Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

General provisions and exemptions

F1 6 The licensing authority.

. . . . . .

Annotations:

Amendments (Textual)

F1 Ss. 2A-9 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

7 General provisions as to dealing with medicinal products.

. . . . . .

Annotations:

Amendments (Textual)

F1 Ss. 2A-9 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

8 Provisions as to manufacture and wholesale dealing.

. . . . . .

Annotations:

Amendments (Textual)

F1 Ss. 2A-9 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

9 Exemptions for doctors and dentists

. . . . . .

Annotations:

Amendments (Textual)

F1 Ss. 2A-9 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

10 Exemptions for pharmacists.

(1) [F2] ... the restrictions imposed by **[**[F3]regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations**]** do not apply to anything which is done in a registered pharmacy, a hospital **[**[F4] , 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 **[**[F5]an appropriate practitioner**]**, or

(b) assembling a medicinal product **[**[F6]provided that where the assembling takes place in a registered pharmacy—

(i) it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail pharmacy business, and

(ii) the medicinal product has not been the subject of an advertisement**]**;

and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, or of procuring the assembly of a medicinal product.

[F7](2) . . . . . .

(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, [F8] ...

(b) . . . . . .

(4) Without prejudice to the preceding subsections, the restrictions imposed by **[**F9 regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for authorisation) of the 2012 Regulations**]** 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 **[**F10provided 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.

[F11(5) Without prejudice to the preceding subsections, the restrictions imposed by **[**F12 regulation 46 of the 2012 Regulations**]** 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 **[**F13 regulation 17(1) of the 2012 Regulations**]** 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.

F14(6A) . . . . . .

F15(7) . . . . . .

[F16(7A) The F17 ... 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 **[**F18 regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations**]** . **]**

[F19(9) In subsection (1) of this section, "care home service" has the meaning given by **[**F20 paragraph 2 of schedule 12 to the Public Services Reform (Scotland) Act 2010 (asp 8) **]** . **]**

Annotations:

Amendments (Textual)

F2 Words in s. 10(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 10(a)** (with regs. 2(4), 3)

F3 Words in s. 10(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(b)** (with Sch. 32)

F4 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)

F5 Words in s. 10(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(a)** (with Sch. 32)

F6 Words added by S.I. 1971/1445, **art. 3(a)**

F7 S. 10(2) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 10(b)** (with regs. 2(4), 3)

F8 S. 10(3)(b) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 10(c)** (with regs. 2(4), 3)

F9 Words in s. 10(4) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(b)** (with Sch. 32)

F10 Words added by S.I. 1971/1445, **art. 3(b)**

F11 S. 10(5)–(8) added by S.I. 1971/1445, **art. 3(c)**

F12 Words in s. 10(5) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(c)** (with Sch. 32)

F13 Words in s. 10(6) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(d)** (with Sch. 32)

F14 S. 10(6A) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 10(d)** (with regs. 2(4), 3)

F15 S. 10(7) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(e)** Sch. 35 (with Sch. 32)

F16 S. 10(7A)-(7C) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 26(1)**, 83(1)(e)

F17 Word in s. 10(7A) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 10(e)** (with regs. 2(4), 3)

F18 Words in s. 10(8) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 3(f)** (with Sch. 32)

F19 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)

F20 Words in s. 10(9) substituted (28.10.2011) by The Public Services Reform (Scotland) Act 2010 (Consequential Modifications of Enactments) Order 2011 (S.I. 2011/2581), art. 1(2)(b), **Sch. 2 para. 1**

Modifications etc. (not altering text)

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

C2 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**)

[F21]11 Exemption for nurses and midwives.

. . . . . .

Annotations:

Amendments (Textual)

F21 Ss. 11-14 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

12 Exemptions in respect of herbal remedies.

. . . . . .

Annotations:

Amendments (Textual)

F21 Ss. 11-14 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

13 Exemptions for imports.

. . . . . .

Annotations:

Amendments (Textual)

F21 Ss. 11-14 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

14 Exemption for re-exports.

. . . . . .

Annotations:

Amendments (Textual)

F21 Ss. 11-14 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

15 Provision for extending or modifying exemptions.

[F22](1) . . . . . .

(2) . . . . . .

(3) The [F23] ... Ministers may by order provide that any of the provisions of **[**[F24] section 10 **]** 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.

Annotations:

Amendments (Textual)

F22 S. 15(1)(2) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 4(a)** Sch. 35 (with Sch. 32)

F23 Word in s. 15(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 11(b)** (with regs. 2(4), 3)

F24 Words in s. 15(3) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 4(b)** Sch. 35 (with Sch. 32)

Modifications etc. (not altering text)

C3 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403 , **art. 3(1)**

F25 16 Transitional exemptions.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

17 Termination of transitional exemptions.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Applications for, and grant and renewal of, licences

18 Application for licence.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

19 Factors relevant to determination of application for licence.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

20 Grant or refusal of licence.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

21 Procedure on reference to appropriate committee

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

22 Procedure in other cases.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

22A . Hearing before person appointed

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

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

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

24 Duration and renewal of licence.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Licences of right

25 Entitlement to licence of right.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F26 26 Scope of licence of right in different cases.

. . . . . .

Annotations:

Amendments (Textual)

F26 S. 26 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), **Sch. 1 Pt. 17** Group 7

27 Proceedings on application for licence of right.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Suspension, revocation and variation of licences

28 General power to suspend, revoke or vary licences.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

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

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

30 Variation of licence on application of holder.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Clinical trials and medicinal tests on animals

[F27]31 Clinical trials.

. . . . . .

Annotations:

Amendments (Textual)

F27 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**

[F28]32 Medicinal tests on animals.

. . . . . .

Annotations:

Amendments (Textual)

F28 Ss. 32-36 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

33 Exemptions in respect of medicinal tests on animals.

. . . . . .

Annotations:

Amendments (Textual)

F28 Ss. 32-36 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

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

. . . . . .

Annotations:

Amendments (Textual)

F28 Ss. 32-36 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

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

. . . . . .

Annotations:

Amendments (Textual)

F28 Ss. 32-36 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

36 Application for, and issue of, certificate.

. . . . . .

Annotations:

Amendments (Textual)

F28 Ss. 32-36 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

F29 37 Transitional provisions as to clinical trials and medicinal tests on animals.

. . . . . .

Annotations:

Amendments (Textual)

F29 S. 37 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), **Sch. 1 Pt. 17** Group 7

F30 38 Duration and renewal of certificate.

. . . . . .

Annotations:

Amendments (Textual)

F30 Ss. 38-40 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

39 Suspension, revocation or variation of certificate.

. . . . . .

Annotations:

Amendments (Textual)

F30 Ss. 38-40 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

Medicated animal feeding stuffs

40 Medicated animal feeding stuffs.

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Annotations:

Amendments (Textual)

F30 Ss. 38-40 omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 15** (with regs. 2(4), 3)

41–42 . . . . . F31

Annotations:

Amendments (Textual)

F31 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.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

44 Provision of information to licensing authority.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

45 Offences under Part II.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

46 Special defences under s. 45.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

47 Standard provisions for licences

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

48 Postponement of restrictions in relation to exports.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

49 Special provisions in respect of exporting certain products.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F32 49A Special provisions in respect of exporting certain products to member States

. . . . . .

Annotations:

Amendments (Textual)

F32 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)

49B. Special provisions in respect of exporting certain products to EEA State s

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

50 Certificates for exporters of medicinal products.

. . . . . .

Annotations:

Amendments (Textual)

F25 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Changes to legislation:
Medicines Act 1968, Part II is up to date with all changes known to be in force on or before 25 December 2017. 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.

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:
Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 69(1A)(1B) added (prosp.) by 1997 c. 19 s. 1 Sch. para. 5(b)
- s. 80(1A)(1B) inserted by S.I. 2016/372 art. 9(3)
- s. 80(2A) inserted by S.I. 2016/372 art. 9(5)
- s. 82A inserted by S.I. 2016/372 art. 11
- s. 84B inserted by S.I. 2016/372 art. 12