Medicines Act 1968

1968 CHAPTER 67

PART III

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Additional provisions

58 Medicinal products on prescription only.

(1) The **[**F1Ministers**]** may by order specify descriptions or classes of medicinal products **[**F2as prescription only medicines**]**

F3(1A) . . . . . .

F4(1ZA) . . . . . .

F5(1B) . . . . . .

F6(2) . . . . . .

F7(3) . . . . . .

(4) Without prejudice to **[**F8 regulation 223(1) of the 2012 Regulations**]** , any order made by the **[**F9 Ministers **]** for the purposes of this section may provide—

(a) that **[**F10 regulation 214(1) or (2) of the 2012 Regulations**]** shall have effect subject to such exemptions as may be specified in the order **[**F11**[**F12 or, in the case of an appropriate practitioner, other than a doctor or dentist, **]** such modifications as may be so specified **]** ;

(b) that, for the purpose of **[**F13 regulation 214(1) of the 2012 Regulations**]** , a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the order are fulfilled.

[F14(4A) An order under this section may provide, in relation to **[**F15an appropriate practitioner, other than a doctor or dentist**]**, that such a person may—

(a) give a prescription for a medicinal product falling within a description or class specified in the order;

(b) administer any such medicinal product; or

(c) give directions for the administration of any such medicinal product,

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

F14(4B) An order under this section may provide, in relation to a condition specified by virtue of subsection (4A), for the condition to have effect subject to such exemptions as may be specified in the order.

F14(4C) Where a condition is specified by virtue of subsection (4A), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the order by virtue of subsection (4)(a) of this section) given by an appropriate practitioner for the purposes of **[**F16 regulation 214(1) or (2) of the 2012 Regulations**]** . **]**

(5) Any exemption conferred **[**F17or modification made**]** by an order in accordance with subsection (4)(a) of this section may be conferred **[**F18or made**]** subject to such conditions or limitations as may be specified in the order.

(6) Before making an order under this section the **[**F19 Ministers **]** shall consult the appropriate committee F20 ....

[F21(7) In subsection (6) "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.**]**

Textual Amendments

F1 Word in s. 58(1) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 29(a)** (with regs. 2(4), 3)

F2 Words in s. 58(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(a)** (with Sch. 32)

F3 S. 58(1A) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 5(b), **Sch. 35** (with Sch. 32)

F4 S. 58(1ZA) omitted (2.12.2019) by virtue of Children and Social Work Act 2017 (c. 16), s. 70(2), **Sch. 5 para. 2**; S.I. 2019/1436, reg. 2(s)

F5 S. 58(1B) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 29(c)** (with regs. 2(4), 3)

F6 S. 58(2) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 5(b), **Sch. 35** (with Sch. 32)

F7 S. 58(3) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 5(b), **Sch. 35** (with Sch. 32)

F8 Words in s. 58(4) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(c)** (with Sch. 32)

F9 Word in s. 58(4) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 29(e)** (with regs. 2(4), 3)

F10 Words in s. 58(4)(a) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(d)(i)** (with Sch. 32)

F11 Words in s. 58(4)(a) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), **s. 1(2)**; S.I. 1994/2408, **art. 2**

F12 Words in s. 58(4)(a) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(d)(ii)** (with Sch. 32)

F13 Words in s. 58(4)(b) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(e)** (with Sch. 32)

F14 S. 58(4A)-(4C) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, **s. 63(5)**; S.I. 2002/1095, **art. 2(1)**

F15 Words in s. 58(4A) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(f)** (with Sch. 32)

F16 Words in s. 58(4C) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(g)** (with Sch. 32)

F17 Words in s. 58(5) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), **s. 1(3)(a)**; S.I. 1994/2408, **art. 2**

F18 Words in s. 58(5) inserted (3.10.1994) by Medicinal Products: Prescripion by Nurses etc. Act 1992 (c. 28), **s. 1(3)(b)**; S.I. 1994/2408, **art. 2**

F19 Word in s. 58(6) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 29(f)** (with regs. 2(4), 3)

F20 Words in s. 58(6) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 10**

F21 S. 58(7) inserted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 5(h)** (with Sch. 32)

Modifications etc. (not altering text)

C1 Pt. III amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), regs. 1(a), **2(12)**

C2 Ss. 57, 58, 61 extended by S.I. 1984/187, **art. 2**
S. 58 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch. 5**

C3 S. 58 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
S. 58 modified (1.1.1995) by S.I. 1994/3144, **reg. 9(10)**

C4 Ss. 58 58A amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759) , regs. 1(a) , **2(12)**

C5 S. 58(1) restricted (1.1.1995) by S.I. 1994/3144, **reg. 8(4)**

C6 S. 58(6) modified (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 1(2)**

[F22 58A [F23Requirement to specify certain products as prescription-only products]

(1) The F24 ... Ministers shall, subject to subsection (4) of this section, so exercise their powers under section 58(1) of this Act as to secure that every product—

F25(a) . . . . . .

F25(b) . . . . . .

(c) to which subsection (2) of this section applies;

[F26is specified as a prescription only medicine**]**.

(2) This subsection applies to any product which—

(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or

(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or

(c) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation; or

(d) is normally prescribed by a doctor or dentist for parenteral administration.

(3) In considering whether subsection (2) of this section applies to a product the [F27] ... Ministers shall take into account whether the product—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the pro duct is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention); or

(c) is likely, if incorrectly used—

(i) to present a substantial risk of medicinal abuse, or

(ii) to lead to addiction, or

(iii) to be used for illegal purposes; or

(d) contains a substance which, by reason of its novelty or properties, might fall within paragraph (c) above, but as to which there is insufficient information available to determine whether it does so fall; or

(e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital; or

(f) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or

(g) is intended for outpatients but may produce very serious sideeffects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(4) Subsection (1) of this section shall not apply in relation to any product if the [F28] ... Ministers so determine having regard to—

(a) the maximum single dose;

(b) the maximum daily dose;

(c) the strength of the product;

(d) its pharmaceutical form;

(e) its packaging; or

(f) such other circumstances relating to its use as may be specified in the determination.

(5) In this section [F29] ...—

"the Narcotic Drugs Convention" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30th March 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972 [X1] ; and

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971 [X2] . **]**

Editorial Information

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

X2 Cmnd. 7330.

Textual Amendments

F22 S. 58A inserted (1.1.1993) by S.I. 1992/3271 , **regs. 1(1)** , 2

F23 Words in s. 58A heading substituted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30**

F24 Word in s. 58A(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(a)** (with regs. 2(4), 3)

F25 S. 58A(1)(a)(b) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 6(a)** (with Sch. 32)

F26 Words in s. 58A(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 6(b)** (with Sch. 32)

F27 Word in s. 58A(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(b)** (with regs. 2(4), 3)

F28 Word in s. 58A(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(c)** (with regs. 2(4), 3)

F29 Words in s. 58A(5) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(d)** (with regs. 2(4), 3)

Modifications etc. (not altering text)

C4 Ss. 58 58A amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759) , regs. 1(a) , **2(12)**

C7 S. 58A extended (with modifications) (14.2.1994) by S.I. 1994/105 , reg. 19 , **Sch. 4**

C8 S. 58A modified (1.1.1995) by S.I. 1994/3144 , **reg. 9(4)(10)**
S. 58A applied (1.1.1995) by 1994/3142, reg. 18

F30 58B Requirement to specify certain products for veterinary use as prescription-only products.

. . . . . .

Textual Amendments

F30 S. 58B omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 31** (with regs. 2(4), 3)

F31 59 Special provisions in relation to new medicinal products.

. . . . . .

Textual Amendments

F31 Ss. 59-61 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

[F31]60 Restricted sale, supply and administration of certain medicinal products.

. . . . . .

Textual Amendments

F31 Ss. 59-61 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

[F31]61 Special restrictions on persons to be supplied with medicinal products.

. . . . . .

Textual Amendments

F31 Ss. 59-61 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

62 Prohibition of sale or supply, or importation, of medicinal products of specified description [F32] ....

(1) Subject to the following provisions of this section, the [F33] ... Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—

(a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or (in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products;

[F34](b) . . . . . .

(2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.

(3) Before making an order under this section the **[**[F35] Ministers **]** , unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health [F36] ..., shall consult the appropriate committee [F37] ....

(4) Where an order is made under this section without prior consultation with the appropriate committee [F38] ... in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).

(5) If any organisation consulted in pursuance of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the **[**[F39]Ministers**]** of their desire to be heard under this subsection, or have made representations in writing to **[**[F40]the Ministers**]** with respect to that proposal, then before making the order—

(a) if the organisation have given notice of their desire to be heard, the **[**[F39]Ministers**]** shall arrange for them to have an opportunity of appearing before, and being heard by, the **[**[F41]appropriate committee**]**, or

(b) if they have made representations in writing, the **[**F39Ministers**]** shall refer those representations to the **[**F41appropriate committee**]**,

and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report their findings and conclusions to the **[**F39Ministers**]** and **[**F40the Ministers**]** shall take that report into account in determining whether to make the order.

(6) Subsection (5) of this section shall not have effect where in the opinion of the F42 ... Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

[F43(7) If an order is made under this section and either—

(a) the appropriate committee have not considered the proposal to make the order, or

(b) the order is made contrary to the advice of the appropriate committee,

the order shall include a statement of the fact that it has been so made.**]**

[F44(8) In this section "the appropriate committee" means whichever the Ministers consider appropriate of—

(a) the Commission; or

(b) an expert committee appointed by the Ministers, or by one of them acting alone.**]**

Textual Amendments

F32 Words in s. 62 heading omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407) , reg. 1 , **Sch. 8 para. 35(a)** (with regs. 2(4) , 3)

F33 Word in s. 62(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(b)(i)** (with regs. 2(4), 3)

F34 S. 62(1)(b) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(b)(ii)** (with regs. 2(4), 3)

F35 Word in s. 62(3) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(c)(i)** (with regs. 2(4), 3)

F36 Words in s. 62(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(c)(ii)** (with regs. 2(4), 3)

F37 Words in s. 62(3) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(2)**

F38 Words in s. 62(4) omitted (30.10.2005) by virtue of Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(3)**

F39 Word in s. 62(5) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(d)(i)** (with regs. 2(4), 3)

F40 Words in s. 62(5) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(d)(ii)** (with regs. 2(4), 3)

F41 Words in s. 62(5) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(4)**

F42 Word in s. 62(6) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 35(e)** (with regs. 2(4), 3)

F43 S. 62(7) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 12(5)**

F44 S. 62(8) added (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 7** (with Sch. 32)

Modifications etc. (not altering text)

C9 S. 62 extended by S.I. 1984/187, **art. 2**

C10 S. 62 extended with modifications by S.I. 1985/1403, **art. 3(1)**
S. 62 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

C11 S. 62 (1)(*a*), (2)–(7) extended by S.I.s 1982/425, art. 3, 1984/187, art. 2 and extended with modifications by S.I. 1985/1403, **art. 3(1)**

C12 S. 62(3) modified (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 3(2)**

63 Adulteration of medicinal products.

No person shall—

(a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state, or

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

Modifications etc. (not altering text)

C13 Ss. 63–65 extended by S.I. 1984/187, **art. 2**

C14 S. 63 applied (1.1.1995) by S.I 1994/3142, reg. 18(2)

64 Protection of purchasers of medicinal products.

(1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.

(2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.

(3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—

(a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and

(b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.

(5) Where a medicinal product is sold or supplied in pursuance of a prescription given by **[**[F45]an appropriate practitioner**]**, the preceding provisions of this section shall have effect as if—

(a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and

(b) in subsection (1) of this section, for the words “demanded by the purchaser", there were substituted the words “specified in the prescription".

Textual Amendments

F45 Words in s. 64(5) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 8** (with Sch. 32)

Modifications etc. (not altering text)

C15 Ss. 63–65 extended by S.I. 1984/187 , **art. 2**

F46 65 Compliance with standards specified in monographs in certain publications.

. . . . . .

Textual Amendments

F46 Ss. 65, 66 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F46 66 Further powers to regulate dealings with medicinal products.

. . . . . .

Textual Amendments

F46 Ss. 65, 66 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, Cross Heading: Additional provisions is up to date with all changes known to be in force on or before 20 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.
View outstanding changes

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. 1Sch. para. 5(b)
- s. 84B inserted by S.I. 2016/372 art. 12