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.

(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.**]**

[F43(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(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 **[**F44a registered F45... nurse or a registered midwife**]** . . . F46

(2) F47

Textual Amendments

F44 Words substituted by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 7 para. 14**(*a*)

F45 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)**

F46 Words repealed by Nurses, Midwives and Health Visitors Act 1979 (c. 36, SIF 83:1), s. 24(2), **Sch. 8**

F47 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.

[F48(1)**]** **[**F49Subject 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.

F50**[**(2) Section 8(3A) of this Act applies to the exportation, or the sale for exportation, of any product to which **[**F51the 2001 Directive applies**]** apply if it is, or is to be exported to **[**F52an EEA State.**]]**

Textual Amendments
F48 S. 14 renumbered as s. 14(1) (14.4.1993) by S.I. 1993/834, **reg. 4(a)**
F49 Words in s. 14(1) inserted (14.4.1993) by S.I. 1993/834, **reg. 4(a)**
F50 S. 14(2) inserted (14.4.1993) by S.I. 1993/834, **reg. 4(b)**
F51 Words in s. 14(2) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(ii)**
F52 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)**

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Point in time view as at 08/11/2005.

Changes to legislation:
Medicines Act 1968, Cross Heading: General provisions and exemptions is up to date with all changes known to be in force on or before 12 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.