Medicines Act 1968

1968 CHAPTER 67

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)

C1 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C2 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**

C3 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,—

(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.

F1(2A) . . . . . .

F1(2B) . . . . . .

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

[F2(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.**]**

[F3(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,

[F4(a) is responsible for the composition of the product, or

[F5(b) if that product is a proprietary medicinal product **[**F6, 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.

[F7(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—

F8(a) . . . . . .

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, F9 . . .

F9(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. **]**

[F10(7) **[**F11In this section—

F12**[**F13 ...

"homoeopathic medicinal product" means any medicinal product (which may contain a number of principles) prepared from F14 ..., substances F14 ... 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; F15 . . . **]**

Textual Amendments

F1 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)**

F2 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**

F3 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)**

F4 Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 2(2)** and (N.I.) S.R. 1977 No. 170, **reg. 3**

F5 S. 7(5)(*b*) substituted by S.I. 1983/1724, **art. 2(2)**
F6 Words in S. 7(5)(b) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(2)**, 4
F7 S. 7(6A)(6B) inserted (3.4.1992) by S.I. 1992/604, **regs. 2(3)**, 4
F8 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))
F9 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)
F10 S. 7(7) substituted by S.I. 1983/1724, **art. 2(3)**
F11 Words in s. 7(7) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(4)**, 4
F12 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)**
F13 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)
F14 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)**
F15 Words in s. 7(7) repealed (3.4.1992) by S.I. 1992/604, **regs. 2(5)**, 4

Modifications etc. (not altering text)
C4 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C5 S. 7 excluded by S.I. 1989/2325, **art. 2(1)**
C6 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)**
C7 S.7 excluded by S.I. 1981/164, **art. 3**
C8 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)
C9 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)**
C10 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) **[**F16Subject to **[**F17subsections (2A) and (2C)**]** of this section**]**No person shall, in the course of a business carried on by him, **[**F18manufacture, 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").

[F19(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.**]**

[F19(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 . **]**

[F20(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

(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.**]**

[F20(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.**]**

[F21(3) **[**F22Subject to **[**F23subsections (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 **[**F24, 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 **[**F25wholesale dealer's licence**]**.**]**

[F26(3A) Without prejudice to the generality of subsection (3) of this section but subject to **[**F27subsections (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 **[**F28the 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 **[**F28the 2001 Directive applies**]** apply by the holder of a manufacturer's licence in respect of it.**]**

[F29(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.**]**

[F30(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.**]**

[F31(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—

F32(a) . . . . . .

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, **[**F33. . .**]**

F33(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,

(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, **[**F34homoeopathic medicinal product,**]**"proprietary medicinal product", "radiopharmaceutical" and "ready-made veterinary drug" have the same meanings as in section 7 of this Act.**]**

[F35(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

F16 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)**

F17 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)

F18 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)

F19 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)**

F20 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)

F21 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**

F22 Words in s. 8(3) inserted (14.4.1993) by S.I. 1993/834, **reg. 2(2)**

F23 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)**

F24 Words in s. 8(3)(b) substituted (3.4.1992) by virtue of S.I.1992/604, **regs. 3(2)**, 4

F25 Words in s. 8(3) substituted (14.4.1993) by S.I. 1993/834, **reg. 2(3)**

F26 S. 8(3A)-(3C) inserted (14.4.1993) by S.I. 1993/834, **reg. 2(4)**
F27 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)**
F28 Words in s. 8(3A)(3C) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(i)**
F29 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)**
F30 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)
F31 S. 8(4)(5)(6) substituted (3.4.1992) for s. 8(4) by virtue of S.I. 1992/604, **regs. 3(3)**, 4
F32 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))
F33 In S. 8(4) paragraph (c) and words immediately preceeding 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)
F34 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)
F35 S. 8(7)(8) added (14.4.1993) by S.I. 1993/834, **reg. 2(5)**

Modifications etc. (not altering text)
C11 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C12 S. 8 excluded by S.I. 1989/2325, **art. 2(3)**
C13 S. 8(2) excluded by S.I. 1979/1114, **arts. 2**, 4 and by S.I. 1979/1585, **arts. 2**, 3
C14 S. 8(3) excluded by S.I. 1989/2322, **art. 2(1)**
C15 S. 8(3) excluded by S.I. 1990/566, **art. 2(1)**
C16 S. 8(3)(*b*) excluded by S.I. 1989/2322, **art. 2(3)**
C17 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.

(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 **[**F36or

(d) in relation to a ready-made veterinary medicinal product as defined in Article 1.2 of the 1981 Directive.**]**

Textual Amendments

F36 S. 9(3)(d) and preceding word inserted (31.12.1994) by S.I. 1994/2987, **reg. 10(2)**

Modifications etc. (not altering text)

C18 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C19 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 **[**F37, 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 **[**F38provided 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

(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 **[**F39provided 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.

[F40(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.

[F41(6A) The preceding provisions of this section shall not have effect so as to exempt from the restrictions imposed by sections 7 and 8 of this Act anything done in a registered 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) **[**F42or (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.

[F43(7A) The Health Ministers may make regulations prescribing conditions which must be complied with if a thing is to be considered for the purposes of this section as done under the supervision of a pharmacist.

(7B) Conditions prescribed under subsection (7A) may relate to supervision in the case where the pharmacist is not at the place where the thing is being done, and in that case the thing is not to be so considered if no such conditions are prescribed.

(7C) In any case, compliance with any applicable conditions is sufficient for the thing to be so considered.**]**

(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.**]**

[F44(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

F37 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)

F38 Words added by S.I. 1971/1445, **art. 3(a)**

F39 Words added by S.I. 1971/1445, **art. 3(b)**

F40 S. 10(5)–(8) added by S.I. 1971/1445, **art. 3(c)**

F41 S. 10(6A) inserted (31.12.1994) by S.I. 1994/2987, **reg. 11(2)**

F42 Words in s. 10(7) inserted (14.4.1993) by S.I. 1993/834, **reg. 3**

F43 S. 10(7A)-(7C) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 26(1)**, 83(1)(e)

F44 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)

C20 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C21 S. 10 amended (E.W.S.) (*prosp*) by 1954 c. 61, **s. 13I(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 **[**F45a registered F46... nurse or a registered midwife**]** . . . F47

(2) F48

Textual Amendments

F45 Words substituted by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 7 para. 14**(*a*)

F46 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)**

F47 Words repealed by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 8**

F48 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)

C22 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

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)

C23 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)
C24 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

14 Exemption for re-exports.

[F49(1)**]** **[**F50Subject 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.

F51**[**(2) Section 8(3A) of this Act applies to the exportation, or the sale for exportation, of any product to which **[**F52the 2001 Directive applies**]** apply if it is, or is to be exported to **[**F53an EEA State.**]]**

Textual Amendments
F49 S. 14 renumbered as s. 14(1) (14.4.1993) by S.I. 1993/834, **reg. 4(a)**
F50 Words in s. 14(1) inserted (14.4.1993) by S.I. 1993/834, **reg. 4(a)**
F51 S. 14(2) inserted (14.4.1993) by S.I. 1993/834, **reg. 4(b)**
F52 Words in s. 14(2) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(ii)**
F53 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)
C25 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C26 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)
C27 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 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 carred 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)
C28 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C29 S. 16(1) modified by S.I. 1985/1403, **art. 3(2)** and S.I. 1985/1539, **art. 1**
C30 S. 16(2)–(5) excluded by S.I. 1981/1690, **art. 2**

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)
C31 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)
C32 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.

[F54(3) Where documents that constitute a dossier for the purposes of **[**F55Article 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 M1 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

F54 S. 18(3) substituted by S.I. 1983/1724, **art. 4**

F55 Words in s. 18(3) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(b)**

Modifications etc. (not altering text)

C33 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C34 S. 18 applied (with modifications)(11.3.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

C35 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**

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.

(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)

C36 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C37 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**

C38 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 **[**F56sections 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 **[**F57and any Community obligation**]**, they consider it necessary or expedient to do so, may refuse to grant a licence.

[F58(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.**]**

[F58(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**]**

[F58(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 F59....

F60(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

F56 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)

F57 Words inserted by (E.W.) S.I. 1977/1050, **art. 4(3)** and (N.I.) S.R. 1977 No. 170, **reg. 5(3)**

F58 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)

F59 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)**

F60 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)

C39 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C40 Ss. 20-22 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C41 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**

[F61 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

(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

(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

F61 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)

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

C43 Ss. 20-22 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C44 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**

C45 S. 21 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

C46 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)**

C47 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)**

C48 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)**

C49 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)**

[F62 22 Procedure in other cases.

(1) This section applies when—

(a) an application is made for the grant of a licence under this Part of this Act; and

(b) the appropriate committee—

(i) is not consulted under subsection (3) of section 20, or

(ii) is consulted under that subsection but does not give a provisional opinion in accordance with section 21(1).

(2) If the licensing authority propose—

(a) to refuse to grant the licence, or

(b) 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—

(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 proposal; 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 subsection (3)(b) of this section, the licensing authority shall take those representations into account before determining the application.

Textual Amendments

F62 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)

C50 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C51 Ss. 20-22 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C52 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**

C53 s. 22 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

C54 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 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

F62 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)

C55 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)**

C56 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)**

C57 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)**)

C58 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 [F63]... 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—

(a) the holder of the licence is also the holder of a product licence which is applicable to medicinal products of that description, or

[[F64](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.

[F65(6) In this section, "clinical trial" and "sponsor", in relation to a clinical trial, have the meaning given by Clinical Trials Regulations.**]**

Textual Amendments

F63 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)**

F64 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)**

F65 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)

C59 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C60 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)

C61 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)

C62 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.

[F66(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 **[**F67licence 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.

[F68(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 **[**F69and any Community obligation under **[**F70the 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.

[F71(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.**]**

(4) In relation to any such application the provisions of sections 18 and 19, subsections (2) to (5) of section 20 and sections **[**F72 21 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.

[F73(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.

F74(7) . . .

Textual Amendments

F66 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)

F67 Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 4(4)** and (N.I.) S.R. 1977 No. 170, **reg. 5(4)**

F68 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)

F69 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)

F70 Words in "s. 24(3)(C)"substituted (28.2.2002) by virtue of S.I. 2002/236, **reg. 2(c)(ii)**

F71 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)

F72 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**

F73 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)

F74 S. 24(7) deleted (28.2.2002) by virtue of S.I. 2002/236, **reg. 2(c)(ii)**

Modifications etc. (not altering text)

C63 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C64 S. 24 applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

Licences of right

25 Entitlement to licence of right.

F75(1) . . . . . .

F75(2) . . . . . .

F75(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

F75 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)

C65 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

F76 26 Scope of licence of right in different cases.

. . . . . .

Textual Amendments

F76 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)

C66 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 **[**F77**]**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 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.

[F78(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.**]**

Textual Amendments

F77 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)**

F78 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)

C67 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C68 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) **[**F79Subject 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;

(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.

[F80(i) that any of the provisions of the licence, insofar as they relate to the incorporation in animal feeding stuffs of any medicinal product . . . F81 are not in accordance with any Community obligation.**]**

[F82(j) that, in relation to medicinal products of any description to which the licence relates **[**F83(other than products to which **[**F84the 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.**]**

[F85(3A) Where a product licence relates to a product to which **[**F84the 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;

(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

F79 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)

F80 S. 28(3)(i) added by (E.W.)(S.) S.I. 1975/1169 (N.I.), S.R. & O (N.I.) 1975/197

F81 Words repealed by Animal Health and Welfare Act 1984 (c. 40, SIF 2:8), s. 16, Sch. 1 para. 3(2), **Sch. 2**

F82 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)**

F83 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)

F84 Words in s. 28(3)(j)(3A) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(iii)**

F85 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)

C69 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C70 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)

C71 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C72 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**

C73 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)**

[F86 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

F86 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)

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

C75 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

[F87]31 Clinical trials.

. . . . . .

Textual Amendments

F87 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)

C76 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.

(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)

C77 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C78 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C79 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—

(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 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)

C80 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C81 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C82 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**)

C83 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)

C84 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C85 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C86 S. 34 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

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 [F88]... an animal test certificate.

(2) The restrictions imposed by section 8(2) of this Act—

[F89](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) [F90]... 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 [F91]... a medicinal test on animals, and—

[[F92](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 [F93]... 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 **[**[F94]section 32**]** of this Act a person shall not be treated as doing anything, or procuring anything to be done, for the purposes [F95]... of a medicinal test on animals if—

(a) the [F96]... 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—

[F97](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 [F98]... 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

F88 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)**

F89 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)**

F90 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)**

F91 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)**
F92 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)**
F93 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)**
F94 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)**
F95 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)**
F96 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)**
F97 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)**
F98 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)
C87 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C88 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 [F99]... 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 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 [F100]... medicinal test on animals.

(3) Subject to the next following section, the provisions of sections 20 to **[**[F101]22A**]** of this Act shall have effect in relation to applications for [F102]... 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
F99 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)**
F100 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)**
F101 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**
F102 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)
C89 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C90 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C91 S. 36 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

F103 37 Transitional provisions as to clinical trials and medicinal tests on animals.

. . . . . .

Textual Amendments

F103 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)

C92 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C93 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 F104... 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.

(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 F105... 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 **[**F106**]**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 **[**F107**]**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 **[**F108**]**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 **[**F109**]**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

F104 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)**

F105 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)**

F106 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)**

F107 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)**

F108 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)**

F109 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)**

Modifications etc. (not altering text)

C94 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C95 Ss. 32-39 modified (1.1.1995) by S.I. 1994, reg. 18(4)

C96 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, **[**F110an 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 F111... 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 [F112]... 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 **[**[F113]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 **[**[F114]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

F110 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)**

F111 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)**

F112 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)**

F113 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)**

F114 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)

C97 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C98 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C99 S. 39 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

Medicated animal feeding stuffs

[[F115]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.

(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 regulations under it; and "the registrar" means any person appointed under section 1 of the Pharmacy Act [M2]1954 as registrar for the purposes of that Act.**]**

Textual Amendments

F115 S. 40 substituted by Animal Health and Welfare Act 1984 (c. 40, SIF 2:8), **s. 13(1)**

Modifications etc. (not altering text)

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

C101 S. 40 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

C102 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 . . . . . [F116]

Textual Amendments

F116 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 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 **[**F117 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

F117 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)

C103 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 **[**F118an 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—

(a) the information requested has been furnished to them, or

(b) 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 **[**F119an 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 F120... 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 F120... 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 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

F118 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**

F119 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**

F120 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)

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

C105 S. 44 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

C106 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)**

C107 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, [F121]... section 32, section 34 or section 40 of this Act, or who is in possession of any medicinal pro4duct 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, [F122]... 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 **[**[F123]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

(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 **[**F124level 3 on the standard scale**]**

Textual Amendments

F121 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)**

F122 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)**

F123 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)**

F124 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)

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

C109 s. 45 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

C110 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)**

C111 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 **[**F125an 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—

(a) that he had communicated those provisions to that other person, and

(b) 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 **[**F125an 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,—

(a) that the other person in question was the holder of a product licence applicable to those products, or of **[**F125an animal test certificate**]** applicable to them, and

(b) that the products were manufactured or assembled in accordance with that product licence or certificate.

(3) F126

Textual Amendments

F125 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**

F126 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)

C112 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C113 S. 46 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

C114 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)**

C115 S. 46(1) applied (wth 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.

(2) Any standard provisions so prescribed may be incorporated by the licensing authority in any licence under this Part of this Act or any F127... 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 [F128]... 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 [M3]Therapeutic Substances Act 1956 or under Part II of the [M4]Diseases of Animals Act 1950, or of the [M5]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 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

F127 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**

F128 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)

C116 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C117 S. 47(1)(2)(3)(4)(6)(7) applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C118 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)

C119 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. 1Sch. 6 para. 3(2)**Sch. 6 para. 3(3)** (with Sch. 6)

C120 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. 1Sch. 6 para. 3(2)**Sch. 6 para. 3(3)** (with Sch. 6)

C121 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. 1Sch. 6 para. 3(2)**Sch. 6 para. 3(3)** (with Sch. 6)

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 **[**[F129]sections 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—

(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

F129 Words in s. 48(1) substituted (14.4.1993) by S.I. 1993/834, **reg. 5**

Modifications etc. (not altering text)

C122 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.

(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)
C123 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

F130
49A Special provisions in respect of exporting certain products to member States

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Textual Amendments

F130 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)

[F131 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

F131 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.

[F132, and

(c) to the provisions of the Clinical Trials Regulations and to any authorisation granted or other thing done by virtue of those regulations.**]**

Textual Amendments

F132 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)

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

C125 S. 50 applied (with modifications)(3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

Status:
Point in time view as at 19/07/2006.

Changes to legislation:
Medicines Act 1968, Part II is up to date with all changes known to be in force on or before 22 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.