pharmacist render him, unfit to be a pharmacist, then, subject to the following provisions of this Part of this Act, the Statutory Committee, after inquiring into the case, may direct that the representative shall be disqualified for the purposes of this Part of this Act.
- (5) In this and the next following section “the relevant Acts” means the <sup>M13</sup>Pharmacy Act 1954. [<sup>F206</sup>the <sup>M14</sup>Pharmacy (Northern Ireland) Order 1976], [<sup>F207</sup>this Act and the <sup>M15</sup>Misuse of Drugs Act 1971], and “representative” has the same meaning as in section 72 of this Act.

#### Textual Amendments

**F206** Words substituted by [S.I. 1976/1213 \(N.I. 22\)](#), **Sch. 5 para. 6**

**F207** Words substituted by [Misuse of Drugs Act 1971 \(c. 38\)](#), **s. 12(7)**

#### Modifications etc. (not altering text)

**C201** S. 80: Power to amend conferred (15.3.2000) by [1999 c. 8, s. 60\(1\)\(2\)\(4\)](#), **Sch. 3 para. 2(3)(a)**; [S.I. 2000/779](#), **art. 2(1)**

#### Marginal Citations

**M13** [1954 c. 61](#).

**M14** [S.I. 1976/1213 \(N.I. 22\)](#)

**M15** [1971 c. 38](#).

## 81 Grounds for disqualification in certain cases.

- (1) The Statutory Committee shall not give a direction under subsection (1) of section 80 of this Act, in a case falling within paragraph (b) of that subsection, and shall not give a direction under subsection (4) of that section, unless—
- (a) one or more of the facts specified in the next following subsection are proved to the satisfaction of the Committee, and
  - (b) the Committee are of the opinion, having regard to those facts, that the board of the body corporate are, or, as the case may be, the representative is, to be regarded as responsible for the offence or misconduct in question.
- (2) The facts referred to in subsection (1)(a) of this section are—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) that the offence or misconduct in question was instigated or connived at by the board or by a member of the board, or by the representative, as the case may be;
- (b) that, in the case of a body corporate, a member of the board, or an officer of or person employed by the body corporate, had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;
- (c) that, in the case of the representative, he or a person employed by him had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and (where it was a similar offence or similar misconduct on the part of an employee) that the representative had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;
- (d) if the offence or misconduct in question is a continuing offence or continuing misconduct, that the board, or the representative, had, or with the exercise of reasonable care would have had, knowledge of its continuance;
- (e) in the case of an offence in respect of a contravention of an enactment contained in any of the relevant Acts, that the board, or the representative, had not exercised reasonable care to secure that the enactment was complied with.

**Modifications etc. (not altering text)**

**C202** S. 81: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), **Sch. 3 para. 2(3)(a)**; S.I. 2000/779, **art. 2(1)**

**82 Procedure relating to disqualification.**

- (1) The Statutory Committee shall not give a direction under section 80 of this Act except with the assent of the chairman of the Committee.
- (2) A direction under that section shall not take effect until the end of the period of three months from the date on which notice of the direction is given to the body corporate or other person to whom it relates, and, if an appeal against the direction is brought under this section, shall not take effect until that appeal has been determined or withdrawn.
- (3) Where any such direction is given, the body corporate or other person to whom it relates may, at any time before the end of the period of three months specified in subsection (2) of this section, appeal against the direction to the High Court.
- (4) The Pharmaceutical Society may appear as respondent on any such appeal; and, for the purpose of enabling directions to be given as to costs on any such appeal, the Pharmaceutical Society shall be deemed to be a respondent to the appeal whether they appear on the hearing of the appeal or not.
- (5) On any such appeal, the High Court may give such directions in the matter as appear to the Court to be appropriate; and it shall be the duty of the Statutory Committee to comply with any such directions and (where appropriate) of the registrar to make such alterations in the register as are necessary to give effect to them.
- (6) No appeal shall lie from any decision of the High Court under this section.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (7) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session, and any reference to costs shall be construed as a reference to expenses.
- (8) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the Supreme Court of Judicature of Northern Ireland.

**Modifications etc. (not altering text)**

**C203** s. 82: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), **Sch. 3 para. 2(3)(a)**; S.I. 2000/779, **art. 2(1)**

**83 Revocation of disqualification.**

- (1) At any time while a direction under section 80 of this Act is in force the Statutory Committee, either on the application of the person to whom it relates or without any such application, may revoke the direction.
- (2) If, on an application to the Statutory Committee to revoke such a direction, the Committee refuse to revoke it, the applicant, at any time before the end of the period of three months from the date on which notice of the refusal is given to him, may appeal to the High Court against the refusal.
- (3) Subsections (4) to (6) of section 82 of this Act shall have effect in relation to any appeal under this section as they have effect in relation to appeals under that section.
- (4) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session; and in the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the Supreme Court of Judicature of Northern Ireland.

**Modifications etc. (not altering text)**

**C204** S. 83: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), **Sch. 3 para. 2(3)(a)**; S.I. 2000/779, **art. 2(1)**

*Supplementary provisions*

**84 Offences under Part IV.**

- (1) Any person who contravenes section 77 of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F208</sup>level 3 on the standard scale].
- (2) Any person who contravenes section 78 of this Act or who contravenes any regulations made under section 79(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F209</sup>level 3 on the standard scale].

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### Textual Amendments

- F208** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), [ss. 38, 46](#), (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)
- F209** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), [ss. 38, 46](#), (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)

## PART V

### CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

#### 85 Labelling and marking of containers and packages.

- (1) The appropriate Ministers may make regulations imposing such requirements as, for any of the purposes specified in subsection (2) of this section, they consider necessary or expedient with respect to any of the following matters, that is to say—
  - (a) the labelling of containers of medicinal products;
  - (b) the labelling of packages of medicinal products;
  - (c) the display of distinctive marks on containers and packages of medicinal products.
- (2) The purposes referred to in the preceding subsection are—
  - (a) securing that medicinal products are correctly described and readily identifiable;
  - (b) securing that any appropriate warning or other appropriate information or instruction is given, and that false or misleading information is not given, with respect to medicinal products;
  - (c) promoting safety in relation to medicinal products.
- (3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.
- (4) In so far as any such requirements relate to the labelling or marking of containers of medicinal products, a person who, in the course of a business carried on by him, sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except in so far as the regulations otherwise provide, be taken to contravene those requirements as if he had sold or supplied it in a container not complying with those requirements.
- (5) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package—
  - (a) falsely describes the product, or
  - (b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

**C205** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C206** Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

**C207** S. 85 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

**86 Leaflets.**

- (1) The appropriate Ministers may make regulations imposing such requirements as, for any of the purposes specified in section 85(2) of this Act, they consider necessary or expedient with respect to leaflets relating to medicinal products which are supplied, or are intended to be supplied, with the products, whether by being enclosed in containers or packages of the products or otherwise.
- (2) No person shall, in the course of a business carried on by him, supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by regulations under this section which are applicable to that leaflet.
- (3) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, supply with a medicinal product of any description, or have in his possession for the purpose of so supplying, a leaflet which—
  - (a) falsely describes the product, or
  - (b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.
- [<sup>F210</sup>(4) No person shall, in the course of a business carried on by him, supply a product to which [<sup>F211</sup>the 2001 Directive applies], unless—
  - (a) a leaflet enclosed in, or supplied with, the container or package of the product, or
  - (b) the container or package itself,contains the particulars which a leaflet relating to the product is required by regulations under subsection (1) of this section to contain, and does so in the manner required by such regulations.]

**Textual Amendments**

**F210** S. 86(4) inserted (13.2.1994) by S.I. 1994/276, **reg. 7(1)** (with **reg. 7(2)**) (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)

**F211** Words in s. 86(4) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(vi)**

**Modifications etc. (not altering text)**

**C208** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C209** Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

**C210** S. 86 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, **Sch.**

S. 86 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 87 Requirements as to containers.

- (1) The appropriate Ministers may make regulations prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as those Ministers consider necessary or expedient for any of the purposes specified in section 85(2) of this Act, or for the purpose of preserving the quality of the products, and in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed.
- (2) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

### Modifications etc. (not altering text)

C211 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, art. 3(1)

C212 Ss. 85–88, 91 extended by S.I. 1984/187, art. 2

## 88 Distinctive colours, shapes and markings of medicinal products.

- (1) Regulations made by the appropriate Ministers may impose such requirements as, for any of the purposes specified in section 85(2) of this Act, those Ministers consider necessary or expedient with respect to any one or more of the following matters, that is to say—
  - (a) the colour of the products;
  - (b) the shape of the products; and
  - (c) distinctive marks to be displayed on the products.
- (2) Regulations made under this section may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations shall not except in such circumstances (if any) as may be so specified, be of any such colour or shape, or display any such mark, as may be so specified.
- (3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by regulations under this section.

### Modifications etc. (not altering text)

C213 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, art. 3(1)

C214 Ss. 85–88, 91 extended by S.I. 1984/187, art. 2

## 89 Display of information on automatic machines.

- (1) Regulations made by the appropriate Ministers may impose such requirements as they consider necessary or expedient with respect to the display on automatic machines of information relating to medicinal products offered or exposed for sale by means of such machines.



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (2) No person shall offer or expose for sale any medicinal product by means of an automatic machine in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

**Modifications etc. (not altering text)**

C215 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, art. 3(1)

**90 Provisions as to medicated animal feeding stuffs.**

- (1) The provisions of subsections (1) to (4) of section 85, subsections (1) and (2) of section 86, and section 87 of this Act shall have effect in relation to animal feeding stuffs in which medicinal products have been incorporated as if in those provisions any reference to the appropriate Ministers were a reference to the Agriculture Ministers and any reference to medicinal products were a reference to animal feeding stuffs in which medicinal products have been incorporated.

- (2) Without prejudice to the preceding subsection, but subject to the next following subsection, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any animal feeding stuff in which a medicinal product of any description has been incorporated, which is in a container or package labelled or marked in such a way that the container or package—
- (a) falsely describes the animal feeding stuff in so far as its composition results from the incorporation of the medicinal product in it, or
  - (b) is likely to mislead as to the nature or quality of the animal feeding stuff in so far as its composition so results, or
  - (c) is likely to mislead as to the uses or effects of animal feeding stuffs in which medicinal products of the description in question have been incorporated, in so far as any such uses or effects are attributable to the incorporation of such medicinal products;

and no person shall, in the course of a business carried on by him, supply with any such animal feeding stuff, or have in his possession for the purpose of so supplying, a leaflet which falsely describes the animal feeding stuff, or is likely to mislead, as mentioned in paragraph (a), paragraph (b) or paragraph (c) of this subsection.

- (3) For the purposes of subsection (2) of this section no account shall be taken—
- [<sup>F212</sup>(a) of any mark which is made on a container or package in pursuance of Part IV of the <sup>M16</sup>Agriculture Act 1970; or
  - (b) of any statement which, in pursuance of that Part, is made in any leaflet supplied, or intended to be supplied, with any material.]
- (4) Section 130(10) of this Act shall have effect with the necessary modifications for the purpose of subsection (2)(c) of this section.

**Textual Amendments**

F212 S. 90(3)(a)(b) substituted by Agriculture Act 1970 (c. 40), s. 87(4)

**Modifications etc. (not altering text)**

C216 Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, art. 3(1)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### Marginal Citations

M16 1970 c. 40.

## 91 Offences under Part V, and supplementary provisions.

- (1) Subject to sections 121 and 122 of this Act, any person who contravenes the provisions of section 85(5), section 86(3) [<sup>F213</sup>or (4)] or section 90(2) of this Act shall be guilty of an offence and liable—
  - (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (2) Any regulations made under this Part of this Act may provide that any person who contravenes the regulations, or who contravenes the provisions of section 85(3), section 86(2) or section 87(2) of this Act or any of those provisions as applied by section 90(1) of this Act, shall be guilty of an offence and—
  - (a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and
  - (b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.
- (3) Without prejudice to the application of section 129(5) of this Act, any power to make regulations conferred by sections 85 to 87 of this Act may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations, and any power to make regulations conferred by those sections as applied by section 90(1) of this Act shall be exercisable in a corresponding way.
- (4) In this Part of this Act “requirements” includes restrictions.

### Textual Amendments

**F213** Words in s. 91(1) inserted (13.2.1994) by S.I. 1994/276, **reg.8** (which S.I. revoked and replaced S.I. 1994/101 before the latter S.I. came into force)

### Modifications etc. (not altering text)

**C217** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C218** Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

**C219** S. 91 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, **Sch.**

**C220** **Criminal Justice Act 1982** (c. 48, SIF 39:1), **ss. 38** (increase of fines) and 46 (substitution of references to levels on the standard scale) apply (E.W.) and **Criminal Procedure (Scotland) Act 1975** (c. 21, SIF 39:1), **ss. 289F**, 289G (increase of fines and substitution of references to levels on the standard scale) apply (S.) and S.I. 1984/703 (N.I. 3), **art. 5** (substitution of references to levels on the standard scale) and art. 6 (increase of fines) apply (N.I.)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## PART VI

### PROMOTION OF SALES OF MEDICINAL PRODUCTS

#### Modifications etc. (not altering text)

C221 Part VI (ss. 92-97) modified (1.1.1995) by S.I. 1994/3144, reg.9(9)

#### 92 Scope of Part VI.

- (1) Subject to the following provisions of this section, in this Part of this Act “advertisement” includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, [<sup>F214</sup> or by means of a photograph, film, sound recording [<sup>F215</sup> or broadcast],], or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.
- (2) Notwithstanding anything in the preceding subsection, in this Part of this Act “advertisement” does not include spoken words except—
  - (a) words forming part of a sound recording [<sup>F216</sup> or film sound track] . . . <sup>F217</sup>, and
  - (b) words broadcast <sup>F218</sup>....
- (3) Except as provided by section 95 of this Act, for the purposes of this Part of this Act neither of the following shall be taken to constitute the issue of an advertisement, that is to say—
  - (a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;
  - (b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description.
- (4) In this Part of this Act “commercially interested party”, in relation to medicinal products of any description, means any person who—
  - (a) is the holder of a licence under Part II of this Act which is applicable to medicinal products of that description, or
  - (b) not being the holder of such a licence, is a person who, in the course of a business carried on by him, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in subsection (2) or subsection (3) of section 7 or in subsection (2) or [<sup>F219</sup>, subsection (3) or (3A) of section 8] of this Act, or
  - (c) sells by retail any medicinal products of that description in the course of a business carried on by him,and any reference to the request or consent of a commercially interested party includes a reference to any request made or consent given by a person acting on behalf of a commercially interested party; and “relevant business” means any business which consists of or includes the sale or supply of medicinal products.
- (5) In this Part of this Act “representation” means any statement or undertaking (whether constituting a condition or a warranty or not) which consists of spoken words other than words falling within paragraph (a) or paragraph (b) of subsection (2) of this section, and any reference to making a representation shall be construed accordingly.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

[<sup>F220</sup>(6) In this section “ film ”, “ sound recording ”, “ broadcast ”, <sup>F221</sup>..., and related expressions, have the same meaning as in Part I of the Copyright, Designs and Patents Act 1988 (copyright). ]

#### Textual Amendments

- F214** Words substituted by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1), **Sch. 7 para. 10(2)**
- F215** Words in s. 92(1) substituted (31.10.2003) by [The Copyright and Related Rights Regulations 2003 \(S.I. 2003/2498\)](#), reg. 1, **Sch. 1 para. 19(a)** (with regs. 31-40)
- F216** Words in s. 92(2)(a) inserted (31.10.2003) by [The Copyright and Related Rights Regulations 2003 \(S.I. 2003/2498\)](#), reg. 1, **Sch. 1 para. 19(b)** (with regs. 31-40)
- F217** Words repealed by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1)(2), Sch. 7 para. 10(1)(3)(a), **Sch. 8**
- F218** Words in s. 92(2)(b) repealed (31.10.2003) by [The Copyright and Related Rights Regulations 2003 \(S.I. 2003/2498\)](#), reg. 1, **Sch. 2** (with regs. 31-40)
- F219** Words in s. 92(4)(b) substituted (14.4.1993) by [S.I. 1993/834](#), **reg. 7**
- F220** S. 92(6) substituted by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(1), **Sch. 7 para. 10(1)(4)**
- F221** Words in s. 92(6) repealed (31.10.2003) by [The Copyright and Related Rights Regulations 2003 \(S.I. 2003/2498\)](#), reg. 1, **Sch. 2** (with regs. 31-40)

#### Modifications etc. (not altering text)

- C222** S. 92 extended by [S.I. 1984/187](#), **art. 2**  
S. 92 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch.4**  
S. 92 modified (1.1.1995) by [S.I. 1994/3144](#), **reg.9(7)**  
S. 92 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 92 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch.5**
- C223** S. 92 amendment to earlier affecting provision [SI 1994/105 Sch. 4 \(30.10.2005\)](#) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(5)**
- C224** S. 92 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)**

### 93 False or misleading advertisements and representations.

- (1) Subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offence.
- (2) Where a licence under Part II of this Act is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, then, subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations shall be guilty of an offence.

---

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) Subject to the following provisions of this section, any person who in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to a medicinal product in connection with the sale, or offer for sale, of that product shall be guilty of an offence; and any person who, in the course of such a business or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to medicinal products of a particular description—
- (a) to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description, or
  - (b) to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description, or
  - (c) to a person for the purpose of inducing him to purchase medicinal products of that description from a person selling them by retail,
- shall be guilty of an offence.
- (4) Where in the circumstances specified in subsection (2) of this section any person, in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business,—
- (a) in connection with the sale, or offer for sale, of a medicinal product of the description in question, makes a representation relating to the product which consists of or includes unauthorised recommendations, or
  - (b) for any such purpose as is specified in paragraphs (a) to (c) of subsection (3) of this section makes a representation relating to medicinal products of that description which consists of or includes unauthorised recommendations,
- that person, subject to the following provisions of this section, shall be guilty of an offence.
- (5) Where a person is charged with an offence under this section, it shall be a defence for him to prove—
- (a) where the offence charged is under subsection (1) or subsection (3) of this section, that he did not know, and could not with reasonable diligence have discovered, that the advertisement or representation was false or misleading;
  - (b) where the offence charged is under subsection (2) or subsection (4) of this section, that he did not know, and could not with reasonable diligence have discovered, that the recommendations made by the advertisement or representation were unauthorised recommendations.
- (6) Without prejudice to the last preceding subsection, where a person is charged with an offence under this section in respect of the issue of an advertisement, it shall be a defence for him to prove that he is a person whose business it is to issue or arrange for the issue of advertisements, and that either—
- (a) he received the advertisement for issue in the ordinary course of business and issued it, or arranged for it to be issued, either unaltered or without any alteration except in respect of lettering or lay-out, or
  - (b) not being a commercially interested party, he received from a commercially interested party the information on which the advertisement was based and in the ordinary course of business prepared the advertisement in accordance with that information for issue at the request of that party,
- and (in either case) that he did not know and had no reason to suspect that the issue of the advertisement would amount to an offence under this section.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (7) For the purposes of this section an advertisement (whether it contains an accurate statement of the composition of medicinal products of the description in question or not) shall be taken to be false or misleading if (but only if)—
- (a) it falsely describes the description of medicinal products to which it relates, or
  - (b) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects,
- and any reference in this section to a false or misleading representation shall be construed in a corresponding way.
- (8) The preceding provisions of this section shall have effect subject to section 121 of this Act.
- (9) Any person guilty of an offence under this section shall be liable—
- (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (10) In this section “unauthorised recommendations”, in relation to the circumstances specified in subsection (2) of this section, means recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence.

#### Modifications etc. (not altering text)

**C225** S. 93 extended by S.I. 1984/187, **art. 2**

S. 93 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

S.93 extended (with modifications) (14.2.1994) by S.I. 1994/105, **reg. 19, Sch.4**

S. 93 applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch.5**

## 94 Advertisements requiring consent of holder of product licence.

- (1) Where a product licence under this Act is in force which is applicable to medicinal products of a particular description, then, except with the consent of the holder of the licence,—
- (a) no commercially interested party (other than the holder of the licence) shall issue, or cause another person to issue, any advertisement relating to medicinal products of that description; and
  - (b) no person who is not a commercially interested party shall, at the request or with the consent of a commercially interested party, issue, or cause another person to issue, any such advertisement.
- (2) Subject to section 121 of this Act, any person who contravenes the preceding subsection shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F222</sup>level 3 on the standard scale].

#### Textual Amendments

**F222** Words substituted by virtue of (E.W.) **Criminal Justice Act 1982 (c. 48, SIF 39:1), ss. 38, 46, (S.) Criminal Procedure (Scotland) Act 1975 (c.21, SIF 39:1), ss. 289F, 289G and (N.I.) S.I. 1984/703 (N.I. 3), arts. 5, 6**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Modifications etc. (not altering text)**

**C226** S. 94 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, Sch.4

S. 94 applied (1.1.1995) by S.I. 1994/3142, reg. 18(2)

S. 94 applied (31.3.1997) by S.I. 1997/322, reg. 34, Sch.5

**95 Powers to regulate advertisements and representations.**

- (1) The appropriate Ministers may by regulations prohibit any one or more of the following, that is to say—
- (a) the issue of advertisements relating to medicinal products of a description, or falling within a class, specified in the regulations;
  - (b) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a disease specified in the regulations or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified;
  - (c) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class specified in the regulations, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in paragraph (b) of this subsection;
  - (d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the appropriate Ministers, is likely to mislead the public as to the nature or effects of the products or as to any condition of body or mind in connection with which the products might be used.
- (2) Where any regulations are made in accordance with paragraph (b), paragraph (c) or paragraph (d) of the preceding subsection, the regulations may prohibit the making of any representation likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified in the regulations in accordance with paragraph (b) of that subsection, or containing a word or phrase specified in the regulations in accordance with paragraph (d) of that subsection, if the representation—
- (a) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which the regulations apply, or
  - (b) is made to a person for the purpose of inducing him to purchase such a medicinal product, substance or article from a person selling by retail medicinal products or other substances or articles to which the regulations apply, or
  - (c) in the case of medicinal products of a description to which the regulations apply, is made to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description or is made to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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 the preceding provisions of this section, the appropriate Ministers may by regulations impose such requirements as, for any of the purposes specified in the next following subsection, they consider necessary or expedient with respect to any one or more of the following matters, that is to say—
- (a) the particulars which advertisements relating to medicinal products must contain;
  - (b) the form of any such advertisements; and
  - (c) in the case of advertisements by way of cinematograph films or television, the duration for which, and the manner in which, any part of such an advertisement which contains particulars of a description specified in the regulations must be exhibited;
- and any such regulations may prohibit the use, in relation to medicinal products of a description specified in the regulations, of advertisements of any particular kind so specified.
- (4) The purposes referred to in subsection (3) of this section are—
- (a) securing that adequate information is given with respect to medicinal products;
  - (b) preventing the giving of misleading information with respect to such products;
  - (c) promoting safety in relation to such products.
- (5) Without prejudice to the application of section 129(5) of this Act, any prohibition imposed by regulations under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the regulations.
- (6) Any regulations made under this section may provide that any person who contravenes the regulations shall be guilty of an offence and—
- (a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and
  - (b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.
- (7) Section 92(3) of this Act shall not have effect for the purposes of paragraphs (b) to (d) of subsection (1) of this section.

**Modifications etc. (not altering text)**

**C227** S. 95 extended by S.I. 1984/187, **art. 2**

S. 95 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

S. 95. applied (31.3.1997), by S.I. 1997/322, **reg. 34, Sch.5**

**C228** Criminal Justice Act 1982 (c. 48, SIF 39:1), **ss. 38** (increase of fines) and 46 (substitution of references to levels on the standard scale) apply (E.W.) and Criminal Procedure (Scotland) Act 1975 (c.21, SIF 39:1), **ss. 289F, 289G** (increase of fines and substitution of references to levels on the standard scale) apply (S.) and S.I. 1984/703 (N.I. 3), **art. 5** (substitution of references to levels on the standard scale) and art. 6 (increase of fines) apply (N.I.)

**96 Advertisements and representations directed to practitioners.**

- (1) On and after the relevant date, no advertisement relating to medicinal products of a particular description, other than a data sheet, shall be sent or delivered to a practitioner—



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) by a commercially interested party, or
  - (b) by any person at the request or with the consent of a commercially interested party,unless the conditions specified in subsection (3) of this section are fulfilled.
- (2) On and after the relevant date, no representation likely to promote the use of medicinal products of a particular description referred to in the representation shall be made to a practitioner by a person carrying on a relevant business, or by a person acting on behalf of a person carrying on such a business, unless the conditions specified in subsection (3) of this section are fulfilled.
- (3) Those conditions are—
  - (a) that a data sheet relating to medicinal products of the description in question is sent or delivered to the practitioner with the advertisement, or is delivered to him at the time when the representation is made, or that such a data sheet has been sent or delivered to him not more than fifteen months before the date on which the advertisement is sent or delivered or the representation is made, and
  - (b) that the advertisement or representation is not inconsistent with the particulars contained in the data sheet.
- (4) For the purposes of this section the relevant date—
  - (a) in relation to medicinal products of any description to which neither subsection (2) nor subsection (3) of section 16 of this Act is applicable, is the first appointed day, and
  - (b) in relation to medicinal products of any description to which either of those subsections is applicable, is the date of expiry of the period of six months from the date (or, if more than one, the latest date) on which, by virtue of one or more orders under section 17 of this Act, those subsections cease (or, if only one of them is applicable, that subsection ceases) to have effect in relation to them.
- (5) Subject to section 121 of this Act, any person who contravenes subsection (1) or subsection (2) of this section shall be guilty of an offence, and, if he contravenes that subsection by not complying with the condition specified in paragraph (b) of subsection (3) of this section, shall be liable—
  - (a) on summary conviction, to a fine not exceeding £400, or
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both,and, in any other case, shall be liable on summary conviction to a fine not exceeding [<sup>F223</sup>level 3 on the standard scale].
- (6) In this and the next following section “data sheet” means a document relating to medicinal products of a particular description, which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products of that description and which—
  - (a) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition of lettering or otherwise) in which any such particulars are to be so contained, as may be prescribed for the purposes of this subsection, and
  - (b) does not contain any information relating to medicinal products of that description except the particulars so prescribed.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

[<sup>F224</sup>(7) Nothing in this section applies in relation to a relevant medicinal product, as defined by paragraph (1) of regulation 2 of the Medicines (Advertising) Regulations 1994, in respect of which there is required to exist a summary of product characteristics as defined by that paragraph.]

#### Textual Amendments

**F223** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\)](#), [ss. 38, 46](#) and (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c. 21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)

**F224** [S. 96\(7\)](#) inserted (29.9.1995) by [S.I. 1995/2321](#), [reg.2](#)

#### Modifications etc. (not altering text)

**C229** [S. 96](#) extended (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
[S. 96](#) applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)

### 97 Power for licensing authority to require copies of advertisements.

- (1) The licensing authority may serve on any person a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority such number of copies (not exceeding twelve) as may be so specified of any advertisement (including any data sheet) relating to medicinal products, or to medicinal products of a description or falling within a class so specified, which he has issued, or has caused to be issued, within the period of twelve months ending with the date of service of the notice, and which he has so issued, or caused to be issued,—
- (a) being a commercially interested party, or
  - (b) at the request or with the consent of a commercially interested party.
- (2) Any person who without reasonable excuse fails to comply with any requirement imposed on him by a notice under this section shall be guilty of an offence, and shall be liable on summary conviction to a fine not exceeding [<sup>F225</sup>level 3 on the standard scale].

#### Textual Amendments

**F225** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c. 48, SIF 39:1\)](#), [ss. 38, 46](#) and (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)

#### Modifications etc. (not altering text)

**C230** [S. 97](#) extended by [S.I. 1984/187](#), [art. 2](#)  
[S. 97](#) extended (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch.4](#)  
[S. 97](#) applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
[S. 97](#) applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## PART VII

### BRITISH PHARMACOPOEIA AND OTHER PUBLICATIONS

#### Modifications etc. (not altering text)

**C231** Part. VII (ss. 99-103) modified (1.1.1995) by [S.I. 1994/3144, reg.9\(9\)](#)

**C232** [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** ..... **F226**

#### Textual Amendments

**F226** 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.
- (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 veterinary drugs 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.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (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 subsection (3)(a) of this section, then, on the recommendation of the Commission, the Health Ministers shall cause it to be published; and where the appropriate body has prepared or caused to be prepared any such compendium or new edition as is mentioned in subsection (3)(b) of this section, then, on the recommendation of the Commission, the Agriculture Ministers shall cause it to be published:  
F227 ...
- (7) In this Part of this Act “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, and “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.

#### Textual Amendments

**F227** S. 99(6) proviso repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), [Sch. 1 Pt. 17](#) Group 7

## 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.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## **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, the Health Ministers or the Agriculture 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 concerned may determine.
- (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.

## **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 Health Ministers may publish any amendment of the British Pharmacopoeia or of any such compendium which in the opinion of those 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;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (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 appropriate 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 appropriate 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 appropriate 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 “the appropriate Ministers”, in relation to any subject-matter required or authorised to be published under this Part of this Act, means the Ministers causing it to be published, and “amendment” includes addition and deletion.

### 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;
  - [<sup>F228</sup>(ca) the International Pharmacopoeia;
  - (cb) the Cumulative List of Recommended International Nonproprietary Names;]
  - (d) the British Veterinary Codex;
  - (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 [<sup>F229</sup>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, 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

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (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 <sup>F230</sup>, 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

**F228** S. 103(1)(ca)(cb) inserted by [Health and Medicines Act 1988 \(c.49, SIF 113:2, 84\)](#), s. 22(1)

**F229** Words substituted by [Health and Medicines Act 1988 \(c. 49, SIF 113:2, 84\)](#), s. 22(4)

**F230** Words inserted by [Health and Medicines Act 1988 \(c. 49, SIF 113:2, 84\)](#), s. 22(6)

#### Modifications etc. (not altering text)

**C233** S. 103 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg. 9(8)

**C234** 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)

## PART VIII

### MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

#### Modifications etc. (not altering text)

**C235** Pt. VIII (ss. 104–136) extended by [S.I.s 1982/425](#), art. 3, [1984/187](#) art. 2; and extended with modifications by [S.I. 1985/403](#), art. 3(1)

## 104 Application of Act to certain articles and substances.

- (1) The Ministers, the Health Ministers or the Agriculture Ministers may by order specify any description or class of articles or substances appearing to them to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and may by the order direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act<sup>F231</sup>, or the Clinical Trials Regulations,] as may

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

be so specified (including provisions so specified which relate to offences or penalties) shall have effect in relation to articles or substances of that description or class as those provisions have effect in relation to medicinal products.

- (2) 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

**F231** Words in s. 104(1) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 17**

#### Modifications etc. (not altering text)

**C236** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

### 105 Application of Act to certain other substances which are not medicinal products.

- (1) The Ministers may by order specify any substance appearing to the Ministers to be a substance which is not itself a medicinal product but—
- (a) is used as an ingredient in the manufacture of medicinal products, or
  - (b) if used without proper safeguards, is capable of causing danger to the health of the community, or of causing danger to the health of animals generally or of one or more species of animals,

and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act<sup>F232</sup>, or the Clinical Trials Regulations,] as may be so specified (including any provisions so specified which relate to offences or penalties) shall have effect in relation to that substance as those provisions have effect in relation to medicinal products.

- (2) The power conferred by the preceding subsection may be exercised in relation to a class of substances if it appears to the Ministers that the conditions specified in paragraph (a) or paragraph (b) of that subsection are fulfilled in relation to all substances falling within that class.
- (3) No order shall be made under this section—
- (a) in relation to a substance as being a substance in respect of which the condition specified in subsection (1)(b) of this section is fulfilled, or
  - (b) in relation to a class of substances as being substances in respect of which that condition is fulfilled,

unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

#### Textual Amendments

**F232** Words in s. 105(1) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 18**

#### Modifications etc. (not altering text)

**C237** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## 106 Extension of references to carrying on business.

- (1) The Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if in those provisions any reference to a business included a reference to an activity (other than a business) of a description specified in the order.
- (2) Without prejudice to the preceding subsection, the Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if, in such circumstances as may be so specified, a business carried on by a person's employer were a business carried on by that person.

### Modifications etc. (not altering text)

**C238** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

**C239** Commentary missing

## 107 Validity of decisions and proceedings relating thereto.

- (1) Except as provided by the following provisions of this section, the validity of any decision of the licensing authority under Part II of this Act or of a Minister under section 75 of this Act, and the validity of any licence or certificate granted or issued or other thing done in pursuance of any such decision, shall not be questioned in any legal proceedings.
- (2) If the person to whom such a decision relates desires to question the validity of the decision on the grounds—
  - (a) that it is not within the powers of this Act, or
  - (b) that any of the requirements of this Act or of any regulations made under this Act, which are applicable to the matter to which the decision relates, have not been complied with,that person may, at any time within the period of three months from the date on which notice of the decision is served on him, make an application to the High Court under this section.
- (3) On any application under this section the High Court—
  - (a) may by interim order suspend the operation of the decision to which the application relates until the final determination of the proceedings;
  - (b) if satisfied that the decision is not within the powers of this Act, or that the interests of the person making the application have been substantially prejudiced by a failure to comply with any of the requirements mentioned in subsection (2)(b) of this section, may quash the decision.
- (4) Where a decision to grant a licence or certificate is quashed under this section, any licence or certificate granted in pursuance of that decision shall be void, and any proceedings on the application for the grant of the licence or certificate may be continued as if no such decision had been made.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (5) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session.
- (6) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the High Court of Justice in Northern Ireland.

#### **Modifications etc. (not altering text)**

- C240** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C241** S. 107 applied (with modifications) (3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch. S. 107 extended (with modifications)(14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)  
S. 107 applied (with modifications) (1.1.1995) by s.I. 1994/3144, reg.10, Sch. 4  
S. 107 applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)
- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\), regs. 1, 47, Schs. 9](#)
- C243** Ss. 107-109 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\), regs. 1\(a\), 11, Schs. 4 \(with Sch. 6\)](#)

### **108 Enforcement in England and Wales.**

- (1) It shall be the duty of the appropriate Minister to enforce in England and Wales, or to secure the enforcement in England and Wales of, the provisions of this Act and any regulations and orders made under it.
- (2) For the purpose of performing that duty in relation to—
- the provisions of any order made under paragraph (a) of section 62(1) of this Act and of section 63(b), sections 64 and 65, subsections (3) to (5) of section 85, and sections 87(2), 88(3) and 89(2) of this Act, in the application of any of those provisions to the retail sale, offer or exposure for retail sale, or possession for the purpose of retail sale, of medicinal products and to the supply, offer or exposure for supply, or possession for the purpose of supply, of medicinal products in circumstances corresponding to retail sale;
  - the provisions of subsections (2) and (3) of section 86 of this Act, in their application to the supply, or possession for the purpose of supply, of leaflets with medicinal products sold or to be sold by retail, or supplied or to be supplied in circumstances corresponding to retail sale; and
  - the provisions of sections 93 and 94 of this Act and any regulations made under section 95 of this Act,

the appropriate Minister shall, in respect of each area for which there is a <sup>F233</sup>drugs authority] make arrangements or give directions whereby the Pharmaceutical Society, or the <sup>F233</sup>drugs authority] for that area, or both the Society and that authority, to such extent as, in the case of that Society or authority, the arrangements or directions may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in paragraphs (a) and (b) of this subsection, in their application as mentioned in those paragraphs, and the provisions and regulations specified in paragraph (c) of this subsection.

- (3) Any arrangements made with, or directions given to, the Pharmaceutical Society under subsection (2) of this section, in so far as they relate to the provisions and regulations

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- specified in paragraph (c) of that subsection, shall be limited to the enforcement of those provisions and regulations in respect of—
- (a) any advertisement issued or representation made on or in any premises, ship, aircraft, vehicle, stall or place where medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale, and
  - (b) any advertisement displayed on, or in close proximity to, an automatic machine in which medicinal products are offered or exposed for sale.
- (4) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that any such body to which this subsection applies as may be specified in the regulations shall, to such extent as in the case of that body may be so specified, and either—
- (a) in respect of England and Wales generally, or
  - (b) in respect of such area in England or Wales as may be so specified,
- have power concurrently with the appropriate Minister, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.
- (5) Subsection (4) of this section applies to the following bodies, that is to say, the Pharmaceutical Society, any, [<sup>F233</sup>drugs authority] the council of any county district which is not a, [<sup>F233</sup>drugs authority] and the overseers of the Inner Temple and the Middle Temple.
- (6) The Pharmaceutical Society shall be under a duty, concurrently with the appropriate Minister,—
- (a) to enforce the provisions of sections [<sup>F234</sup>40], 52 and 58 of this Act [<sup>F234</sup>and of any regulations made under section 40 of this Act] in their application to England and Wales;
  - (b) to enforce the provisions of any regulations made under section 60 or section 61 of this Act in their application to premises in England and Wales at which medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale; and
  - (c) to enforce the provisions of sections 77 and 78 of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.
- (7) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that, in respect of each area in England or Wales for which there is a food and drugs authority, the Pharmaceutical Society, or the food and drugs authority for that area, or both the Society and that authority, to such extent as, in the case of that Society or authority, the regulations may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions of sections 53 and 54 of this Act.
- (8) The council of every county [<sup>F235</sup>or county borough][<sup>F236</sup>and of every metropolitan district] . . . <sup>F237</sup> in England and Wales, the council of every London borough and the Common Council of the City of London shall be under a duty, concurrently with the appropriate Minister, to enforce in their area—
- (a) any order made under paragraph (b) of section 62(1) of this Act, and
  - (b) the provisions of section 90 of this Act and any regulations made by virtue of that section.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (9) Notwithstanding anything in subsections (2) to (8) of this section, no duty or power conferred or imposed by or under any of those subsections shall be performed or be exercisable in relation to—
- (a) any hospital, or
  - (b) so much of any premises as is used by a practitioner for carrying on his practice, or
  - (c) so much of any premises (not falling within either of the preceding paragraphs) as is used for veterinary medicine or veterinary surgery for the purposes of any institution.
- (10) If the appropriate Minister is satisfied, after making such inquiry as he thinks fit, that the Pharmaceutical Society or any other body on whom a duty to enforce any provisions is imposed by or under subsections (4) to (8) of this section have in relation to any matter failed to perform that duty, and that the public interest requires that the provisions in question should be enforced in relation to it, he may determine that he will himself enforce those provisions in relation to that matter.
- (11) In this section “the appropriate Minister”—
- (a) in relation to the performance of any function under this section (whether by making any arrangements or giving any direction or otherwise) where the function is or is to be performed exclusively in relation to veterinary drugs, or to section 90 of this Act or any regulations made by virtue of that section, means the Minister of Agriculture, Fisheries and Food, and
  - (b) in all other respects, means the [<sup>F238</sup>Secretary of State].
- [<sup>F239</sup>(12) In this section “drugs authority” means—
- (a) as respects each London borough, metropolitan district [<sup>F240</sup>, county borough] or non-metropolitan county, the council of that borough, district [<sup>F240</sup>, county borough] or county; and
  - (b) as respects the City of London (including the Temples), the Common Council of that City.]

#### Textual Amendments

- F233** Words substituted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), **Sch. 3 para. 8(a)**
- F234** Words inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, **Sch. 1 para. 3(4)**
- F235** [S. 108\(8\)](#) words inserted (1.4.1996) by [1994 c. 19, s. 66\(6\)](#), **Sch. 16 para. 33(a)**; [S.I. 1996/396](#), art. 4, **Sch.2**
- F236** Words inserted by [S.I. 1988/1955](#), **art. 2**
- F237** Words repealed by [Local Government Act 1972 \(c. 70\)](#), **Sch. 30**
- F238** Words substituted by virtue of [S.I. 1968/1699](#), **arts. 2, 5(4)(a)**
- F239** [S. 108\(12\)](#) inserted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), **Sch. 3 para. 8(b)**
- F240** [S. 108\(12\)\(a\)](#) words inserted (1.4.1996) by [1994 c. 19, s. 66\(6\)](#), **Sch. 16 para. 33(b)**; [S.I. 1996/396](#), art. 4, **Sch. 2**

#### Modifications etc. (not altering text)

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C243** Ss. 107-109 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with **Sch. 6**)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- C244** Power to modify s. 108(8)(W.) conferred by [Local Government Act 1972 \(c. 70\), s. 200\(3\)](#)
- C245** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: [S.I. 1969/388, art. 2\(1\)](#)
- C246** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C247** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520, reg. 12.](#)
- C248** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605, regs. 2\(3\), 3](#)  
Ss. 108-115 applied (3.10.1994) by S.I 1994/2328, reg. 11(c)(ii)(aa)
- C249** S. 108 modified (30.1.1992) by [S.I. 1992/32, reg. 12\(1\)\(2\)](#)  
S. 108 extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)  
S. 108 applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)  
s. 108 extended (1.1.1995) by [S.I. 1994/3142, reg. 18\(7\)](#)  
S. 108 applied (with modifications) (1.1.1995) by [S.I. 1994/3144, reg.10, Sch. 4](#)  
S. 108 applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)  
Ss. 108-110 applied (1.2.2000) by [S.I. 2000/7, reg. 5](#)
- C250** S. 108: Functions transferred (W.) (1.7.1999) by virtue of [S.I. 1999/672, art. 2, Sch. 1](#)

## 109 Enforcement in Scotland.

- (1) It shall be the duty of the Secretary of State to enforce in Scotland, or to secure the enforcement in Scotland of, the provisions of this Act and of any regulations and orders made under it.
- (2) Subsections (2) and (3) and (6) to (10) of section 108 of this Act shall have effect in relation to Scotland as if—
- (a) any reference to the appropriate Minister or to the Minister of Health and the Minister of Agriculture, Fisheries and Food acting jointly were a reference to the Secretary of State;
  - (b) any reference to England and Wales were a reference to Scotland; and
  - <sup>[F241]</sup>  
<sup>F242</sup>(c) references to a food and drugs authority and to the area of any such authority were references respectively to a local authority as defined by section 26(4) of the <sup>M17</sup>Food and Drugs (Scotland) Act 1956 and to the area of such an authority; and]
  - (d) references to any such council as is mentioned in section 108(8) of this Act and to the area of any such council were references respectively to a <sup>[F243]</sup>council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 and the area of such a council].]
- <sup>[F244]</sup>(2A) Subsection (12) of section 108 of this Act shall have effect in relation to Scotland as if for paragraphs (a) and (b) there were substituted the words <sup>[F245cc</sup> a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 ”]]
- (3) Regulations made by the Secretary of State may provide that, to such extent as may be specified in the regulations—
- (a) the Pharmaceutical Society, in respect of Scotland generally, or in respect of such area in Scotland as may be so specified,
  - (b) a local authority within the meaning of section 26(4) of the <sup>M18</sup>Food and Drugs (Scotland) Act 1956, in respect of their area,
- shall have power concurrently with the Secretary of State, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) Nothing in this section shall be construed as authorising an enforcement authority to institute proceedings for any offence.

#### Textual Amendments

- F241** S. 109(2)(c)(d) substituted (S.) for s. 109(2)(c) by [Local Government \(Scotland\) Act 1973 \(c. 65\)](#), [Sch. 27 Pt. II para. 191](#)
- F242** S. 109(2)(c) repealed (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), [Sch. 3 para. 9\(a\)](#)
- F243** Words in s. 109(2)(d) substituted (S.) (1.4.1996) by 1994 c. 39, s. 180(1), [Sch. 13 para. 79\(a\)](#); S.I. 1996/323, [art.4\(c\)](#)
- F244** S. 109(2A) inserted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), [Sch. 3 para. 9\(b\)](#)
- F245** Words in s. 109(2A) substituted (S.) (1.4.1996) by 1994 c. 39, s. 180(1), [Sch. 13 para. 79\(b\)](#); S.I. 1996/323, [art. 4\(1\)\(c\)](#)

#### Modifications etc. (not altering text)

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)
- C243** Ss. 107-109 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, [Schs. 4](#) (with [Sch. 6](#))
- C251** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C252** S. 109 modified (30.1.1992) by [S.I. 1992/32](#), [reg. 12\(1\)\(2\)](#)  
S. 109 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
S. 109 extended (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(7\)](#)  
S. 109 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 109 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)  
S. 109 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg.10](#), [Sch. 4](#)  
Ss. 108-110 applied (1.2.2000) by [S.I. 2000/7](#), [reg. 5](#)
- C253** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520](#), [reg. 12](#).
- C254** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\)](#), 3  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), [reg. 11\(c\)](#)
- C255** S. 109: Functions transferred (S.) (1.7.1999) by [S.I. 1999/1750](#), [art. 2](#), [Sch. 1](#) (with [art. 7](#))
- C256** S. 109(1): power to transfer functions conferred (1.5.2000) by [S.I. 2000/745](#), [art. 2\(1\)](#), [Sch. para. 1](#)

#### Marginal Citations

- M17** 1956 c. 30.  
**M18** 1956 c. 30.

## 110 Enforcement in Northern Ireland.

- (1) Subject to the provisions of subsection (4) of this section, it shall be the duty of the Minister of Health and Social Services for Northern Ireland (in this section referred to as “the Minister”) to enforce in Northern Ireland, or to secure the enforcement in Northern Ireland of, the provisions of this Act and of any regulations and orders made under it.
- (2) For the purpose of performing that duty in relation to the provisions specified in paragraphs (a) and (b) of subsection (2) of section 108 of this Act in their application as mentioned in those paragraphs, and the provisions and regulations specified in

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- paragraph (c) of that subsection, within the <sup>F246</sup>district] of any <sup>F246</sup>district council], the Minister may make arrangements or give directions whereby the <sup>F246</sup>district council], to such extent as the arrangements or directions may provide, shall have power concurrently with the Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in the said paragraphs (a) and (b) in their application as so mentioned and the provisions and regulations specified in the said paragraph (c).
- (3) For the purpose of performing that duty in relation to the provisions of sections 53 and 54 of this Act and any regulations made under section 66 of this Act within the <sup>F246</sup>district] of any <sup>F246</sup>district council], the Minister may make arrangements or give directions whereby the <sup>F246</sup>district council], to such extent as the arrangements or directions may provide, shall have power concurrently with the Minister, or shall be under a duty concurrently with him, to enforce those provisions and regulations.
- (4) In relation to veterinary drugs and animal feeding stuffs in which medicinal products have been incorporated or in which any substance or article has been incorporated for a medicinal purpose, arrangements may be made between the Minister and the Minister of Agriculture for Northern Ireland, and by them varied or revoked, and fresh arrangements made by them, for the performance by the Minister of Agriculture for Northern Ireland of any function conferred or imposed by this section on the Minister; and where any such arrangements are for the time being in force this section shall have effect as if it conferred or imposed the function in question on the Minister of Agriculture for Northern Ireland.
- (5) Subsections (9) and (10) of section 108 of this Act shall have effect in relation to Northern Ireland as if—
- (a) in the said subsection (9) the reference to subsections (2) to (8) of that section were a reference to subsections (2) and (3) of this section; and
- (b) in the said subsection (10) any reference to the appropriate Minister were a reference to the Minister within the meaning of this section, and for the words “the Pharmaceutical Society or any other body” there were substituted the words “any <sup>F246</sup>district council]” and the reference to subsections (4) to (8) of that section were a reference to subsection (3) of this section.
- (6) . . . . . <sup>F247</sup>
- <sup>F248</sup>(8) In this section “district council” means a council established under the <sup>M19</sup>Local Government Act (Northern Ireland) 1972.]

**Textual Amendments**

- F246** Words substituted by S.R. & O. (N.I.) 1973 No. 211 , **Sch.**  
**F247** S. 110(6)(7) repealed by S.R. & O. (N.I.) 1973 No. 211 , **Sch.**  
**F248** S. 110(8) substituted by S.R. & O. (N.I.) 1973 No. 211 , **Sch.**

**Modifications etc. (not altering text)**

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C257** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#) , **art. 3(1)**
- C258** S. 110 modified (30.1.1992) by [S.I. 1992/32](#) , **reg. 12(1)(2)**  
S. 110 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#) , **reg. 19** , **Sch.4**  
S. 110 applied (1.1.1995) by [S.I. 1994/3142](#) , **reg. 18(2)**  
S. 110 applied (31.3.1997) by [S.I. 1997/322](#) , **reg. 34** , **Sch.5**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

S. 110 extended (1.1.1995) by S.I.1994/ 3142, reg. 18(7)

S. 110 (except (4)) applied (with modifications) (1.1.1995) by S.I. 1994/3144 , **reg.10**

Ss. 108-110 applied (1.2.2000) by S.I. 2000/7 , **reg. 5**

**C259** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520 , **reg.12** .

**C260** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605 , **regs. 2(3) , 3**

Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328 , **reg. 11(c)**

**C261** S. 110 applied in part (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750) , regs. 1(a) , 11 , **Schs. 4** (with Sch. 6 )

#### **Marginal Citations**

**M19** 1972 c. 9 (N.I.)

### **111 Rights of entry.**

- (1) Subject to the following provisions of this section, any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises—
  - (a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce,<sup>F249</sup> ...
  - [<sup>F250</sup>(aa) for the purpose specified in the third sub-paragraph of Article 111(1) of the 2001 Directive, or]
  - (b) generally for the purposes of the performance by the authority of their functions under this Act or under any such regulations or order.
- (2) Any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time—
  - (a) to enter any ship, aircraft or hover vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce;
  - (b) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship, for any purpose for which under subsection (1) of this section the person so authorised would have a right to enter any premises.
- (3) Without prejudice to subsection (1) of this section, any person duly authorised in writing by the licensing authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part II of this Act for the purpose of verifying any statement contained in the application for the licence or certificate.
- (4) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of the preceding provisions of this section unless twenty-four hours' notice of the intended entry has been given to the occupier.
- (5) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entering any premises for any purpose for which a person authorised by an enforcement authority has a right to enter them in accordance with the preceding provisions of this section, and is also satisfied—



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) that admission to the premises has been refused, or that a refusal is apprehended, and (in either case) that notice of the intention to apply for a warrant has been given to the occupier, or
  - (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or
  - (c) that the case is one of urgency, or
  - (d) that the premises are unoccupied or the occupier is temporarily absent,
- the justice may by warrant under his hand authorise the enforcement authority, or any person duly authorised by them, to enter the premises, if need be by force.
- (6) The last preceding subsection shall have effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under subsection (2) of this section as it has effect in relation to entering any premises, as if in the last preceding subsection any reference to the occupier were a reference to the master, commander or other person in charge of the ship, aircraft, vehicle, stall or place.
- (7) Any warrant granted under this section shall continue in force for a period of one month.
- (8) In this section “home-going ship” means a ship plying exclusively in inland waters or engaged exclusively in coastal voyages; and for the purposes of this subsection “inland waters” means any canal, river, lake, loch, navigation or estuary and “coastal voyage” means a voyage which starts and ends in the United Kingdom and does not involve calling at any place outside the United Kingdom.
- (9) In the application of this section to Scotland, references to a justice of the peace include references to the sheriff and a magistrate.

#### Textual Amendments

- F249** Word in s. 111(1)(a) repealed (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 9\(a\)](#) (with Sch. 6 )
- F250** S. 111(1)(aa) inserted (30.10.2005) by [The Medicines for Human Use \(Manufacturing, Wholesale Dealing and Miscellaneous Amendments\) Regulations 2005 \(S.I. 2005/2789\)](#), reg. 1(1), [Sch. 5 para. 9\(b\)](#) (with Sch. 6 )

#### Modifications etc. (not altering text)

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)
- C262** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C263** S. 111 modified (30.1.1992) by [S.I. 1992/32](#), [reg. 12\(1\)\(2\)](#)  
S. 111 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
S. 111 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 111 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)  
S. 111 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)  
S. 111 (other than s. 111(3)) applied (1.2.2000) by [S.I. 2000/7](#), [reg. 5](#)
- C264** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520](#), [reg. 12](#).
- C265** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\)](#), 3  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), [reg. 11\(c\)](#)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C266** Ss. 111-116 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750) , regs. 1(a) , 11 , Schs. 4 (with Sch. 6 )

## 112 Power to inspect, take samples and seize goods and documents.

- (1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act an enforcement authority is required or empowered to enforce, any person duly authorised in writing by that authority shall have a right to inspect—
  - (a) any substance or article appearing to him to be a medicinal product;
  - (b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or
  - (c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.
- (2) Where for the purpose specified in the preceding subsection a person authorised as mentioned in that subsection requires a sample of any substance or article appearing to him to be—
  - (a) a medicinal product sold or supplied or intended to be sold or supplied, or
  - (b) a substance or article used or intended to be used in the manufacture of a medicinal product,
 he shall (if he does not obtain the sample by purchase) have a right to take a sample of that substance or article.
- (3) For the purpose specified in subsection (1) of this section, any person authorised as mentioned in that subsection shall have a right—
  - (a) to require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control;
  - (b) to take copies of, or of any entry in, any book or document produced in pursuance of the preceding paragraph.
- (4) Any person so authorised shall have a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.
- (5) For the purpose of exercising any such right as is specified in subsection (4) of this section the person having that right may, so far as is reasonably necessary in order to secure that the provisions of this Act and any regulations or order made thereunder are duly observed, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (6) Where a person seizes any substance or article (including any document) in the exercise of such a right as is specified in subsection (4) of this section, he shall inform the person from whom it is seized, and, in the case of anything seized from a vending machine, the person whose name and address are stated on the machine as being those of the owner of the machine, or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.
- (7) Without prejudice to the preceding provisions of this section, any person duly authorised in writing by the licensing authority shall have the rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for a licence or certificate under Part II of this Act, and may exercise those rights for the purpose of verifying any statement contained in the application for the licence or certificate; and, where by virtue of this subsection a person exercises any such right as is specified in subsection (4) of this section, he shall be subject to the duty imposed by subsection (6) of this section.
- (8) Notwithstanding anything in the preceding provisions of this section, where a person claiming to exercise a right by virtue of this section is required to produce his credentials, the right shall not be exercisable by him except on production of those credentials.
- (9) The provisions of Schedule 3 to this Act shall have effect with respect to samples obtained on behalf of enforcement authorities for the purposes of this Act.

**Modifications etc. (not altering text)**

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C266** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C267** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C268** S. 112 modified by [S.I. 1985/273](#), reg. 2, **Sch. 1 Pt. I**
- C269** S. 112 restricted by [S.I. 1985/273](#), **reg. 3(3)**
- C270** S. 112 modified (30.1.1992) by [S.I. 1992/32](#), **reg. 12(1)(2)**  
S. 112 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch.4**  
S. 112 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 112 applied (with modifications) (1.1.1994) by [S.I. 1994/3144](#), reg.10, **Sch. 4**  
S. 112 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch.5**  
S. 112 (other than s. 112(7)) applied (1.2.2000) by [S.I. 2000/7](#), **reg. 5**
- C271** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520](#), **reg.12.**
- C272** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), **regs. 2(3)**, 3  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), **reg. 11(c)**

**113 Application of sampling procedure to substance or article seized under s. 112.**

- (1) The provisions of this section shall have effect where a person (in this section referred to as an “authorised officer”) seizes a substance or article (other than a document) in the exercise of such a right as is specified in subsection (4) of section 112 of this Act (including that subsection as applied by subsection (7) of that section).

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (2) If any person who in accordance with subsection (6) of that section is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then, subject to the next following subsection, the authorised officer shall either—
- (a) set aside a sample of the substance or article seized, or
  - (b) treat that substance or article as a sample,
- whichever he considers more appropriate having regard to the nature of that substance or article.
- (3) An authorised officer shall not be required by virtue of subsection (2) of this section to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.
- (4) Where in accordance with subsection (2) of this section an authorised officer sets aside a sample, or treats a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one part of it to the person who made the request under subsection (2) of this section.
- (5) Paragraphs 10, 11 and 12 and paragraphs 15 to 27 of Schedule 3 to this Act shall have effect in relation to a sample set aside, or a substance or article treated as a sample, in accordance with subsection (2) of this section as they have effect in relation to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if in those paragraphs—
- (a) any reference to a sampling officer were a reference to an authorised officer;
  - (b) any reference to a sample included a reference to a substance or article treated as a sample;
  - (c) any reference to the preceding provisions of that Schedule were a reference to the preceding provisions of this section; and
  - (d) any reference to the relevant enforcement authority were a reference to the authority by whom the authorised officer is authorised for the purposes of section 112 of this Act,
- and as if in paragraph 24(1) of that Schedule the reference to a substance or article obtained as mentioned in paragraph 1 of that Schedule were a reference to a substance or article of which a sample has been set aside, or which has been treated as a sample, in accordance with subsection (2) of this section.

#### **Modifications etc. (not altering text)**

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C266** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C273** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C274** S. 113 modified by [S.I. 1985/273](#), **reg. 2, Sch. 1 Pt. I**
- C275** S. 113 modified (30.1.1992) by [S.I. 1992/32](#), **reg. 12(1)(2)**  
S. 113 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 113 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10, Sch. 4**  
S. 113 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch.5**  
S. 113 applied (1.2.2000) by [S.I. 2000/7](#), **reg. 5**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C276** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.

**C277** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**

Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**

## **114 Supplementary provisions as to rights of entry and related rights.**

- (1) Any person entering any property (that is to say, any premises, ship, aircraft, vehicle, stall or place) by virtue of section 111 of this Act (whether in pursuance of a warrant or not) may take with him such other persons and such equipment as may appear to him to be necessary; and on leaving any such property which he has entered in pursuance of a warrant under that section he shall, if the property is unoccupied or the occupier (or, in the case of a ship, aircraft, vehicle, stall or place, the master, commander or other person in charge of it) is temporarily absent, leave it as effectively secured against trespass as he found it.
- (2) Any person who—
  - (a) wilfully obstructs a person acting in pursuance of this Act and duly authorised so to act by an enforcement authority, or
  - (b) wilfully fails to comply with any requirement properly made to him by a person so acting under section 112 of this Act, or
  - (c) without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him for the purpose of the performance of his functions under this Act,shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [<sup>F251</sup>level 3 on the standard scale]
- (3) If any person, in giving any such information as is mentioned in subsection (2)(c) of this section, makes any statement which he knows to be false, he shall be guilty of an offence and shall be liable—
  - (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (4) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or (where that person is married) the husband or wife of that person.

### **Textual Amendments**

**F251** Words substituted by virtue of (E.W.) Criminal Justice Act 1982 (c. 48, SIF 39:1), **ss. 38, 46** and (S.) Criminal Procedure (Scotland) Act 1975 (c.21, SIF 39:1), **ss. 289F, 289G** and (N.I.) S.I. 1984/703 (N.I. 3), **arts. 5, 6**

### **Modifications etc. (not altering text)**

**C242** Ss. 107-116 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), **regs. 1, 47, Schs. 9**

**C266** Ss. 111-116 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), **regs. 1(a), 11, Schs. 4** (with Sch. 6)

**C278** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

**C279** S. 114 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**

S. 114 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- S. 114 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**  
 S. 114 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**  
 S. 114 applied (1.2.2000) by S.I. 2000/7, **reg. 5**  
**C280** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12.**  
**C281** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**  
 Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**

## 115 Analysis of samples in other cases.

- (1) A person who, not being a person authorised in that behalf by an enforcement authority, has purchased a medicinal product may submit a sample of it for analysis to the public analyst for the area in which the product was purchased, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area.
- (2) Paragraphs 2 to 13 of Schedule 3 to this Act shall have effect in relation to a person proposing to submit a sample in pursuance of the preceding subsection, as if in those paragraphs any reference to the sampling officer were a reference to that person.
- (3) Subject to the following provisions of this section, a public analyst to whom a sample is submitted under subsection (1) of this section shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.
- (4) If the public analyst to whom a sample is submitted under subsection (1) of this section determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and (subject to the next following subsection) that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.
- (5) A public analyst to whom a sample is submitted or sent under this section may demand payment in advance of the prescribed fee, and, if he demands such payment, he shall not be required to analyse the sample or cause it to be analysed until the fee has been paid.
- (6) A public analyst who has analysed a sample or caused a sample to be analysed under this section shall issue a certificate specifying the result of the analysis to the person by whom the sample was originally submitted.
- (7) Any certificate issued under subsection (6) of this section shall be in a form prescribed by the Ministers and shall be signed by the public analyst who issues the certificate.
- (8) Paragraphs 21 to 23 of Schedule 3 to this Act shall have effect in relation to a certificate issued under subsection (6) of this section as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.
- (9) Any regulations prescribing a fee for the purposes of this section shall be made by the Ministers.
- (10) In this section “public analyst” has the meaning assigned to it by paragraph 1(2) of Schedule 3 to this Act.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### **Modifications etc. (not altering text)**

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C266** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C282** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C283** S. 115 modified by [S.I. 1985/273](#), **reg. 2 Sch. 1 Pt. 1**  
S. 115 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 115 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10, Sch. 4**  
S. 115 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch.5**
- C284** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), **regs. 2(3), 3**  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), **reg. 11(c)**

#### **[<sup>F252</sup>115A] Facilities for microbiological examinations.**

A drugs authority or the council of a non-metropolitan district may provide facilities for microbiological examinations of drugs.]

#### **Textual Amendments**

- F252** S. 115A inserted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), **Sch. 3 para. 10**

#### **Modifications etc. (not altering text)**

- C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C266** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C285** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C286** S. 115A applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10, Sch. 4**

#### **116 Liability to forfeiture under Customs and Excise Act 1952.**

- (1) For the purposes of [<sup>F253</sup>section 49 of the Customs and Excise Management Act 1979] (forfeiture of goods improperly imported) any imported goods shall be deemed to be imported contrary to a restriction for the time being in force with respect to them under this Act if—
- they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and
  - they are imported in such circumstances as are specified in that order.
- (2) For the purposes of [<sup>F253</sup>section 68 of the Customs and Excise Management Act 1979] (offences in relation to exportation of prohibited or restricted goods) any goods shall be deemed to be exported contrary to a restriction for the time being in force with respect to them under this Act if—
- they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and
  - they are exported in such circumstances as are specified in that order.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) Any class of goods specified in an order under subsection (1) or subsection (2) of this section shall be so specified as to consist exclusively of goods appearing to the Ministers to be goods which are, or normally are, medicinal products or are, or normally are, animal feeding stuffs in which medicinal products have been incorporated.

#### Textual Amendments

**F253** Words substituted by [Customs and Excise Management Act 1979 \(c. 2, SIF 40:1\)](#), s. 177(1), **Sch. 4 para. 12** Table Pt. I

#### Modifications etc. (not altering text)

**C242** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**

**C266** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)

**C287** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

**C288** S. 116 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg.10, **Sch. 4**

### 117 Special enforcement and sampling provisions relating to animal feeding stuffs.

- (1) For the purposes of the application of the provisions of sections 112, 113 and 115 of this Act in relation to animal feeding stuffs, regulations made by the Agriculture Ministers may provide that any of those provisions specified in the regulations shall have effect subject to such modifications as may be so specified.
- (2) Regulations made by the Agriculture Ministers—
- (a) may make provision as to the manner in which samples may be taken by virtue of the provisions of section 112 of this Act as modified by any regulations made under the preceding subsection, as to the manner in which samples may be set aside, or substances or articles may be treated as samples, by virtue of the provisions of section 113 of this Act as so modified, or as to the manner in which samples may be submitted for analysis by virtue of the provisions of section 115 of this Act as so modified, and
  - (b) in relation to samples so taken, set aside or submitted for analysis, or substances or articles so treated as samples, may make provision (either in substitution for, or by way of modification of or addition to, any of the provisions of Schedule 3 to this Act) as to the manner in which such samples, substances and articles are to be dealt with.
- (3) For the purposes of proceedings for such offences under this Act relating to animal feeding stuffs as may be prescribed by regulations made under subsection (2) of this section, the regulations may—
- (a) prescribe a method of analysis to be used in analysing samples of animal feeding stuffs in order to determine what quantity or proportion (if any) of a substance or article of a description or class specified in the regulations has been incorporated in them, and
  - (b) provide that, on production in the proceedings of such evidence as may be so prescribed of the results of an analysis of a sample performed by the method



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

so prescribed, evidence of the results of any analysis of any part of the sample performed by any other method shall not be admissible in those proceedings.

- (4) In relation to the incorporation in animal feeding stuffs of substances or articles of any description or class specified in an order made under this subsection by the Agriculture Ministers, so much of any licence granted or animal test certificate issued under Part II of this Act as imposes any restriction or requirement by reference to the quantity to be incorporated, or the proportion in which any substance or article may be incorporated, in any animal feeding stuff shall not be taken to be contravened in any particular case if the discrepancy does not exceed such limit as may be specified by the order in relation to substances or articles of that description or class.
- (5) Where a label or mark on a container or package containing any animal feeding stuff, or a leaflet supplied or to be supplied with any animal feeding stuff, specifies a quantity or proportion of a medicinal product of a particular description as being incorporated in the animal feeding stuff, section 90(2) of this Act shall not be taken to be contravened by reason only that the quantity or proportion actually incorporated in the animal feeding stuff is greater than that so specified, if the discrepancy does not exceed such limit as the Agriculture Ministers may by order specify in relation to medicinal products of that description, or in relation to a class of medicinal products which includes medicinal products of that description.
- [<sup>F254</sup>(5A) The power conferred by subsection (1) of this section to provide for the purposes there mentioned that any of the provisions of section 115 of this Act shall have effect (with or without modifications) in relation to animal feeding stuffs includes power to provide in relation to animal feeding stuffs that, in place of all or any of those provisions, provisions specified in the regulations shall have effect, being provisions corresponding to any of those made by sections 75 and 78 of the <sup>M20</sup> Agriculture Act 1970.]
- (6) In section 114(2)(b) of this Act the reference to section 112 of this Act shall be construed as including a reference to the provisions of that section as modified by any regulations made under this section [<sup>F255</sup> and the reference in subsection (2) of this section to the provisions of section 115 of this Act as modified by any such regulations shall be construed as including a reference to any provisions specified in the regulations in place of any of the provisions of section 115 of this Act.]
- (7) The powers conferred by subsection (2) of this section shall be exercisable in addition to any power exercisable by virtue of paragraph 27 of Schedule 3 to this Act.
- [<sup>F256</sup>(8) References in subsections (1), (3) and (5A) of this section to animal feeding stuffs include a reference to any medicated feeding stuff, within the meaning of section 130(3A) of this Act.]

#### Textual Amendments

**F254** S. 117(5A) inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 15(1)

**F255** Words inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 15(2)

**F256** S.117(8) added by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, [Sch. 1 para. 3\(5\)](#)

#### Modifications etc. (not altering text)

**C289** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), art. 3(1)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### Marginal Citations

M20 1970 c.40 (2:1).

## 118 Restrictions on disclosure of information.

- (1) If any person discloses to any other person—
- (a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 111 of this Act, or
  - (b) any information obtained by or furnished to him in pursuance of this Act,
- he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

[<sup>F257</sup>(1A) Subsection (1) of this section does not apply if—

- (a) the person making the disclosure is, or is acting on behalf of a person who is, a public authority for the purposes of the Freedom of Information Act 2000, and
- (b) the information is not held by the authority on behalf of another person.]

(2) Any person guilty of an offence under this section shall be liable—

- (a) on summary conviction, to a fine not exceeding £400;
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

### Textual Amendments

**F257** S. 118(1A) inserted (1.1.2005) by [Freedom of Information \(Removal and Relaxation of Statutory Prohibitions on Disclosure of Information\) Order 2004 \(S.I. 2004/3363\)](#), arts. 1, 4

### Modifications etc. (not altering text)

**C290** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

**C291** S. 118 modified (3.4.1992) by [S.I. 1992/605](#), **regs. 2(3)**, 3

S. 118 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19**, **Sch. 4**

S. 118 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg. 10**, **Sch. 4**

**C292** S. 118 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**

**C293** S. 118 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)

## 119 Protection for officers of enforcement authorities.

- (1) An officer of an enforcement authority shall not be personally liable in respect of any act done by him in the execution or purported execution of this Act and within the scope of his employment if he did it in the honest belief that his duty under this Act required or entitled him to do it.
- (2) Where an action has been brought against an officer of an enforcement authority in respect of an act done by him in the execution or purported execution of this Act, and the circumstances are such that he is not legally entitled to require the enforcement authority to indemnify him, the authority may nevertheless indemnify him against the

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

whole or part of the damages and costs or expenses which he may have been ordered to pay or may have incurred, if they are satisfied that he honestly believed that his duty under this Act required or entitled him to do it.

- (3) In this section any reference to an officer of an enforcement authority shall be construed as including a reference to any person who, not being an officer of the authority, is authorised to act in pursuance of this Act by such an authority; and in relation to any such person any reference in this section to the scope of his employment shall be construed as a reference to the scope of the authorisation under which he acts.

**Modifications etc. (not altering text)**

- C294** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C295** S. 119 modified (3.4.1992) by [S.I. 1992/605, regs. 2\(3\), 3](#)
- C296** S. 119 modified (30.1.1992) by [S.I. 1992/32, reg. 12\(1\)\(2\)](#)
- C297** S. 119 applied (with modifications) (1.7.1992) by [S.I. 1992/1520, reg.12](#)  
S. 119 extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)  
S. 119 applied (3.10.1994) by [S.I. 1994/2328, reg. 11\(c\)](#)  
S. 119 applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)  
S. 119 applied (with modifications) (1.1.1995) by [S.I. 1994/3144, reg.10, Sch. 4](#)  
S. 119 applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)  
S. 119 applied (1.2.2000) by [S.I. 2000/7, reg. 5](#)
- C298** S. 119 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\), regs. 1, 47, Schs. 9](#)
- C299** S. 119 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\), regs. 1\(a\), 11, Schs. 4 \(with Sch. 6\)](#)

<sup>F258</sup> **120 Compensation for loss of employment or loss or diminution of emoluments.**

.....

**Textual Amendments**

- F258** S. 120 repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\), Sch. 1 Pt. 17](#) Group 7

**Modifications etc. (not altering text)**

- C300** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

**121 Contravention due to default of other person.**

- (1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Act, and is due to an act or default of another person, then, whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence, and shall be liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had been convicted of the offence.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (2) Where a person who is charged with an offence under this Act in respect of a contravention of a provision to which this section applies proves to the satisfaction of the court—
- (a) that he exercised all due diligence to secure that the provision in question would not be contravened, and
  - (b) that the contravention was due to the act or default of another person,
- the first-mentioned person shall, subject to the next following subsection, be acquitted of the offence.
- (3) A person shall not, without the leave of the court, be entitled to rely on the defence provided by subsection (2) of this section unless, not later than seven clear days before the date of the hearing, he has served on the prosecutor a notice in writing giving such information identifying, or assisting in the identification of, the other person in question as was then in his possession.
- (4) This section applies to the following provisions, that is to say, sections 63 to 65, 85 to 90, and 93 to 96, and the provisions of any regulations made under any of those sections.

**Modifications etc. (not altering text)**

- C301** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C302** S. 121 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), [Sch. 4](#)  
S. 121 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
S. 121 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 121 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)  
S. 121 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)
- C303** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [regs. 1, 47](#), [Schs. 9](#)
- C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with [Sch. 6](#))

**122 Warranty as defence.**

- (1) Subject to the following provisions of this section, in any proceedings for an offence under this Act in respect of a contravention of a provision to which this section applies, it shall be a defence for the defendant to prove—
- (a) that he purchased the substance or article to which the contravention relates in the United Kingdom as being a substance or article which could be lawfully sold, supplied, or offered or exposed for sale, or could be lawfully sold, supplied, or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty to that effect;
  - (b) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and
  - (c) that the substance or article was then in the same state as when he purchased it.
- (2) This section applies to the following provisions, that is to say, section 63(b), sections 64 and 65, sections 85 to 88 and section 90 and the provisions of any regulations made under any of those sections.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than three clear days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it, and has also sent a like notice to that person.
- (4) Where the defendant is a servant of the person who purchased the substance or article under the warranty, he shall be entitled to rely on the provisions of this section in the same way as his employer would have been entitled to do if he had been the defendant.
- (5) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing and to give evidence, and the court may, if it thinks fit, adjourn the hearing to enable him to do so.
- (6) For the purposes of this section a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description by any person without contravening any provision to which this section applies.
- (7) In the application of this and the next following section to Scotland, any reference to the defendant shall be construed as a reference to the accused.

#### **Modifications etc. (not altering text)**

- C303** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C305** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- S. 122 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.
- S. 122 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19**, **Sch.4**
- S. 122 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**
- S. 122 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10**, **Sch. 4**
- S. 122 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34**, **Sch.5**

### **123 Offences in relation to warranties and certificates of analysis.**

- (1) If a defendant in any such proceedings as are mentioned in section 122(1) of this Act wilfully applies to any substance or article—
  - (a) a warranty given in relation to a different substance or article, or
  - (b) a certificate issued under section 115 of this Act, or under paragraph 19 of Schedule 3 to this Act, which relates to a sample of a different substance or article,he shall be guilty of an offence.
- (2) A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 122 of this Act, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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) Where the defendant in any such proceedings as are mentioned in section 122(1) of this Act relies successfully on a warranty given to him or to his employer, any proceedings for an offence under subsection (2) of this section in respect of the warranty may, at the option of the prosecutor, be taken either before a court having jurisdiction in the place where a sample of the substance or article to which the warranty relates was procured, or before a court having jurisdiction in the place where the warranty was given.
- (4) Any person guilty of an offence under this section shall be liable—
- (a) on summary conviction, to a fine not exceeding £400;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

**Modifications etc. (not altering text)**

- C303** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C306** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C307** S. 123 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 123 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10, Sch. 4**  
S. 123 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch.5**

**124 Offences by bodies corporate.**

- (1) Where an offence under this Act which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.
- (2) In relation to a body corporate carrying on a retail pharmacy business as mentioned in subsection (1) of section 71 of this Act, the preceding subsection shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in the preceding subsection)—
- (a) is the superintendent referred to in subsection (1) of that section, or
  - (b) at any premises where the business is carried on, is the pharmacist referred to in subsection (1)(a) of that section who acts under the directions of the superintendent,
- as if he were such an officer of the body corporate as is mentioned in the preceding subsection.
- (3) In this section “director”, in relation to a body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### **Modifications etc. (not altering text)**

- C303** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C308** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C309** S. 124 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19, Sch. 4**  
S. 124 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 124 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg. 10, Sch. 4**  
S. 124 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch. 5**
- C310** S. 124(1)(3) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.

## **125 Prosecutions.**

- (1) Notwithstanding anything in [<sup>F259</sup>section 127(1) of the Magistrates' Courts Act 1980], a magistrates' court in England or Wales may try an information for an offence under this Act if the information was laid at any time within twelve months from the commission of the offence.
- (2) Notwithstanding anything in [<sup>F260</sup>section 331 of the <sup>M21</sup>Criminal Procedure (Scotland) Act 1975] (limitation of time for proceedings in statutory offences) summary proceedings in Scotland for an offence under this Act may be commenced at any time within twelve months from the time when the offence was committed, and [<sup>F260</sup>subsection 3 of the said section 331] shall apply for the purposes of this subsection as it applies for the purposes of that section.
- (3) Notwithstanding anything in [<sup>F261</sup>section 34 of the <sup>M22</sup>Magistrates' Courts Act (Northern Ireland) 1964][<sup>F261</sup>Article 19(1) of the Magistrates' Courts (Northern Ireland) Order 1981], a magistrates' court in Northern Ireland may hear and determine a complaint for an offence [<sup>F262</sup>punishable under this Act upon summary conviction other than an offence which is also triable upon indictment] if the complaint was made at any time within twelve months from the commission of the offence.
- (4) Neither the Pharmaceutical Society nor any other body referred to in subsection (2) or subsection (8) of section 108 of this Act shall institute proceedings for an offence under this Act in respect of a contravention of a provision which, by virtue of either of those subsections, that Society or body have a power or duty to enforce, unless they have given to the appropriate Minister not less than twenty-eight days' notice of their intention to institute proceedings, together with a summary of the facts upon which the charges are founded.
- (5) For the purposes of subsection (4) of this section the appropriate Minister, in relation to a contravention of any provision, is the Minister who in accordance with section 108 of this Act has a concurrent duty to enforce that provision.
- (6) [<sup>F263</sup>A district council] (as defined by section 110 of this Act) shall not prosecute for an offence under this Act in respect of a contravention of any provision which, by virtue of subsection (2) of that section, the authority have a power or duty to enforce, unless the authority have given to the Minister of Health and Social Services for Northern Ireland not less than twenty-eight days' notice of their intention to begin the prosecution, together with a summary of the facts upon which the charges are founded.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (7) A certificate of the Minister who is the appropriate Minister for the purposes of subsection (4) of this section that the requirements of that subsection have been complied with in relation to any proceedings, and a certificate of the Minister of Health and Social Services for Northern Ireland that the requirements of subsection (6) of this section have been complied with in relation to any prosecution, shall be conclusive evidence that those requirements have been so complied with; and any document purporting to be such a certificate and to be signed by or on behalf of that Minister shall be presumed to be such a certificate unless the contrary is proved.

#### Textual Amendments

- F259** Words substituted by [Magistrates' Courts Act 1980 \(c. 43, SIF 82\)](#), s. 154, [Sch. 7 para. 76](#)  
**F260** Words substituted by virtue of [Criminal Procedure \(Scotland\) Act 1975 \(c. 21\)](#), s. 460(1)(b)  
**F261** Words substituted(N.I.) by [S.I. 1981/1675 \(N.I. 26\)](#), [Sch. 6 Pt. I para. 15](#)  
**F262** Words substituted by [S.I. 1980/704](#), [Sch. 1 Pt. II para. 50](#)  
**F263** Words substituted by [S.R. &O. \(N.I.\) 1973 No. 211](#), [Sch.](#)

#### Modifications etc. (not altering text)

- C303** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)  
**C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, [Schs. 4](#) (with [Sch. 6](#))  
**C311** Pt. VIII (ss. 104–136) extended by [S.I.s 1982/425](#), art. 3, [1984/187](#) art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)  
**C312** S. 125 modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\)](#), 3  
 S. 125 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
 S. 125 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg.10](#), [Sch. 4](#)  
 S. 125 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)

#### Marginal Citations

- M21** [1975 c. 21](#).  
**M22** [1964 c. 21 \(N.I.\)](#)

## 126 Presumptions.

- (1) For the purposes of any proceedings under this Act for an offence consisting of—
- offering any animal feeding stuff for sale in contravention of section [<sup>F264</sup>40] of this Act, or
  - offering a medicinal product for sale by retail in contravention of section 52 or section 53 of this Act, or
  - offering a medicinal product for sale in contravention of section 63(b) of this Act,

where it is proved that the animal feeding stuff or medicinal product in question was found on a vehicle from which animal feeding stuffs or medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that animal feeding stuff or medicinal product for sale and, in a case falling within paragraph (b) of this subsection, that he offered it for sale by retail.

- (2) For the purposes of any proceedings under this Act for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person's having any medicinal product or animal feeding stuff in his possession



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

for the purpose of sale or supply, where it is proved that the medicinal product or animal feeding stuff in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had that medicinal product or animal feeding stuff in his possession for the purpose of sale or supply.

- (3) Subsection (2) of this section applies to the following provisions of this Act, that is to say, section 63(b), subsections (3) and (5) of section 85, subsection (2) of section 87 and subsection (3) of section 88, to any of those provisions as applied by subsection (1) of section 90, and to subsection (2) of section 90 except in so far as it relates to leaflets.
- (4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of subsection (2) or subsection (3) of section 86 of this Act, or of so much of subsection (2) of section 90 of this Act as relates to leaflets, where it is proved that the leaflet in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had the leaflet in his possession—
- (a) where the offence charged relates to section 86 of this Act, for the purpose of supplying it with a medicinal product, or
  - (b) where the offence charged relates to section 90 of this Act, for the purpose of supplying it with animal feeding stuff in which a medicinal product has been incorporated.

#### Textual Amendments

**F264** Words substituted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, **Sch. 1 para. 3(6)**

#### Modifications etc. (not altering text)

**C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)

**C313** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

**C314** S. 126 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch. 4**

S. 126 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**

S. 126 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg. 10, **Sch. 4**

S. 126 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**

**C315** S. 126(4) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.

## 127 Service of documents.

Any notice or other document required or authorised by any provision of this Act to be served on any person, or to be given or sent to any person, may be served, given or sent—

- (a) by delivering it to him; or
- (b) by sending it by post to him at his usual or last-known residence or place of business in the United Kingdom; or

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office.

**Modifications etc. (not altering text)**

- C304** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C316** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C317** S. 127 applied by [S.I. 1986/1180](#), **art. 2(2)** and [S.I. 1984/673](#), **art. 2(2)**
- C318** S. 127 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch. S. 127 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), **reg. 19**, **Sch.4**  
S. 127 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 127 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10**, **Sch. 4**  
S. 127 applied (8.12.1995) by [S.I. 1995/2808](#), **art. 2(2)**  
S. 127 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34**, **Sch.5**
- C319** S. 127 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**

**128 Financial provisions.**

- (1) Any expenses incurred in consequence of this Act by any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, other than expenses so incurred exclusively in respect of executing this Act in Northern Ireland, shall be defrayed out of moneys provided by Parliament.
- (2) There shall be defrayed out of moneys provided by Parliament any increase attributable to the provisions of this Act in—
- (a) the sums payable out of moneys so provided in respect of rate support grants to local authorities in England and Wales which may arise from the inclusion, in the expenditure relevant to the fixing of the aggregate amount of those grants, of expenditure under this Act, or
- (b) the sums payable out of moneys so provided under any enactment relating to local government in Scotland.
- (3) ..... <sup>F265</sup>
- (4) Where the Pharmaceutical Society or any other body enforces any provision of this Act or of any regulations or order made thereunder in the performance of a duty imposed, or the exercise of a power conferred, under section 108(2) or section 110(2) of this Act, the Minister who has a concurrent duty to enforce that provision shall pay to the Society or other body such charges as they may reasonably require to be paid in respect of expenses incurred by them in the enforcement of that provision.
- (5) Where under subsection (10) of section 108 of this Act (or under that subsection as modified in relation to Northern Ireland by section 110(5) of this Act) a Minister makes a determination in respect of the enforcement of any provision in relation to a particular matter, he shall be entitled to recover from the Pharmaceutical Society or other body who were under a duty to enforce that provision in relation to that matter any expenses reasonably incurred by that Minister in taking steps to enforce that provision in relation to that matter.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (6) Any fees and other sums received by virtue of this Act by any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, other than Ministers in the Government of Northern Ireland, shall be paid into the Exchequer.
- (7) Such sums paid out of the Exchequer of the United Kingdom in connection with the execution of this Act as may be determined by the Joint Exchequer Board to be properly payable by the Government of Northern Ireland shall be made good by means of deductions from the Northern Ireland residuary share of reserved taxes.

#### Textual Amendments

**F265** S. 128(3) repealed by [Medicines Act 1971 \(c. 69\), s. 1\(4\)](#)

#### Modifications etc. (not altering text)

**C320** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

**C321** S. 128 applied (with modifications) (3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.

**C322** S. 128(1)(6)(7) extended by [Medicines Act 1971 \(c. 69\), s. 1\(3\)\(a\)](#)

## 129 Orders and regulations.

- (1) The Ministers may make regulations for any purpose for which regulations are authorised or required to be made under this Act, other than any purpose for which any provision of this Act authorises or requires regulations to be made otherwise than by the Ministers.
- (2) Any power to make orders or regulations under this Act (other than any order made by a court or judge or any order or regulations made in relation to Northern Ireland under paragraph 1, paragraph 5 or paragraph 6 of Schedule 4 to this Act or any regulations made solely by the Minister of Health and Social Services for Northern Ireland under section 120 of this Act) shall be exercisable by statutory instrument.
- (3) Any statutory instrument consisting of—
  - (a) an order made under any of the following provisions of this Act, that is to say, sections 13, 15(1), 35(2)(b), 49, 54(2), 55(2), 56, 57(1), 58, 62, 79, 106, 116, 117 and 130(5)(c) and paragraph 27 of Schedule 3, or
  - (b) an order made under section 105 of this Act otherwise than as mentioned in subsection (3) of that section, or
  - (c) any regulations made under any provision, other than section 79, of this Act, shall be subject to annulment in pursuance of a resolution of either House of Parliament.
- (4) Any power to make an order under any provision, other than sections 16(1), 17, 25(1), 37(3), 52 and 69(3), of this Act shall include power to revoke or vary the order by a subsequent order made under that provision.
- (5) Any power to make regulations under this Act may be exercised so as to make different provision for different areas or in relation to different cases or different circumstances to which the power is applicable, and to make any such provision subject to such exceptions, limitations and conditions (if any) as the authority making the regulations considers necessary or expedient.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (6) Before making any regulations under this Act and before making any order under this Act (except an order made in accordance with any provision of this Act under which, in case of urgency, an order can be made with immediate effect) the Ministers proposing to make the regulations or order shall consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order.
- [<sup>F266</sup>(6A) The organisations to be consulted under subsection (6) of this section include, where any provisions of the regulations or order apply to veterinary products as defined in section 29(2) of the Food Standards Act 1999, the Food Standards Agency.]
- (7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III, Part V or Part VI of this Act, or under section 104 or section 105 of this Act, and they consult a committee established under section 4 of this Act, or the Commission, with respect to that proposal, they shall take the advice of the committee or of the Commission into account before proceeding with those proposals.

#### Textual Amendments

**F266** S. 129(6A) inserted (1.4.2000) by 1999 c. 28, s. 18, **Sch. 3 Pt. III**, para. 15(3); S.I. 2000/1066, **art. 2**

#### Modifications etc. (not altering text)

**C323** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

**C324** S. 129 modified (1.1.1995) by S.I. 1994/3144, **reg. 9(10)**  
S. 129 applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch. 5**

**C325** S. 129 applied (with modifications) (1.5.2004) by **Medicines for Human Use (Clinical Trials) Regulations 2004** (S.I. 2004/1031), **regs. 1, 47, Schs. 9**

**C326** S. 129 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)**

**C327** S. 129(1)(2)(3)(5) applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2), Sch.**

**C328** S. 129(2)(3)(c)(5)(6) extended by **Medicines Act 1971** (c. 69), **s. 1(3)(b)**

### 130 Meaning of “medicinal product” and related expressions.

- (1) Subject to the following provisions of this section, in this Act “medicinal product” means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say—
- use by being administered to one or more human beings or animals for a medicinal purpose;
  - use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.
- (2) In this Act “a medicinal purpose” means any one or more of the following purposes, that is to say—
- treating or preventing disease;
  - diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (c) contraception;
  - (d) inducing anaesthesia;
  - (e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.
- (3) In paragraph (b) of subsection (1) of this section the reference to use in circumstances to which that paragraph applies is a reference to any one or more of the following, that is to say—
- (a) use in a pharmacy or in a hospital;
  - (b) use by a practitioner;
  - (c) use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies.
- [<sup>F267</sup>(3A) An order made by the Agriculture Ministers may provide that, for the purposes of this Act, any specified description or class of medicated feeding stuff—
- (a) is to be treated as a medicinal product (subject to the following provisions of this section), or
  - (b) is not to be so treated (notwithstanding anything in subsection (1) of this section).
- (3B) In subsection (3A) of this section, “ medicated feeding stuff ” means any substance which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say—
- (a) use by being fed to one or more animals for a medicinal purpose or for purposes that include that purpose, or
  - (b) use as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose.
- (3C) No order shall be made under subsection (3A) of this section unless a draft of the order has been laid before Parliament and approved by resolution of each House of Parliament.]
- (4) Notwithstanding anything in subsection (1) [<sup>F268</sup>or (3A)] of this section, in this Act “medicinal product” does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, where it is to be administered to them—
- (a) in the course of the business of the person who has manufactured it (in this subsection referred to as “the manufacturer”), or on behalf of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person, and
  - (b) solely by way of a test for ascertaining what effects it has when so administered, and
  - (c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous in relation to, those animals, as the case may be,
- and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in paragraphs (a) to (c) of this subsection.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (5) In this Act “medicinal product” shall also be taken not to include—
- (a) substances used in dental surgery for filling dental cavities;
  - (b) bandages and other surgical dressings, except medicated dressings [<sup>F269</sup> within subsection (5A) below];
  - [<sup>F270</sup>(ba) whole human blood and human blood components;]
  - (c) substances and articles of such other descriptions or classes as may be specified by an order made by the Ministers, the Health Ministers or the Agriculture Ministers for the purposes of this subsection.
- [<sup>F271</sup>(5A) Medicated dressings are within this subsection (and accordingly are not excluded from the definition of “medicinal product” by subsection (5)(b) above) if—
- (a) their medication has a curative function which is not limited to sterilising the dressing; and
  - (b) they are not dressings of a kind to which the requirements of Article 2 of Council Directive 93/42/ EEC<sup>F272</sup> (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.]
- [<sup>F273</sup>(5B) For the purposes of this section, “human blood component” means any of the following constituents of human blood: red cells, white cells, platelets and plasma.]
- (6) Where in accordance with the preceding provisions of this section a substance or article is a medicinal product immediately after it has been manufactured, imported or exported as mentioned in subsection (1) [<sup>F274</sup> or (3B) ] of this section, or immediately after the first occasion on which it has been sold or supplied as mentioned in [<sup>F275</sup> the relevant ] subsection, then . . . <sup>F276</sup> it shall not cease to be a medicinal product for the purposes of this Act by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in a way other than those specified in [<sup>F277</sup> the relevant subsection ] .
- (7) . . . . . <sup>F278</sup>
- (8) For the purposes of this Act medicinal products are of the same description if (but only if)—
- (a) they are manufactured to the same specification, and
  - (b) they are, or are to be, sold, supplied, imported or exported in the same pharmaceutical form,
- and in this Act “ description ”, in relation to medicinal products, shall be construed accordingly.
- (9) In this Act “ administer ” means administer to a human being or an animal, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not; and any reference in this Act to administering [<sup>F279</sup> (or feeding) ] a substance or article is a reference to administering [<sup>F279</sup> (or feeding) ] it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle.
- (10) For the purposes of this Act a document, advertisement or representation shall be taken to be likely to mislead as to the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters, that is to say—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) any purposes for which medicinal products of that description can with reasonable safety be used;
- (b) any purposes for which such products cannot be so used; and
- (c) any effects which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

#### Textual Amendments

- F267** S. 130(3A)–(3C) inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 13(2)
- F268** Words inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(7\)](#)
- F269** Words in s. 130(5)(b) substituted (1.1.1995) by [S.I. 1994/3119](#) , [reg. 2\(a\)](#)
- F270** S. 130(5)(ba) inserted (8.11.2005) by [The Blood Safety and Quality Regulations 2005 \(S.I. 2005/50\)](#) , [regs. 1\(2\)](#) , [25\(1\)\(c\)](#) (with [reg. 2\(2\)-\(4\)](#) )
- F271** S. 130(5A) inserted (1.1.1995) by [S.I. 1994/ 3119](#) , [reg. 2\(b\)](#)
- F272** O.J. No. L 169 12.7.93 p.1.
- F273** S. 130(5B) inserted (8.11.2005) by [The Blood Safety and Quality Regulations 2005 \(S.I. 2005/50\)](#) , [regs. 1\(2\)](#) , [25\(1\)\(d\)](#) (with [reg. 2\(2\)-\(4\)](#))
- F274** Words inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(8\)](#) ( a )
- F275** Words substituted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(8\)](#) ( b )
- F276** Words repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(8\)\(c\)](#) , [Sch. 2](#)
- F277** Words substituted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(8\)](#) ( d )
- F278** S. 130(7) repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(9\)](#) , [Sch. 2](#)
- F279** Words inserted by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#) , s. 16 , [Sch. 1 para. 3\(10\)](#)

#### Modifications etc. (not altering text)

- C329** Pt. VIII (ss. 104–136) extended by [S.I.s 1982/425](#) , [art. 3](#) , [1984/187 art. 2](#); and extended with modifications by [S.I. 1985/403](#) , [art. 3\(1\)](#)

### 131 Meaning of “wholesale dealing”, “retail sale” and related expressions.

- (1) In this Act any reference to selling anything by way of wholesale dealing is a reference to selling it to a person as being a person who buys it for one or more of the purposes specified in subsection (2) of this section, except that it does not include any such sale by the person who manufactured it.
- (2) The purposes referred to in the preceding subsection, in relation to a person to whom anything is sold, are the purposes of—
  - (a) selling or supplying it, or
  - (b) administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person.
- (3) In this Act any reference to selling by retail, or to retail sale, is a reference to selling a substance or article to a person as being a person who buys it otherwise than for a purpose specified in subsection (2) of this section.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) In this Act any reference to supplying anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of—
- (a) selling or supplying it, or
  - (b) administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person.
- (5) For the purposes of this section the provision of services by or on behalf of the Minister of Health, the Secretary of State or the Ministry of Health and Social Services for Northern Ireland under the [<sup>F280M23</sup>National Health Service Act 1977], the National Health Service (Scotland) [<sup>F281M24</sup>Act 1978] or the [<sup>F282M25</sup>Health and Personal Social Services (Northern Ireland) Order 1972] shall be treated as the carrying on of a business by that Minister, the Secretary of State or that Ministry, as the case may be.

#### Textual Amendments

**F280** Words substituted by [National Health Service Act 1977 \(c. 49\), Sch. 15 para. 49](#)

**F281** Words substituted by [National Health Service \(Scotland\) Act 1978 \(c. 29\), Sch. 16 para. 30](#)

**F282** Words substituted by [National Health Service Reorganisation Act 1973 \(c. 32\), Sch. 4 para. 128\(2\)](#)

#### Modifications etc. (not altering text)

**C330** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

**C331** S. 131 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\), regs. 1, 47, Schs. 9](#)

#### Marginal Citations

**M23** 1977 c. 49.

**M24** 1978 c. 29.

**M25** S.I. 1972 No. 1265.

## 132 General interpretation provisions.

- (1) In this Act, except in so far as the context otherwise requires, the following expressions have the meanings hereby assigned to them respectively, that is to say:—

[<sup>F283</sup>“Advisory Body” has the meaning given to it by paragraph 1 of Schedule 1A to this Act;]

“analysis” includes micro-biological assay but no other form of biological assay, and “analyse” has a corresponding meaning;

“animal” includes any bird, fish or reptile;

[<sup>F284</sup> “ animal feeding stuff ” means any substance which is intended for use either by being fed to one or more animals or as an ingredient in the preparation of such a substance, not being in either case a medicinal product. ]

“animal test certificate” has the meaning assigned to it by section 32 of this Act;

“the appropriate committee” has the meaning assigned to it by section 4(6) of this Act;

“the appropriate Ministers” shall be construed in accordance with section 1(2) of this Act;



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

“assemble”, in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and “assembly” has a corresponding meaning;

“business” includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate;

F285

...  
[<sup>F286</sup>“the Clinical Trials Regulations” means the Medicines for Human Use (Clinical Trials) Regulations 2004;]

“the Commission” means the [<sup>F287</sup>Commission for Human Medicines] established under this Act;

“composition”, in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degrees of strength, quality and purity, in which those ingredients are contained in it respectively;

“container”, in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

“contravention” includes failure to comply and “contravene” has a corresponding meaning;

“dentist” means a person registered in the dentists register under the [<sup>F288</sup>Dentists Act 1984 or entered in the list of visiting [<sup>F289</sup>EEA practitioners] under Schedule 4 to that Act;]

F290

...  
“the 1981 Directive” means Council Directive [81/851/EEC](#) of 28th September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (as amended by Council Directive [90/676/EEC](#));

[<sup>F291</sup>“the 2001 Directive” means Directive [2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use ] [<sup>F292</sup>, as amended ] [<sup>F293</sup>by—

- (a) Directive [2002/98/EC](#) of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components,
- (b) Commission Directive [2003/63/EC](#) amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use,
- (c) Directive [2004/24/EC](#) of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use; and
- (d) Directive [2004/27/EC](#) of the European Parliament and of the Council amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use;]

“disease” includes any injury, ailment or adverse condition, whether of body or mind;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

[<sup>F294</sup> “ doctor ” means a registered medical practitioner person within the meaning of Schedule 1 to the Interpretation Act 1978 ]

[<sup>F295</sup> “ drugs authority ” has the meaning assigned to it by section 108(12) of this Act; ]

[<sup>F296</sup> “ EEA State ” means a Member State, Norway, Iceland or Liechtenstein; and]

“enforcement authority” means any Minister or body on whom a duty or power to enforce any provisions of this Act or of any regulations or order made thereunder is imposed or conferred by or under sections 108 to 110 of this Act;

[<sup>F297</sup> “ Expert Advisory Group ” means an Expert Advisory Group established under paragraph 3 or 4 of Schedule 1A to this Act;]

“export” means export from the United Kingdom, whether by land, sea or air, and “import” has a corresponding meaning;

“the first appointed day” has the meaning assigned to it by section 16(1) of this Act;

[<sup>F298</sup> “ food and drugs authority ” has the meaning assigned to it for the purposes of the <sup>M26</sup> Food and Drugs Act 1955 by [<sup>F299</sup> section 198 of the <sup>M27</sup> Local Government Act 1972 ] ; ]

“the Gazette” means the London, Edinburgh and Belfast Gazettes;

“health centre” means a health centre maintained under [<sup>F300</sup> section 2 or 3 of the <sup>M28</sup> National Health Service Act 1977] [<sup>F301</sup> section 36 of the <sup>M29</sup> National Health Service (Scotland) Act 1978] or [<sup>F302</sup> Article 5 of the <sup>M30</sup> Health and Personal Social Services (Northern Ireland) Order 1972];

[<sup>F303</sup> “ the Herbal Regulations ” means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;]

“herbal remedy” means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance;

“herd” includes a flock;

[<sup>F304</sup> “ the Homoeopathic Regulations ” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994]

“hospital” includes a clinic, nursing home or similar institution;

“hover vehicle” means a vehicle designed to be supported on a cushion of air;

[<sup>F296</sup> “ import from a third country ” means import from any country other than an EEA State; and]

“ingredient”, in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared;

“labelling”, in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and “label” has a corresponding meaning;

“leaflet” includes any written information;

“the licensing authority” has the meaning assigned to it by section 6 of this Act;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

“licence of right” has the meaning assigned to it by section 25(4) of this Act;

“manufacture”, in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it and does not include the incorporation of the product in any animal feeding stuff;

[<sup>F305</sup>“the Marketing Authorisation Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;]

“medicinal test on animals” has the meaning assigned to it by section 32 of this Act;

“offence under this Act” includes an offence under any regulations or order made under this Act;

“package”, in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question;

“Pharmaceutical Society” in relation to Great Britain means the Pharmaceutical Society of Great Britain, and in relation to Northern Ireland means the Pharmaceutical Society of Northern Ireland;

“pharmacist” in relation to Great Britain means a person registered in the register of pharmaceutical chemists established in pursuance of the <sup>M31</sup>Pharmacy Act 1852 and maintained in pursuance of section 2(1) of the <sup>M32</sup>Pharmacy Act 1954, and in relation to Northern Ireland (subject to any order made under paragraph 1 of Schedule 4 to this Act) means a person registered in the register of pharmaceutical chemists for Northern Ireland made out and maintained under [<sup>F306</sup>Articles 6 and 9 of the <sup>M33</sup>Pharmacy (Northern Ireland) Order 1976];

“plant” includes any part of a plant;

“poultry” means domestic fowls, turkeys, geese, ducks, guinea-fowls, pigeons, pheasants and partridges;

“practitioner” (except where that word occurs as part of the expression “veterinary practitioner”) means a doctor, dentist, veterinary surgeon or veterinary practitioner;

“prescribed” means prescribed by regulations under this Act;

“product licence”, “manufacturer’s licence” and “wholesale dealer’s licence” have the meanings assigned to them by sections 7 and 8 of this Act;

“registered pharmacy” has the meaning assigned to it by section 74 of this Act;

“retail pharmacy business” means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not);

“substance” means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour;

“the time allowed”, in Part II of, and Schedule 2 to, this Act has the meaning assigned to it by [<sup>F307</sup>section 21(12)] of this Act;

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

“treatment”, in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not;

“veterinary drug” means a medicinal product which is manufactured, sold, supplied, imported or exported for the purpose of being administered to animals, but not for the purpose of being administered to human beings;

“veterinary practitioner” means a person registered in the supplementary veterinary register kept under section 8 of the <sup>M34</sup>Veterinary Surgeons Act 1966;

“veterinary surgeon” means a person registered in the register of veterinary surgeons kept under section 2 of the <sup>M35</sup>Veterinary Surgeons Act 1966;

“writing” includes any form of notation, whether by hand or by printing, typewriting or any similar process, and “written” has a corresponding meaning.

- (2) For the purposes of this Act considerations of safety, in relation to any substance or article, shall be taken to include consideration of the extent (if any) to which the substance or article—
- (a) if used without proper safeguards, is capable of causing danger to the health of the community, or of causing danger to the health of animals generally or of one or more species of animals, or
  - (b) if administered to an animal, may be harmful to the animal or may induce disease in other animals or may leave a residue in the carcase or produce of the animal which may be harmful to human beings, or
  - (c) may interfere with the treatment, prevention or diagnosis of disease, or
  - (d) may be harmful to the person administering it or (in the case of an instrument, apparatus or appliance) the person operating it,
- and any reference in this Act to safety or to the interests of safety shall be construed accordingly.
- (3) In this Act any reference to doing anything in accordance with a licence under Part II of this Act shall be construed as a reference to doing it in pursuance of such a licence and in compliance with any conditions and any limitations (whether as to area or otherwise) to which the licence is subject, and so as not to fall within any exceptions to which it is subject, and any reference to doing anything in accordance with <sup>F308</sup>... an animal test certificate shall be construed in a corresponding way.
- (4) Any reference in this Act to the holder of a licence or certificate shall be construed as a reference to the holder of a licence or certificate which is for the time being in force.
- (5) For the purposes of this Act medicinal products of any description shall be taken to be effectively on the market in the United Kingdom at a particular time if (but only if) during the whole of the period of one month ending with that time adequate stocks of medicinal products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in the United Kingdom as were likely to require them.
- (6) Except in so far as the context otherwise requires, any reference in this Act to an enactment shall be construed as a reference to that enactment as amended or extended by or under any other enactment, including this Act.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### Textual Amendments

- F283** Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(a)**
- F284** Definition inserted by Animal Health and Welfare Act 1984 (c. 40, SIF 2:8), **s. 13(3)**
- F285** Words in s. 132(1) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(i)**
- F286** Words in s. 132(1) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(ii)**
- F287** Words in s. 132(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(b)**
- F288** Words substituted by virtue of Dentists Act 1984 (c. 24, SIF 83:1), s. 54(1), **Sch. 5 para. 2**
- F289** Words in definition in s. 132(1) substituted (1.7.1996) by S.I. 1996/1496, **reg. 7(a)**
- F290** S. 132: definition of “the 1965 Directive” deleted (28.2.2002) by virtue of S.I. 2002/236, **reg. 2(d)(i)**
- F291** S. 132: definition of “the 2001 Directive” inserted (28.2.2002) by S.I. 2002/236, **reg. 2(d)(ii)**
- F292** Words in s. 132(1) inserted (31.10.2003) by Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003 (S.I. 2003/2321), regs. 1(2)(b), **2**
- F293** Words in s. 132 inserted (30.10.2005) by The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/2789), reg. 1(1), **Sch. 5 para. 10(a)** (with Sch. 6)
- F294** Definition substituted by Medical Act 1983 (c. 54, SIF 83:1), **Sch. 5 para. 5**
- F295** Words inserted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 11**
- F296** Words in s. 132 inserted (30.10.2005) by The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (S.I. 2005/2789), reg. 1(1), **Sch. 5 para. 10(b)** (with Sch. 6)
- F297** Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(c)**
- F298** Definition repealed (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1)(4), Sch. 3 para. 11, **Sch. 5**
- F299** Words substituted by Local Government Act 1972 (c. 70), **s. 198(2)**
- F300** Words substituted by National Health Service Act 1977 (c. 49), **Sch. 15 para. 50**
- F301** Words substituted by National Health Service (Scotland) Act 1978 (c. 29), **Sch. 16 para. 31**
- F302** Words substituted by National Health Service Reorganisation Act 1973 (c. 32), **Sch. 4 para. 128(3)**
- F303** Words in s. 132 inserted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 3**
- F304** Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(d)**
- F305** Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(e)**
- F306** Words substituted by S.I. 1976/1213 (N.I. 22), **Sch. 5 para. 7**
- F307** Words in s. 132(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(f)**
- F308** Words in s. 132(3) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(ii)**

### Modifications etc. (not altering text)

- C332** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**
- C333** S. 132 extended (3.4.1992) by S.I. 1992/605, **regs. 2(4), 3**  
S. 132 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
S. 132 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch. 5**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**C334** S. 132(1) applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)

#### Marginal Citations

**M26** 1955 c. 16 (4 & 5 Eliz. 2).  
**M27** 1972 c. 70.  
**M28** 1977 c. 49.  
**M29** 1978 c. 29.  
**M30** S.I. 1972 No. 1265.  
**M31** 1852 c. 56.  
**M32** 1954 c. 61.  
**M33** S.I. 1976/1213 (N.I. 22)  
**M34** 1966 c. 36.  
**M35** 1966 c. 36.

### 133 General provisions as to operation of Act.

- (1) The provisions of this Act, and of any regulations or orders made under it, shall operate cumulatively; and any exemption or exception from any of those provisions shall not be construed as conferring any exemption or exception in relation to any other of those provisions.
- (2) Except in so far as this Act otherwise expressly provides, and subject to the provisions of section 33 of the <sup>M36</sup>Interpretation Act 1889 (which relates to offences under two or more laws), the provisions of this Act shall not be construed as—
  - (a) conferring a right of action in any civil proceedings (other than proceedings for the recovery of a fine) in respect of any contravention of this Act or of any regulations or order made under this Act, or
  - (b) affecting any restriction imposed by or under any other enactment, whether contained in a public general Act or in a local or private Act, or
  - (c) derogating from any right of action or other remedy (whether civil or criminal) in proceedings instituted otherwise than under this Act.
- (3) No exemption conferred by or under any provision of this Act shall be construed as derogating from any exemption or immunity of the Crown.

#### Modifications etc. (not altering text)

**C335** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)  
**C336** S. 133 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), Sch.  
**C337** S.133(2) applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
 S. 132(2) applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)

#### Marginal Citations

**M36** 1889 c. 63.

### 134 Special provisions as to Northern Ireland.

- (1) Nothing in this Act shall authorise any department of the Government of Northern Ireland to incur any expenses attributable to the provisions of this Act, which are not

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

expenses falling to be defrayed in accordance with section 128(1) of this Act, until provision has been made by the Parliament of Northern Ireland for those expenses to be defrayed out of moneys provided by that Parliament.

- (2) ..... <sup>F309</sup>
- (3) The provisions of Schedule 4 to this Act shall have effect with respect to the application of this Act in relation to Northern Ireland.
- (4) In this Act “enactment” includes an enactment of the Parliament of Northern Ireland; and (without prejudice to section 132(6) of this Act) any reference in this Act to such an enactment shall include a reference to any enactment re-enacting it with or without modifications.
- (5) [<sup>F310</sup>Sections 16(1) and 17(2)(a) of the <sup>M37</sup>Interpretation Act 1978] shall have the like operation in relation to any repeal by this Act of an enactment of the Parliament of Northern Ireland as it has in relation to the repeal of an enactment of the Parliament of the United Kingdom.

#### Textual Amendments

**F309** S. 134(2) repealed by [Northern Ireland Constitution Act 1973 \(c. 36\), Sch. 6 Pt. I](#)

**F310** Words substituted by virtue of [Interpretation Act 1978 \(c. 30\), s. 25\(2\)](#)

#### Modifications etc. (not altering text)

**C338** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

**C339** S. 134 applied (with modifications) (3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.

**C340** S. 134(3)(4)(5) applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)

S. 134(3)(4)(5) applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch. 5](#)

#### Marginal Citations

**M37** [1978 c. 30.](#)

### 135 Minor and consequential amendments and repeals.

- (1) The enactments of the Parliament of the United Kingdom which are specified in Schedule 5 to this Act shall have effect subject to the amendments set out in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.
- (2) The enactments of that Parliament which are specified in Schedule 6 to this Act are hereby repealed to the extent specified in the third column of that Schedule :  
<sup>F311</sup>  
...
- (3) The enactments of the Parliament of Northern Ireland which are specified in Schedule 7 to this Act shall have effect subject to the amendments specified in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.
- (4) The enactments of the Parliament of Northern Ireland specified in Schedule 8 to this Act are hereby repealed to the extent specified in the third column of that Schedule.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

#### Textual Amendments

**F311** S. 135(2) proviso repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), [Sch. 1 Pt. 17](#) Group 7

#### Modifications etc. (not altering text)

**C341** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**C342** The text of s. 135 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

### 136 Short title, extent and commencement.

- (1) This Act may be cited as the Medicines Act 1968.
- (2) This Act extends to Northern Ireland.
- (3) The following provisions of this Act, that is to say, sections 63 to 65, 77, 85(5), 86(3), 90(2), 93, 97 and 135, shall not come into operation on the passing of this Act but shall come into operation on such day as the Ministers may by order appoint, and different days may be so appointed for, or for different purposes of, any one or more of those provisions (including, in the case of section 135 of this Act, the amendment or repeal of different enactments to which that section is applicable).
- (4) Any order made under this section may make such transitional provision as appears to the Ministers to be necessary or expedient in connection with the provisions of this Act which are thereby brought (wholly or in part) into force, including such adaptations of those provisions or any provision of this Act then in force as appear to them to be necessary or expedient in consequence of the partial operation of this Act (whether before, on or after the day appointed by the order).

#### Modifications etc. (not altering text)

**C343** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**C344** Power of appointment conferred by s. 136(3) fully exercised except in relation to s. 135(as to which it has been exercised in part only):S.I.s 1972/188, 1225; 1973/1851, 1529; 1989/192

**C345** S. 136(3) extended (E.W.S.) by [Animal Health Act 1981 \(c. 22, SIF 4:4\)](#), [s. 95\(4\)](#)



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

## SCHEDULES

### <sup>F312</sup>SCHEDULE 1

Section 5.

#### Textual Amendments

**F312** Sch. 1 repealed (31.5.2005 for specified purposes, 30.10.2005 in so far as not already in force) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1)(2)**7(1)**

### <sup>F313</sup>SCHEDULE 1A

Section 5

#### PROVISIONS RELATING TO COMMISSION AND COMMITTEES

#### Textual Amendments

**F313** Sch. 1A inserted (31.5.2005 for specified purposes, 30.10.2005 in so far as not already in force) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1)(2)**7(2)**

#### *Interpretation*

1. In this Act, “Advisory Body” means the Commission or a committee established under section 4 of this Act.

#### *Co-opted members*

2. (1) Subject to the approval of the Secretary of State, at any meeting of an Advisory Body, that Advisory Body may co-opt additional members.  
(2) A co-opted member shall hold office only in relation to the meeting for which he is co-opted.

#### *Expert Advisory Groups*

3. (1) Subject to paragraph 4 of this Schedule, an Advisory Body, or any two or more Advisory Bodies acting jointly, may, subject to the approval of the Secretary of State, appoint sub-committees, to be known as Expert Advisory Groups.  
(2) The Secretary of State may direct an Advisory Body to appoint an Expert Advisory Group to advise on such matters as may be specified in the direction.  
(3) An Expert Advisory Group may include or consist of persons who are not members of the Advisory Body or Bodies which appointed that Expert Advisory Group.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (4) Subject to paragraph 4(2) of this Schedule, the Advisory Body or Bodies which appointed the Expert Advisory Group shall appoint one of the members of the Expert Advisory Group as chairman.
- (5) At any meeting of an Expert Advisory Group, the chairman of that Group may, after consulting the chairman or chairmen of the Advisory Body or Bodies which appointed that Group, co-opt additional members of that Group.
- (6) Members co-opted in accordance with sub-paragraph (5) of this paragraph shall hold office only in relation to the meeting for which they are co-opted.

#### *Appointment by the Commission of Expert Advisory Groups*

4. (1) The Commission shall establish—
  - (a) an Expert Advisory Group to be called “the Biologicals Expert Advisory Group”, to advise on the safety, quality and efficacy of medicinal products of biological or bio-technological origin, including vaccines;
  - (b) an Expert Advisory Group to be called “the Chemistry, Pharmacy and Standards Expert Advisory Group”, to advise on the quality, and quality in relation to safety and efficacy, of medicinal products which are the subject of an application for a product licence under this Act, a marketing authorization under the Marketing Authorisation Regulations<sup>F314</sup>, a certificate of registration under the Homoeopathic Regulations, a traditional herbal registration under the Herbal Regulations], or a request for authorisation pursuant to regulation 17 of the Clinical Trials Regulations;
  - (c) an Expert Advisory Group to be called “the Pharmacovigilance Expert Advisory Group”, to advise on pharmacovigilance and other issues relating to the safety of medicinal products; and
  - (d) such other Expert Advisory Groups as it considers appropriate.
- (2) The chairmen of the Expert Advisory Groups referred to in paragraphs (a) to (c) of sub-paragraph (1) above shall be appointed by the Ministers.

#### **Textual Amendments**

**F314** Words in Sch. 1A para. 4(1)(b) inserted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), Sch. 1 para. 4(a)

#### *Delegation of functions by Advisory Bodies*

5. (1) Subject to sub-paragraph (2) of this paragraph, an Advisory Body may delegate to an Expert Advisory Group such of its functions as it thinks fit.
  - (2) Subject to sub-paragraph (3) of this paragraph, an Advisory Body may not delegate any function which consists of advising the licensing authority in cases where the licensing authority is required to consult that Advisory Body pursuant to the provisions of—
    - (a) Part 2 of this Act;
    - (b) the Clinical Trials Regulations;
    - [ the Herbal Regulations;]
- <sup>F315</sup>(bb)

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (c) the Homoeopathic Regulations; or
- (d) the Marketing Authorisation Regulations.

- (3) An Advisory Body may arrange for an Expert Advisory Group to provide advice or assistance in relation to the performance of any function referred to in subparagraph (2) of this paragraph.

#### Textual Amendments

**F315** Sch. 1A para. 5(2)(bb) inserted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), Sch. 1 para. 4(b)

#### *Terms of office of members*

6. The Ministers may make provision by regulations with respect to one or more of the following matters—
- (a) the terms on which members of Advisory Bodies shall hold and vacate office, including the terms on which any person appointed as chairman of such a Body shall hold and vacate office as chairman; and
  - (b) the terms on which members of Expert Advisory Groups shall hold and vacate office, including the terms on which any person appointed as chairman of such a Group shall hold and vacate office as chairman.

#### *Staff, premises and facilities*

7. The Ministers shall provide each Advisory Body and any committee appointed under section 60 of this Act with such staff and such accommodation, services and other facilities as appear to the Ministers to be necessary or expedient for the proper performance of their functions.

#### *Validity of proceedings*

8. The validity of any proceedings of an Advisory Body, Expert Advisory Group or any committee appointed under section 60 of this Act shall not be affected by—
- (a) a vacancy among the members of that Advisory Body, Expert Advisory Group, or committee, or
  - (b) a defect in the appointment of any member of that Advisory Body, Expert Advisory Group or committee.

#### *Proceedings*

9. (1) An Advisory Body may, subject to approval by the Secretary of State, make such provision as it thinks fit to regulate its own proceedings.
- (2) The Secretary of State may make such provision as he thinks fit to regulate the proceedings of Expert Advisory Groups.
- (3) A committee established under section 60 of this Act shall have the power to regulate their procedure.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

### *Remuneration and expenses of members*

10. The Ministers may pay to the members of each Advisory Body and Expert Advisory Group and of any committee appointed under section 60 of this Act such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.

### *Expenses of Advisory Bodies and Expert Advisory Groups*

11. The Ministers shall defray any expenses incurred with their approval by each Advisory Body and Expert Advisory Group or by any committee appointed under section 60 of this Act.

### *Status*

12. No Advisory Body, no Expert Advisory Group and no committee appointed under section 60 of this Act shall be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown.]

[<sup>F316</sup> SCHEDULE 2

Section 29.

## SUSPENSION, REVOCATION OR VARIATION OF LICENCE

### **Textual Amendments**

**F316** Sch. 2 substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 15](#)

### **Modifications etc. (not altering text)**

**C346** Sch. 2 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), Sch.

Sch. 2 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)

**C347** Sch. 2 amendment to earlier affecting provision [SI 1992/605 Sch. \(30.10.2005\)](#) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), [reg. 1\(2\)\(b\)](#), [Sch. 4 para. 6\(b\)](#)

**C348** Sch. 2 amendment to earlier affecting provision [SI 1994/105 Sch. 4 \(30.10.2005\)](#) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), [19\(2\)](#)

### *Procedure on consultation with appropriate committee*

- 1 Subject to paragraph 8 below, where the licensing authority propose, in the exercise of their powers under section 28 of this Act—
- (a) to suspend, revoke or vary a product licence on the grounds specified in paragraph (a) or paragraph (c) of subsection (3) of that section, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products to which the licence relates, or
  - (b) to suspend, revoke or vary a product licence on any of the grounds specified in paragraph (g) or paragraph (h) of that subsection,
- the licensing authority shall not suspend, revoke or vary the licence except after consultation with the appropriate committee.

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- 2
- (1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on such grounds as are mentioned in that paragraph, they may have to advise the licensing authority that the product licence ought to be revoked, varied or suspended, the appropriate committee shall notify the holder of the licence accordingly.
  - (2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.
  - (3) The appropriate committee shall give the holder of the licence an opportunity to make such representations in accordance with sub-paragraphs (4) to (7) of this paragraph.
  - (4) Subject to sub-paragraph (5) of this paragraph, the holder of the licence shall provide the appropriate committee with—
    - (a) his written representations or a written summary of the oral representations he intends to make; and
    - (b) any documents on which he wishes to rely in support of those representations,before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph, or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1) of this paragraph.
  - (5) If the holder of the licence so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4) of this paragraph, up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph.
  - (6) The holder of the licence may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) of this paragraph has expired, except with the permission of the appropriate committee.
  - (7) If the holder gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4) of this paragraph, arrange for the holder to make such representations at a hearing before the committee.
  - (8) The appropriate committee shall—
    - (a) take into account such representations as are made in accordance with this paragraph; and
    - (b) report their findings and advice to the licensing authority, together with the reasons for their advice.
- 3
- (1) After receiving the report of the appropriate committee the licensing authority shall—
    - (a) decide whether to continue with the proposal to revoke, vary or suspend the product licence; and
    - (b) take the report into account when making their decision.
  - (2) The licensing authority shall then notify the holder of the licence of—
    - (a) the decision made pursuant to sub-paragraph (1) of this paragraph; and
    - (b) the advice given to them by the appropriate committee and the reasons for that advice.
- 4
- If—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) the appropriate committee was consulted under paragraph 1 of this Schedule;
  - (b) the committee did not give a provisional opinion under paragraph 2(1) of this Schedule; and
  - (c) the licensing authority propose—
    - (i) to determine the matter in a way which differs from the advice of the committee, or
    - (ii) to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,
 the authority shall notify the holder of the licence accordingly.
- (2) A notification given under sub-paragraph (1) of this paragraph shall state—
- (a) the advice of the committee and the reasons stated by the committee for that advice; and
  - (b) the proposals of the licensing authority and the reasons for them.
- 5 (1) Subject to sub-paragraph (4) of this paragraph, a person to whom a notification has been given under paragraph 3(2) of this Schedule may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.
- (2) A person to whom a notification has been given under paragraph 4(1) of this Schedule may, within the time allowed—
- (a) notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority, or
  - (b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.
- (3) If the applicant makes written representations in accordance with sub-paragraph (2) (b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.
- (4) Sub-paragraph (1) of this paragraph shall not apply where—
- (a) the person has not made any representations in accordance with paragraph 2(4) to (7) of this Schedule; and
  - (b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

**Modifications etc. (not altering text)**

- C349** Sch. 2 para. 5(4) applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 5 para. 6(4)**
- C350** Sch. 2 para. 5(4)(a) applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 5 para. 2(5)**
- C351** Sch. 2 para. 5(4)(a) applied (with modifications) (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), **Sch. 5 para. 11(4)**

*Procedure in other cases*

6. (1) This paragraph applies where the licensing authority propose, in the exercise of the powers conferred by section 28 of this Act—

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- (a) to suspend, revoke or vary a licence under Part 2 of this Act, other than a product licence; or
  - (b) to suspend, revoke or vary a product licence where the holder of the licence has been given neither—
    - (i) notice of any provisional opinion or any advice of the appropriate committee which led to that proposal under paragraphs 2 and 3 of this Schedule; nor
    - (ii) notice of that proposal under paragraph 4 of this Schedule,and the provisions of paragraph 8 of this Schedule do not apply.
- (2) The licensing authority shall notify the holder of the licence of—
- (a) their proposals;
  - (b) the reasons for them; and
  - (c) the date (not being earlier than twenty-eight days from the date of the notification) on which it is proposed that the suspension, revocation or variation should take effect.
- (3) The holder of the licence may, before the date specified in the notification—
- (a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or
  - (b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.
- (4) If the applicant makes written representations in accordance with sub-paragraph (3) (b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

*Hearing before person appointed*

- 7
- (1) If the holder of the licence gives notice under paragraph 5 or 6 of this Schedule of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—
- (a) make that appointment; and
  - (b) arrange for the applicant to have an opportunity of appearing before that person.
- (2) The person appointed—
- (a) shall not be, or at any time have been, a member of—
    - (i) the Commission on Human Medicines or any of its Expert Advisory Groups,
    - (ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or
    - (iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and
  - (b) shall not be an officer or servant of any Minister of the Crown.
- (3) Subject to sub-paragraph (4) of this paragraph, the holder of the licence shall provide the person appointed with—
- (a) a written summary of the oral representations he intends to make; and
  - (b) any documents on which he wishes to rely in support of those representations,

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

- (4) If the holder of the licence so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3) of this paragraph, up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.
- (5) If the holder of the licence fails to comply with the time limit in sub-paragraph (3) of this paragraph, or, where he has been granted an extended time limit under sub-paragraph (4) of this paragraph, that time limit—
  - (a) he may not appear before or be heard by the person appointed, and
  - (b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.
- (6) The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.
- (7) At the hearing before the person appointed, both the holder of the licence and the licensing authority may make representations.
- (8) If the holder of the licence so requests the hearing shall be in public.
- (9) After the hearing—
  - (a) the person appointed shall provide a report to the licensing authority; and
  - (b) the licensing authority shall take this report into account and decide whether to revoke, vary or suspend the licence.
- (10) The licensing authority shall then—
  - (a) notify the holder of the licence of their decision;
  - (b) if the holder so requests, provide the holder with a copy of the report of the person appointed.

**Modifications etc. (not altering text)**

**C352** Sch. 2 para. 7 excluded (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), [Sch. 5 para. 19\(3\)\(a\)\(ii\)](#)

*Procedure in cases of urgency*

- 8 Notwithstanding anything in paragraphs 1 to 7 of this Schedule, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under Part 2 of this Act with immediate effect, the licensing authority may do so, for a period not exceeding three months.
- 9 If the licence is a product licence, the licensing authority shall report the suspension forthwith to the appropriate committee.
10. If, after the suspension has taken effect—
  - (a) it appears to the licensing authority; or
  - (b) in the case of a product licence, they are advised by the appropriate committee,



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority (subject to paragraph 11 of this Schedule) shall proceed in accordance with such of the provisions of paragraphs 1 to 7 of this Schedule as are applicable in the circumstances.

11. (1) This paragraph applies where, in the circumstances specified in paragraph 10 of this Schedule, the licensing authority proceed as mentioned in that paragraph and any proceedings under paragraphs 1 to 7 of this Schedule relating to a further suspension of the licence have not been finally disposed of before the end of the period—
- (a) for which the licence was suspended under paragraph 8 of this Schedule; or
  - (b) for which it has been further suspended under this paragraph.
- (2) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each such further suspension) shall not exceed three months.
- (3) The provisions of section 27(7) of this Act shall, with the necessary modifications, have effect for the purpose of determining the date on which any proceedings are taken to be finally disposed of.

#### *Interpretation*

- 12 In this Schedule, the “the time allowed” means the period of twenty-eight days from the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.]

### SCHEDULE 3

#### SAMPLING

##### **Modifications etc. (not altering text)**

- C353** Sch. 3 modified (3.4.1992) by [S.I. 1992/605](#), **regs. 2(3), 3**  
Sch. 3 applied (3.10.1994) by [S.I. 1994/2328](#), **reg. 11(c)**  
Sch. 3 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), **reg.10, Sch. 4**  
Sch. 3 applied (31.3.1997) by [S.I. 1997/322](#), **reg. 34, Sch.5**  
Sch. 3 applied (1.2.2000) by [S.I. 2000/7](#), **reg. 5**
- C354** Sch. 3 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), **regs. 1, 47, Schs. 9**
- C355** Sch. 3 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), **regs. 1(a), 11, Schs. 4 (with Sch. 6)**

#### *Introductory*

- 1 (1) The provisions of this Schedule shall have effect where a person authorised in that behalf by an enforcement authority (in this Schedule referred to as a “sampling officer”) obtains a sample of any substance or article—
- (a) for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention of any provisions of this Act or of any regulations or order made thereunder which, by or under

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

any provisions of sections 108 to 110 of this Act, that authority (in this Schedule referred to as “the relevant enforcement authority”) is required or empowered to enforce, or

(b) otherwise for any purpose connected with the performance by that authority of their functions under this Act or under any such regulations or order,

and the sampling officer obtains the sample by purchase or in the exercise of any power conferred by section 112 of this Act.

(2) In this Schedule “public analyst”, [<sup>F317</sup>except in relation to Northern Ireland, has the meaning assigned to it by section 27 of the Food Safety Act 1990], and in relation to Northern Ireland has the meaning assigned to it by [<sup>F318</sup>Article 27(1) of the Food Safety (Northern Ireland) Order 1991].

#### Textual Amendments

**F317** Words in Sch. 3 para. 1(2) substituted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\), ss. 54, 59\(1\), Sch. 3 para. 12](#)

**F318** Words in Sch. 3 para. 1(2) substituted (N.I.) (21.5.1991) by [S.I. 1991/762, art. 51\(1\), Sch. 2 para.10; S.R. 1991/175, art. 2\(1\)](#).

#### *Division of sample*

- 2 The sampling officer shall forthwith divide the sample into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.
- 3 If the sample was purchased by the sampling officer, otherwise than from an automatic machine, he shall supply one part of the sample to the seller.
- 4 If the sampling officer obtained the sample from an automatic machine, then—
- (a) if a person’s name, and an address in the United Kingdom, are stated on the machine as being the name and address of the owner of the machine, the sampling officer shall supply one part of the sample to that person;
- (b) in any other case, the sampling officer shall supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.
- 5 If the sample is of goods consigned from outside the United Kingdom and was taken by the sampling officer before delivery to the consignee, the sampling officer shall supply one part of the sample to the consignee.
- 6 If, in a case not falling within any of paragraphs 3 to 5 of this Schedule, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer shall supply one part of the sample to the seller.
- 7 If, in a case not falling within any of paragraphs 3 to 6 of this Schedule, the sample was taken in transit, the sampling officer shall supply one part of the sample to the consignor.
- 8 In any case not falling within any of paragraphs 3 to 7 of this Schedule the sampling officer shall supply one part of the sample to the person appearing to him to be the owner of the substance or article from which the sample was taken.
- 9 In every case falling within any of paragraphs 3 to 8 of this Schedule the sampling officer shall inform the person to whom the part of the sample in question is supplied

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- that the sample has been obtained for the purpose of analysis or other appropriate examination.
- 10 Of the remaining parts of the sample into which the sample is divided in accordance with paragraph 2 of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall—
- (a) retain one part for future comparison, and
  - (b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.
- 11 Where a sample consists of substances or articles enclosed in unopened containers, and it appears to the sampling officer that to open the containers and divide the contents into parts—
- (a) is not reasonably practicable, or
  - (b) might affect the composition or impede the proper analysis or other examination of the contents,
- the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them.
- 12 Section 127 of this Act shall have effect in relation to supplying any part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.
- 13 If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample ought to be supplied in pursuance of the preceding paragraphs, he may retain that part of the sample instead of supplying it.

*Notice to person named on container*

- 14 (1) Where it appears to the sampling officer that a substance or article of which he has obtained a sample was manufactured or assembled by a person whose name and address in the United Kingdom are stated on its container, and who is not a person to whom a part of the sample is required to be supplied under the preceding provisions of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall serve notice on that person—
- (a) stating that the sample has been obtained by the sampling officer, and
  - (b) specifying the person from whom the sampling officer purchased it, or, if he obtained it otherwise than by purchase, the place from which he obtained it.
- (2) The notice required to be served under the preceding sub-paragraph shall be served before the end of the period of three days beginning with the day on which the sample was obtained.

*Analysis or other examination of sample*

- 15 If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall—
- (a) submit it for analysis to the public analyst for the area in which the sample was obtained, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area, or
  - (b) submit it for other appropriate examination to the person having the management or control of any laboratory available for the purpose in

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

accordance with any arrangements made in that behalf by the relevant enforcement authority.

16 Where the relevant enforcement authority is a Minister or the Pharmaceutical Society, and the sampling officer decides to have the sample analysed, he may (instead of submitting it to a public analyst) submit it for analysis to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.

17 Any such arrangements as are mentioned in paragraph 15(b) or paragraph 16 of this Schedule,—

- (a) if they relate exclusively to the examination or analysis of veterinary drugs and are made by an enforcement authority in England and Wales other than the Minister of Agriculture, Fisheries and Food, shall be arrangements approved by that Minister;
- (b) if in any other case they are made by an enforcement authority in England and Wales other than [<sup>F319</sup>the Secretary of State], shall be arrangements approved by [<sup>F319</sup>the Secretary of State];
- (c) if they are made by an enforcement authority in Scotland other than the Secretary of State, shall be arrangements approved by the Secretary of State;

and any such arrangements as are mentioned in paragraph 15(b) of this Schedule, if made by a [<sup>F320</sup>district council] in Northern Ireland, shall be arrangements approved by the Minister of Health and Social Services for Northern Ireland.

#### Textual Amendments

**F319** Words substituted by virtue of S.I. 1968/1699, arts. 2, 5(4)(a)

**F320** Words substituted by S.R. &O. (N.I.) 1973 No. 211, Sch.

#### Modifications etc. (not altering text)

**C356** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: S.I. 1969/388, art. 2(1)

18 (1) Subject to the following sub-paragraph, the person to whom the sample is submitted under paragraph 15 or paragraph 16 of this Schedule shall analyse or examine the sample (as the case may be), or cause the sample to be analysed or examined by some other person under his direction, as soon as practicable.

(2) If the person to whom the sample is so submitted is a public analyst, and that analyst determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

19 (1) A public analyst who has analysed a sample submitted to him under the preceding provisions of this Schedule, or who has caused such a sample to be analysed by some other person under his direction, shall issue and send to the sampling officer a certificate specifying the result of the analysis.

(2) A person having the management or control of a laboratory in which a sample submitted to him under the preceding provisions of this Schedule has been analysed

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

or examined, or a person appointed by him for the purpose, shall issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

- (3) Any certificate issued under this paragraph shall be in a form prescribed by the Ministers and shall be signed by the person who issues the certificate.
- 20 (1) Any person to whom, in accordance with paragraphs 2 to 8 of this Schedule, a part of the sample is required to be supplied shall, on payment of the prescribed fee to the relevant enforcement authority, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19 of this Schedule.
- (2) Any regulations prescribing a fee for the purposes of this paragraph shall be made by the Ministers.

*Provisions as to evidence*

- 21 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 of this Schedule shall be sufficient evidence of the facts stated in the document, unless the other party requires that the person who issued the certificate shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 22 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings, which has been supplied to him by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated in the document.
- 23 (1) If in any such proceedings before a magistrates' court a defendant intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, a notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least three clear days before the day on which the summons is returnable.
- (2) If the preceding sub-paragraph is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper.
- (3) In Scotland, if in any such proceedings in the sheriff court the accused intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.
- (4) If sub-paragraph (3) of this paragraph is not complied with, the sheriff may, if he thinks fit, adjourn the diet on such terms as he deems proper.

*Analysis under direction of court*

- 24 (1) In any proceedings for an offence under this Act, where the proceedings relate to a substance or article of which a sample has been obtained as mentioned in paragraph 1 of this Schedule, the part of the sample retained in pursuance of paragraph 10(a) of this Schedule shall be produced as evidence; and the court—
- (a) at the request of either party to the proceedings shall, and
- (b) in the absence of any such request may if it thinks fit,

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, the Government Chemist for Northern Ireland) or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.

- (2) If, in a case where an appeal is brought, no action has been taken under the preceding sub-paragraph, the provisions of that sub-paragraph shall have effect in relation to the court by which the appeal is heard.
  - (3) A person to whom a part of a sample is sent under this paragraph for analysis or other examination shall analyse or examine it, or cause it to be analysed or examined on his behalf, and shall transmit to the court a certificate specifying the result of the analysis or examination.
  - (4) Any such certificate shall be signed by that person, or signed on his behalf by the person who made the analysis or examination or a person under whose direction it was made.
  - (5) Any such certificate shall be evidence (and, in Scotland, shall be sufficient evidence) of the facts stated in the certificate unless any party to the proceedings requires that the person by whom it was signed shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 25 The costs of any analysis or examination under paragraph 24 of this Schedule shall be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

*Proof by written statement*

- 26 In relation to England and Wales section 9 of the <sup>M38</sup>Criminal Justice Act 1967, and in relation to Northern Ireland any corresponding enactment which may be passed by the Parliament of Northern Ireland, shall not have effect with respect to any document produced as mentioned in paragraph 21 or paragraph 22 of this Schedule or with respect to any certificate transmitted to a court under paragraph 24 of this Schedule.

**Marginal Citations**

**M38** 1967 c. 80.

*Power to modify sampling provisions*

- 27 The Ministers may by order provide that, in relation to substances or articles of any such description as may be specified in the order, the preceding provisions of this Schedule shall have effect subject to such exceptions and modifications as may be specified in the order.

*Payment for sample taken under compulsory powers*

- 28 (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 112 of this Act he shall, if payment is demanded, pay the value of the sample

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

to the person to whom a part of the sample is required under paragraph 5, paragraph 7 or paragraph 8 of this Schedule (as the case may be) to be supplied.

- (2) In default of agreement between the sampling officer and the person mentioned in the preceding sub-paragraph, the value of the sample shall be determined by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question or, if they are unable to agree on the appointment of an arbitrator, shall be determined by the county court for the district (or, in Northern Ireland, the division) in which the sample was taken.
- (3) In the application of this paragraph to Scotland, for references to an arbitrator there shall be substituted references to an arbiter and for the reference to the county court there shall be substituted a reference to the sheriff.

*Application of s. 64 to samples*

- 29 Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 112 of this Act, the provisions of subsections (1) to (4) of section 64 of this Act shall have effect as if the taking of the product as a sample were a sale of it to the sampling officer by the person from whom it is taken; and, if the product was prepared in pursuance of a prescription given by a practitioner, those provisions shall so have effect as if, in subsection (1) of that section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”

SCHEDULE 4

Section 134.

PROVISIONS RELATING TO NORTHERN IRELAND

**Modifications etc. (not altering text)**

C357 Sch. 4 applied (31.3.1997) by S.I. 1997/322, reg. 34, Sch.5

C358 Paras. 6, 8, 11 extended by Medicines Act 1971 (c. 69), s. 1(3)(c)

- 1 (1) The Minister of Health and Social Services for Northern Ireland may by order make provision for the application of this Act in relation to druggists subject to such exceptions and modifications as may be specified in the order.
- (2) In this paragraph “druggist” means a person registered in the register of druggists for Northern Ireland made out and maintained under [<sup>F321</sup>Articles 6 and 9 of the <sup>M39</sup>Pharmacy (Northern Ireland) Order 1976].

**Textual Amendments**

F321 Words substituted by S.I. 1976/1213 (N.I. 22), Sch. 5 para. 8

**Marginal Citations**

M39 S.I. 1976/1213 (N.I. 22)

- 2 Where the Minister of Agriculture for Northern Ireland is of the opinion that there are special circumstances which render it expedient that any description or class of

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

veterinary drugs which is proposed to be specified or designated by an order under section 51 of this Act should not be so specified or designated in relation to Northern Ireland, an order under that section may specify or designate that description or class of veterinary drugs for the purposes of the application of this Act in Great Britain but not in Northern Ireland.

- 3 A product licence, in so far as it is applicable to veterinary drugs of any description, or contains provisions relating to the incorporation of substances or articles in animal feeding stuffs, or an animal test certificate, except where it is issued by the Minister of Agriculture for Northern Ireland (whether acting with or without any one or more than one of the other Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act), shall not authorise the doing of anything in or in relation to Northern Ireland except to the extent (if any) to which the licence or certificate is expressed to do so.
- 4 Notwithstanding anything contained in section 28(3) or section 39(2) of this Act, the powers conferred by sections 28 and 30 and by section 39 of this Act to vary the provisions of a product licence and an animal test certificate respectively shall include power for the Minister of Agriculture for Northern Ireland (whether acting with or without any one or more than one of the other Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act) to extend to Northern Ireland any product licence or, as the case may be, any animal test certificate, or any provision of such a licence or certificate, which by virtue of paragraph 3 of this Schedule does not extend to Northern Ireland.
- 5 Where by virtue of paragraph 3 of this Schedule a product licence or animal test certificate, in so far as it is applicable to veterinary drugs of any description or contains provisions relating to the incorporation of substances or articles in animal feeding stuffs, does not extend to Northern Ireland, the Minister of Agriculture for Northern Ireland may by order prohibit (subject to such exceptions as may be provided for by or under the order) any person from landing in Northern Ireland, or having in his possession in Northern Ireland, a veterinary drug of that description or any animal feeding stuffs in which a substance or article to which those provisions relate has been incorporated, and may by the order provide for the imposition of penalties, not exceeding on summary conviction a fine of [<sup>F322</sup>level 5 on the standard scale], for contravention of any provision of the order.

#### Textual Amendments

**F322** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c. 48, SIF 39:1\)](#), [ss. 38, 46](#) and (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)

- 6 The appropriate Northern Ireland Minister or Ministers may in relation to Northern Ireland exercise any power of making an order or regulations which is conferred on the appropriate Ministers by any provision of this Act (except a provision contained in section 15(3), section 35, . . . <sup>F323</sup> or section 57(3) of this Act) where in his or their opinion there are special circumstances which render it expedient to do so.

#### Textual Amendments

**F323** Words repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, Sch. 1 para. 3(11), [Sch. 2](#)



*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

- 7 Where an order is made by virtue of paragraph 6 of this Schedule prohibiting or restricting the sale, supply or administration in, or the importation into, Northern Ireland of veterinary drugs of any description or class or any particular veterinary drugs or animal feeding stuffs in which medicinal products of any description or class have been incorporated or any particular animal feeding stuffs in which medicinal products have been incorporated, the order may also contain provisions for prohibiting (subject to such exceptions as may be provided for by or under the order) any person from landing in Northern Ireland or having in his possession in Northern Ireland any veterinary drug, or animal feeding stuffs containing medicinal products, of that description or class or, as the case may require, any such particular veterinary drugs or animal feeding stuffs.
- 8 Every order or regulation under this Act made by the Minister of Health and Social Services for Northern Ireland, or the Minister of Agriculture for Northern Ireland, or both those Ministers, by virtue of the power conferred by paragraph 1, paragraph 5 or paragraph 6 of this Schedule, and every regulation made solely by the Minister of Health and Social Services for Northern Ireland under section 120 of this Act, shall be subject to negative resolution within the meaning of section 41(6) of the <sup>M40</sup>Interpretation Act (Northern Ireland) 1954 as if it were a statutory instrument within the meaning of that Act.

#### Marginal Citations

**M40** 1954 c. 33 (N.I.)

- 9 In this Schedule “the appropriate Northern Ireland Minister or Ministers”—
- (a) for the purpose of making any order or regulations relating exclusively to matters other than veterinary drugs and the treatment of diseases of animals, means the Minister of Health and Social Services for Northern Ireland;
  - (b) for the purpose of making any order containing provisions such as are mentioned in paragraph 7 of this Schedule, means the Minister of Agriculture for Northern Ireland; and
  - (c) in any other case, means the Minister of Health and Social Services for Northern Ireland and the Minister of Agriculture for Northern Ireland acting jointly,
- and “landing”, in relation to any medicinal product or any feeding stuffs, means landing it or them from a vessel, aircraft or vehicle or otherwise introducing it or them into Northern Ireland.
- 10 In this Act any reference to the Minister of Health and Social Services for Northern Ireland or to the Minister of Agriculture for Northern Ireland, and any reference which is to be construed as including a reference to either or both of those Ministers, shall include a reference to the Ministry of Health and Social Services for Northern Ireland or, as the case may require, the Ministry of Agriculture for Northern Ireland, or both those Ministries.
- 11 [<sup>F324</sup>The Statutory Rules (Northern Ireland) Order 1979, except article 5(2)(a) of that Order] (which requires the responsible officer of each rule-making authority making any statutory rules to send copies of them, and certain information, to the Ministry of Finance for Northern Ireland for registration [<sup>F324</sup>under that Order]), shall not apply to any orders or regulations made under this Act by statutory instrument.

Status: Point in time view as at 08/11/2005.

Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)

**Textual Amendments**

F324 Words substituted by S.I. 1979/1573, Sch. 4 para. 10

SCHEDULE 5

Section 135(1)

AMENDMENTS OF ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM.

*The Venereal Disease Act 1917 (c. 21).*

F325 1 . . . . .

**Textual Amendments**

F325 Sch. 5 para. 1 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), Sch. 1 Pt. 17 Group 7

**Modifications etc. (not altering text)**

C359 The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

2, 9. . . . . F326

**Textual Amendments**

F326 Sch. 5 paras. 2–9 repealed by Poisons Act 1972 (c. 66), Sch. 2

*The Cancer Act 1939 (c. 13.)*

10 In section 4, in subsection (4)(a)(v), for the words “authorised sellers of poisons” there shall be substituted the words “persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968”.

**Modifications etc. (not altering text)**

C360 The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

11 . . . . . F327

**Textual Amendments**

F327 Sch. 5 para. 11 repealed by National Health Service Act 1977 (c. 49), Sch. 16

12 . . . . . F328

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Textual Amendments**

**F328** Sch. 5 para. 12 repealed by [National Health Service \(Scotland\) Act 1978 \(c. 29\)](#), **Sch. 17**

<sup>F329</sup> 13 . . . . .

**Textual Amendments**

**F329** Sch. 5 para. 13 repealed (5.11.1993) by [1993 c. 50, s. 1\(1\)](#), **Sch. 1Pt. XII**

14, 15. . . . . <sup>F330</sup>

**Textual Amendments**

**F330** Sch. 5 paras. 14, 15 repealed by [Misuse of Drugs Act 1971 \(c. 38\)](#), **Sch. 6**

*The Trade Descriptions Act 1968 (c. 29).*

16 In section 2, in subsection 5, after the word “section” there shall be inserted “(a)”, and at the end of the subsection there shall be inserted the following paragraph:—

“(b) where by virtue of any provision made under Part V of the Medicines Act 1968 (or made under any provisions of the said Part V as applied by an order made under section 104 or section 105 of that Act) anything which, in accordance with this Act, constitutes the application of a trade description to goods is subject to any requirements or restrictions imposed by that provision, any particular description specified in that provision, when applied to goods in circumstances to which those requirements or restrictions are applicable, shall be deemed not to be a trade description.”

**Modifications etc. (not altering text)**

**C361** The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

[<sup>F331</sup> 17 In section 22, in subsection (2), after the words “the Food and Drugs Act (Northern Ireland) 1958 <sup>M41</sup>” there shall be inserted the words “or the Medicines Act 1968” ; in paragraph (b) the word “and”, where it occurs at the end of that paragraph, shall be omitted ; and at the end of paragraph (c) there shall be inserted the words

(d) in relation to the said Act of 1968, so much of Schedule 3 to that Act as is applicable to the circumstances in which the sample was procured,”

at the end of the subsection there shall be inserted the words “or paragraph 27 of Schedule 3 to the said Act of 1968”.]

**Textual Amendments**

**F331** Sch. 5 para. 17 repealed (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(4), **Sch. 5**

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

**Marginal Citations**

M41 1958 c. 27 (N.I.)

SCHEDULE 6

Section 135(2)

ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM REPEALED.

**Modifications etc. (not altering text)**

**C362** The text of Sch. 6 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991

Section 135(2). SCHEDULE 6  
 ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM REPEALED

Chapter	Short Title	Extent of Repeal
7 & 8 Geo. 5, c. 21, 23 & 24 Geo. 5, c. 22.	The Venereal Disease Act 1917. The Pharmacy and Poisons Act 1933.	Section 2(2), except the proviso. Sections 8 to 14. In section 17, in subsection (2), the words "of persons who are to be entitled to sell poisons in Part II", and, in subsection (6), the words from "and in this Act" to the end of the subsection. In section 18(2)(a)(ii) the word "registered". Section 19. In section 23, in subsection (1), paragraph (e), paragraph (f) (i) and paragraph (f); and in subsection (3), in the reference to paragraphs (e), (9)(a), (e), (f) and (g), the references to paragraphs (e) and (f). In section 25, in subsection (1) the words "Part I of this Act and of section nineteen and", in subsection (4) those words and the word "registered", and subsection (9). In section 29, the definitions of "authorised seller of poisons" and "poison" and paragraph (e) of the definition of "registered". In section 4, subsection (1)(b), subsection (3) and subsection (4)(a)(v)(d). The whole Act.
2 & 3 Geo. 6, c. 13.	The Cancer Act 1939.	In section 4, subsection (1)(b), subsection (3) and subsection (4)(a)(v)(d).
4 & 5 Geo. 6, c. 42, 11 & 12 Geo. 6, c. 37.	The Pharmacy and Medicines Act 1941. The Radioactive Substances Act 1948.	The whole Act. Sections 3 and 4. In section 12, the definition of "authorised seller of poisons".

Chapter	Short Title	Extent of Repeal	Sch. 6
14 Geo. 6, c. 36.	The Diseases of Animals Act 1950.	Part II and Schedule 3.	
2 & 3 Eliz. 2, c. 61, 4 Eliz. 2, c. 16.	The Pharmacy Act 1954. The Food and Drugs Act 1955.	Section 19. In section 1, subsection (2) and subsection (3)(b). In section 2(3), the words from "except" to "drugs". Section 3(2). In section 6(1), the words from "except" to "drugs". In section 9(1), the words from "but" to the end of the subsection. In section 10(3)(a), the words from "so" to the end of the paragraph. In section 11(4), the words from "the authority concerned" to "in any other case". The words "or drug" and "drug" wherever they occur, except in section 135. In Schedule 8, in column 2, in the first paragraph, the words from "other" to "drug". In Part I of Schedule 9, in column 2, paragraph (a)(iii) of the definition relating to sections 331 to 335 of the Public Health Act 1936. The whole Act.	
4 & 5 Eliz. 2, c. 23, 4 & 3 Eliz. 2, c. 30.	The Therapeutic Substances Act 1956. The Food and Drugs (Scotland) Act 1956.	In section 1, subsection (2) and subsection (3)(b). In section 2(3) the words from "except" to "drugs". Section 3(2). In section 6(1) the words from "except" to "drugs". In section 28(2) the words from "but" to the end of the subsection. The words "or drug" and "drug" wherever they occur, except in section 58. Section 47. Section 57(9) and (10).	
4 & 5 Eliz. 2, c. 76, 1963 c. 9.	The Medical Act 1956. The Purchase Tax Act 1963.	In Part II of Schedules 1, in paragraph 3(2), the definition of "authorised seller of poisons".	

3 N\*

Chapter	Short Title	Extent of Repeal	Sch. 6
1964 c. 64.	The Drugs (Prevention of Misuse) Act 1964.	In section 1, in subsection (7), the reference to, and the paragraph substituted for, paragraph (b) of subsection (2). In section 9 the definition of "authorised seller of poisons".	
1965 c. 15.	The Dangerous Drugs Act 1965.	In section 11, in subsection (4) the words "in subsection (1) thereof".	

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

F332F332 SCHEDULE 7

**Textual Amendments**

**F332** Sch. 7 repealed by S.I. 1976/1213 (N.I. 22), Sch. 6 and 1976/1214 (N.I. 23), Sch. 3

F332

SCHEDULE 8

Section 135(4)

ENACTMENTS OF PARLIAMENT OF NORTHERN IRELAND REPEALED.

**Modifications etc. (not altering text)**

**C363** The text of Sch. 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991

SCHEDULE 8		
ENACTMENTS OF PARLIAMENT OF NORTHERN IRELAND REPEALED		
Session or Year and Chapter	Short Title	Extent of Repeal
15 & 16 Geo. 5, c. 8 (N.I.), 1945 c. 9 (N.I.)	The Pharmacy and Poisons Act (Northern Ireland) 1925, The Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945	Section 17, Section 18, Schedule 3, Part I. In section 14, in subsection (1) the words "if he is a registered person" and the words from "and, if he is a representative" onwards; and in subsection (2) the proviso, Sections 15 to 18. In section 19, in subsection (1) the words "or to be an authorised seller of poisons" and the words from ", or if the owner is a body corporate" to "employee of the body corporate."; in subsection (2) in paragraph (a) the words from "or, if the owner" onwards and in paragraph (b) the words from "or, if the owner is a body corporate" to "employee of the body corporate."; and subsection (3). In section 27(1)(a)(iii) the words from "in accordance" onwards. Section 28. In section 32, in subsection (1) paragraphs (a), (b)(i) and (i), and in subsection (3) the references to paragraphs (a) and (i) of subsection (1). In section 33(3) the words "section four, section five or". In section 36(2) and (3) the words "I and". Section 37. In section 38(1) the definitions of "authorised seller of poisons", "poison", "premises having an annual licence" and "retailing". In Schedule 2 in the proviso to paragraph (1) the word "or" at the end of paragraph (a) and paragraphs (b) and (c).

*Status: Point in time view as at 08/11/2005.*

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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)*

Sect. 8	Session or Year and Chapter	Short Title	Extent of Repeal
	1955 c. 31 (N.I.)	The Pharmacy and Poisons Act (Northern Ireland) 1955.	Section 2. Section 14.
	1958 c. 13 (N.I.)	The Diseases of Animals Act (Northern Ireland) 1958.	Part II. In Schedule 4, Part I.
	1958 c. 27 (N.I.)	The Food and Drugs Act (Northern Ireland) 1958.	In section 1 subsection (2), subsection (5)(b) and in subsection (6) the words " or drug ". In section 2 in subsection (1) the words " or drug " in both places where they occur, and in subsection (3) the words " , except so far as it relates to drugs, " . Section 3(2). In section 6 in subsection (1) the words " or drug " in each of the three places where they occur, in subsection (2) those words in each of the two places where they occur, in subsection (3) those words and in subsection (6) the words " , except so far as it relates to drugs, " . In section 33 in subsection (2) the words " or drug " and subsection (3). In section 34 in subsection (1) the word " , drug " and in subsection (2) the words " or drug " . In section 35 in subsections (1) and (4) the word " , drug " . In section 38 the word " , drug " in both places where it occurs. In section 44 in subsection (2)(a) the word " , drug " in both places where it occurs and in subsection (3) that word in both places where it occurs. In section 47, in subsection (1) the words " so far as those sections or regulations relate to food " , and in subsection (1)(a) the words " so far as it relates to food " .
	1966 c. 23 (N.I.)	The Diseases of Animals (Amendment) Act (Northern Ireland) 1966.	Section 3(2).

Session or Year and Chapter	Short Title	Extent of Repeal
1967 c. 12 (N.I.)	The Pharmacy Act (Northern Ireland) 1967.	Section 5. In Schedule 1 the entries amending sections 17 and 27 of the Pharmacy and Poisons Act (Northern Ireland) 1925 and the entries amending the proviso to section 14(2) and sections 15, 16, 17 and 18 of, and paragraph 1 of Schedule 2 to, the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945.
1967 c. 29 (N.I.)	The Increase of Fines Act (Northern Ireland) 1967.	In the Schedule the entries relating to sections 15(4) and 16(1A) of the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945 and Section 32 of the Diseases of Animals Act (Northern Ireland) 1958.

Sect. 8

**Status:**

Point in time view as at 08/11/2005.

**Changes to legislation:**

Medicines Act 1968 is up to date with all changes known to be in force on or before 12 April 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.