Medicines Act 1968

1968 CHAPTER 67

PART III

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Modifications etc. (not altering text)

C1 Part III (ss.51-68) modified (1.1.1995) by S.I. 1994/3144, **reg. 9(9)**

C2 Pt. III amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), regs. 1(a), **2(12)**

Provisions as to sale or supply of medicinal products

F1 51 General sale lists.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F1 52 Sale or supply of medicinal products not on general sale list.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F1 53 Sale or supply of medicinal products on general sale list.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F1 54 Sale of medicinal products from automatic machines.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Exemptions from sections 52 and 53

F1 55 Exemptions for doctors and dentists etc

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F1 56 Exemptions in respect of herbal remedies.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

F1 57 Power to extend or modify exemptions.

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Textual Amendments

F1 Ss. 16-57 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

Additional provisions

58 Medicinal products on prescription only.

(1) The **[**F2Ministers**]** may by order specify descriptions or classes of medicinal products **[**F3as prescription only medicines**]**

F4(1A) . . . . . .

F5(1ZA) . . . . . .

F6(1B) . . . . . .

F7(2) . . . . . .

F8(3) . . . . . .

(4) Without prejudice to **[**F9 regulation 223(1) of the 2012 Regulations**]** , any order made by the **[**F10 Ministers **]** for the purposes of this section may provide—

(a) that **[**F11 regulation 214(1) or (2) of the 2012 Regulations**]** shall have effect subject to such exemptions as may be specified in the order **[**F12**[**F13 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 **[**F14 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.

[F15(4A) An order under this section may provide, in relation to **[**F16an 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.

F15(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.

F15(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 **[**F17 regulation 214(1) or (2) of the 2012 Regulations**]** . **]**

(5) Any exemption conferred **[**F18or modification made**]** by an order in accordance with subsection (4)(a) of this section may be conferred **[**F19or made**]** subject to such conditions or limitations as may be specified in the order.

(6) Before making an order under this section the **[**F20 Ministers **]** shall consult the appropriate committee F21 ....

[F22(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

F2 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)

F3 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)

F4 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)

F5 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)

F6 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)

F7 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)

F8 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)

F9 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)

F10 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)

F11 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)

F12 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**

F13 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)

F14 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)

F15 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)**

F16 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)

F17 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)

F18 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**

F19 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**

F20 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)

F21 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**

F22 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)

C3 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**

C4 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)**
C5 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)**
C6 S. 58(1) restricted (1.1.1995) by S.I. 1994/3144, **reg. 8(4)**
C7 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)**

[F23 58A [F24Requirement to specify certain products as prescription-only products]

(1) The F25 ... 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—

F26(a) . . . . . .

F26(b) . . . . . .

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

[F27is 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 F28 ... 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 [F29] ... 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 [F30] ...—

"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

F23 S. 58A inserted (1.1.1993) by S.I. 1992/3271 , **regs. 1(1)** , 2
F24 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**
F25 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)
F26 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)
F27 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)
F28 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)
F29 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)
F30 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)

C5 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)**
C8 S. 58A extended (with modifications) (14.2.1994) by S.I. 1994/105 , reg. 19 , **Sch. 4**
C9 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

[F31]58B Requirement to specify certain products for veterinary use as prescription-only products.

. . . . . .

Textual Amendments

F31 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)

[F32]59 Special provisions in relation to new medicinal products.

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Textual Amendments

F32 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)

[F32]60 Restricted sale, supply and administration of certain medicinal products.

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Textual Amendments

F32 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)

[F32]61 Special restrictions on persons to be supplied with medicinal products.

. . . . . .

Textual Amendments

F32 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 [F33] ....

(1) Subject to the following provisions of this section, the [F34] ... 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;

[F35](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 **[**F36 Ministers **]** , unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health F37 ..., shall consult the appropriate committee F38 ....

(4) Where an order is made under this section without prior consultation with the appropriate committee F39 ... 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 **[**F40Ministers**]** of their desire to be heard under this subsection, or have made representations in writing to **[**F41the 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 **[**F40Ministers**]** shall arrange for them to have an opportunity of appearing before, and being heard by, the **[**F42appropriate committee**]**, or

(b) if they have made representations in writing, the **[**F40Ministers**]** shall refer those representations to the **[**F42appropriate 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 **[**F40Ministers**]** and **[**F41the 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 F43 ... Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

[F44(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.**]**

[F45(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

F33 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)

F34 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)

F35 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)

F36 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)
F37 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)
F38 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)**
F39 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)**
F40 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)
F41 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)
F42 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)**
F43 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)
F44 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)**
F45 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)
C10 S. 62 extended by S.I. 1984/187, **art. 2**
C11 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)**
C12 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)**
C13 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)
C14 Ss. 63–65 extended by S.I. 1984/187, **art. 2**
C15 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 **[**F46an 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

F46 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)

C16 Ss. 63–65 extended by S.I. 1984/187 , **art. 2**

F47 65 Compliance with standards specified in monographs in certain publications.

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Textual Amendments

F47 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)

F47 66 Further powers to regulate dealings with medicinal products.

. . . . . .

Textual Amendments

F47 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)

Offences, and provision for disqualification

67 Offences under Part III.

(1) The following provisions of this section shall have effect subject to sections 121 and 122 of this Act.

[F48(1A) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an order under section 58 of this Act by virtue of subsection (4A) of that section shall be guilty of an offence.

(1B) Any person who—

(a) is an appropriate practitioner **[**F49 within the meaning of regulation 214 of the 2012 Regulations**]** ; and

(b) gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner,

shall be guilty of an offence.**]**

(2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections **[**F50 63 and 64**]**, or who contravenes F51... any order made under section 62 of this Act, shall be guilty of an offence.

(3) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 62 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.

F52(3A) . . . . . .

(4) Any person guilty of an offence under **[**F53 subsection (1A), (1B), (2) or (3)**]** 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.

F54(5) . . . . . .

F54(6) . . . . . .

Textual Amendments

F48 S. 67(1A)(1B) inserted (6.3.2002 for certain purposes and 1.4.2002 otherwise) by 2001 c. 15, **s. 63(7)(a)** (with ss. 64(9), 65(4)); S.I. 2002/1095, **art. 2(1)** (with transitional provisions in art. 3)

F49 Words in s. 67(1B)(a) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(2)** (with Sch. 32)

F50 Words in s. 67(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(3)(a)** (with Sch. 32)
F51 Words in s. 67(2) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(3)(b)** (with Sch. 32)
F52 S. 67(3A) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 9(4), **Sch. 35** (with Sch. 32)
F53 Words in s. 67(4) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 9(5)** (with Sch. 32)
F54 S. 67(5)(6) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 9(6), **Sch. 35** (with Sch. 32)

Modifications etc. (not altering text)
C17 S. 67 extended by S.I.s 1982/425, art. 3, 1984/187, art. 2 and extended with modifications by S.I. 1985/1403, **art. 3(1)**
S. 67 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
S. 67 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch. 5**

[F55 67A. Defence to offence of contravening section 63(a) or (b): product not sold or supplied

(1) This section applies in a case where—
(a) a person ("the defendant") is charged with an offence under section 67(2) of contravening section 63(a) or (b) in respect of a medicinal product; and
(b) the product is not sold or supplied in its adulterated state.

(2) Where the defendant is charged with contravening section 63(a), it is a defence for the defendant to prove that—
[F56(a) the adulteration took place—
(i) at a registered pharmacy, or
(ii) in the course of the provision of a relevant pharmacy service;**]**
(b) the defendant—
(i) was a registrant acting in the course of his or her profession, or
(ii) was acting under the supervision of a person who was a registrant acting in the course of his or her profession; and
(c) at the time of the alleged contravention, the defendant did not know that the product was being adulterated.

(3) Where the defendant is charged with contravening section 63(b), it is a defence for the defendant to prove that—
[F57(a) the adulteration took place—
(i) at a registered pharmacy, or
(ii) in the course of the provision of a relevant pharmacy service;**]**
(b) the person who adulterated the product—
(i) was a registrant acting in the course of his or her profession, or
(ii) was acting under the supervision of a person who was a registrant acting in the course of his or her profession; and
(c) at the time of the alleged contravention, the defendant did not know that the product had been adulterated.

Textual Amendments

F55 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F56 S. 67A(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **5(2)** (with art. 3); S.I. 2022/1024, art. 2

F57 S. 67A(3)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **5(3)** (with art. 3); S.I. 2022/1024, art. 2

67B. Defence to offence of contravening section 63(a) or (b): product sold or supplied

(1) This section applies in a case where—

(a) a person ("the defendant") is charged with an offence under section 67(2) of contravening section 63(a) or (b) in respect of a medicinal product; and

(b) the product was sold or supplied in its adulterated state.

(2) It is a defence for the defendant to prove that—

[F58(a) the adulteration took place—

(i) at a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the person who adulterated the product—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person ("the supervising registrant") who was a registrant acting in the course of his or her profession;

(c) the product was—

(i) sold or supplied in pursuance of a prescription or directions given by a relevant prescriber or a patient group direction, or

(ii) a prescription only medicine that was sold or supplied in circumstances where there was an immediate need for it to be sold or supplied and a prescription could not have been obtained without undue delay; and

(d) Condition A or B is met.

(3) Condition A is that before the defendant was charged—

(a) the defendant did not know that the product had been adulterated; and

(b) if the defendant is a person within subsection (4), neither the person who adulterated the product nor (in a case within subsection (2)(b)(ii)) the supervising registrant knew that the product had been adulterated.

(4) A defendant is a person within this subsection if the defendant is any of the following—

(a) the person who adulterated the product;

(b) (in a case within subsection (2)(b)(ii)) the supervising registrant;

(c) the person carrying on the retail pharmacy business **[**F59, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied.

(5) Condition B is that—

(a) before the defendant was charged, an appropriate person, on becoming aware that the product had been adulterated—

(i) promptly ensured that all reasonable steps were taken to ensure that the person to whom the product was intended to be administered was notified that the product had been adulterated, or

(ii) reasonably formed the view that it was not necessary or appropriate to do so, in the circumstances of the case; and

(b) the defendant did not know at the time that the product was sold or supplied that it had been adulterated.

(6) In subsection (5), "appropriate person" means any of the following—

(a) the person who adulterated the product or (in a case within subsection (2)(b)(ii)) the supervising registrant;

(b) the person carrying on the retail pharmacy business **[**F60, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied, or any person acting on that person's behalf.

Textual Amendments

F55 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F58 S. 67B(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(2)** (with art. 3); S.I. 2022/1024, art. 2

F59 Words in s. 67B(4)(c) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(3)** (with art. 3); S.I. 2022/1024, art. 2

F60 Words in s. 67B(6)(b) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **6(4)** (with art. 3); S.I. 2022/1024, art. 2

67C. Defence to offence of contravening section 64

(1) This section applies in a case where a person ("the defendant") is charged with an offence under section 67(2) of contravening section 64 in respect of a medicinal product.

(2) It is a defence for the defendant to prove that—

[F61(a) the product was dispensed—

(i) at or from a registered pharmacy, or

(ii) in the course of the provision of a relevant pharmacy service;**]**

(b) the person who dispensed the product—

(i) was a registrant acting in the course of his or her profession, or

(ii) was acting under the supervision of a person ("the supervising registrant") who was a registrant acting in the course of his or her profession;

(c) the product was—

(i) sold or supplied in pursuance of a prescription or directions given by a relevant prescriber or a patient group direction, or

(ii) a prescription only medicine that was sold or supplied in circumstances where there was an immediate need for it to be sold or supplied and a prescription could not have been obtained without undue delay; and

(d) Condition A or B is met.

(3) Condition A is that before the defendant was charged—

(a) the defendant did not know that the product was not of the required nature or quality; and

(b) if the defendant is a person within subsection (4), neither the person who dispensed the product nor (in a case within subsection (2)(b)(ii)) the supervising registrant knew that the product was not of the required nature or quality.

(4) A defendant is a person within this subsection if the defendant is any of the following—

(a) the person who dispensed the product;

(b) (in a case within subsection (2)(b)(ii)) the supervising registrant;

(c) the person carrying on the retail pharmacy business **[**F62, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied.

(5) Condition B is that—

(a) before the defendant was charged, an appropriate person, on becoming aware that the product was not of the required nature or quality—

(i) promptly ensured that all reasonable steps were taken to ensure that the person to whom the product was intended to be administered was notified that the product was not of the required nature or quality, or

(ii) reasonably formed the view that it was not necessary or appropriate to do so, in the circumstances of the case; and

(b) the defendant did not know at the time the product was sold or supplied that it was not of the required nature or quality.

(6) In subsection (5), "appropriate person" means any of the following—

(a) the person who dispensed the product or (in a case within subsection (2)(b)(ii)) the supervising registrant;

(b) the person carrying on the retail pharmacy business **[**F63, or the relevant pharmacy service,**]** in the course of which the product was sold or supplied, or any person acting on that person's behalf.

(7) In this section, "the required nature or quality", in relation to a product, means—

(a) where the product is sold or supplied in pursuance of a prescription, the nature or quality specified in the prescription; or

(b) in any other case, the nature or quality demanded by the purchaser of the product.

Textual Amendments

F55 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F61 S. 67C(2)(a) substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(2)** (with art. 3); S.I. 2022/1024, art. 2

F62 Words in s. 67C(4)(c) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(3)** (with art. 3); S.I. 2022/1024, art. 2

F63 Words in s. 67C(6)(b) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **7(4)** (with art. 3); S.I. 2022/1024, art. 2

67D. Defences under sections 67A, 67B and 67C: evidence etc.

(1) This section applies for the purposes of sections 67A to 67C.

(2) If evidence is adduced that is sufficient to raise an issue with respect to the doing of an act by a person in the course of his or her profession, the court must assume that the person did that act in the course of his or her profession unless the prosecution proves the contrary beyond reasonable doubt.

(3) The court must assume that the prosecution has proved the contrary beyond reasonable doubt if the prosecution proves beyond reasonable doubt that, in doing that act—

(a) the person used his or her professional skills for an improper purpose; or

(b) the person deliberately failed to have due regard for patient safety.

(4) Proof that a registrant failed to comply with a procedure established in relation to a registered pharmacy **[**F64or a relevant pharmacy service**]** does not of itself constitute proof that the registrant was not acting in the course of his or her profession.

(5) Knowledge acquired after a product is sold or supplied does not count if it is acquired only as a result of an investigation into whether an offence has been committed in respect of a product.

(6) If evidence is adduced that is sufficient to raise an issue with respect to doing of an act promptly, the court must assume that the act was done promptly unless the prosecution proves the contrary beyond reasonable doubt.

(7) A medicinal product is taken to be sold or supplied to a person in pursuance of a prescription or direction even if that person is not the person for whom it was dispensed in pursuance of the prescription or direction.

Textual Amendments

F55 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F64 Words in s. 67D(4) inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **8** (with art. 3); S.I. 2022/1024, art. 2

67E. Sections 67A to 67D: [F65"adulteration" and "registrant"]

In sections 67A to 67D—

"adulteration", in relation to a medicinal product, means the addition of a substance to, or the abstraction of a substance from, the product, so as to affect injuriously its composition (and related expressions are to be construed accordingly);

"registrant" means—

(a) where it is alleged that the offence in question took place in Great Britain, a person who is entered in Part 1, **[**[F66]or 2**]** of the register of pharmacists and pharmacy technicians established and maintained under article 19 of the Pharmacy Order 2010 (SI 2010/231); or

(b) where it is alleged that the offence in question took place in Northern Ireland, a person registered in the register of pharmaceutical chemists for Northern Ireland [F67]... maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 (SI 1976/1213 (NI 22)).**]**

Textual Amendments

F55 Ss. 67A-67E inserted (16.4.2018) by The Pharmacy (Preparation and Dispensing Errors Registered Pharmacies) Order 2018 (S.I. 2018/181), arts. 1(3), **4** (with art. 2); S.I. 2018/402, art. 2

F65 Words in s. 67E heading substituted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **9(2)** (with art. 3); S.I. 2022/1024, art. 2

F66 Words in s. 67E substituted (31.12.2020) by The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 3(a)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

F67 Words in s. 67E omitted (31.12.2020) by virtue of The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/593), reg. 1(2), **Sch. 2 para. 3(b)** (with reg. 12A, Sch. 2 Pt. 2) (as amended by S.I. 2020/1394, regs. 4, 10(3)-(7)); 2020 c. 1, Sch. 5 para. 1(1)

[[F68]67F Sections 67A to 67D: "relevant pharmacy service"

(1) For the purposes of sections 67A to 67D a pharmacy service is a relevant pharmacy service if conditions A and B are met in respect of it.

(2) Condition A is met in respect of a pharmacy service if—

(a) the service is provided in England by a person in the course of carrying on a regulated activity in respect of which the person is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008;

(b) the service is provided in Wales—

(i) in the course of the business of a hospital,

(ii) in a prison or youth detention accommodation within the meaning of sections 185 to 187 of the Social Services and Well-being (Wales) Act 2014 (anaw 4) (see section 188 of that Act),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act),

(iv) by a person in the course of carrying on or managing an establishment in respect of which the person is registered under Part 2 of the Care Standards Act 2000, or

(v) by a person in the course of providing a regulated service in respect of which the person is registered under Chapter 2 of Part 1 of the Regulation and Inspection of Social Care (Wales) Act 2016 (anaw 2);

(c) the service is provided in Scotland—

(i) in the course of the business of a hospital,

(ii) in a prison within the meaning of section 49C of the Criminal Law (Consolidation) (Scotland) Act 1995 (see subsection (7) of that section),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act),

(iv) by a person in the course of providing an independent health care service which is registered under section 10P of the National Health Service (Scotland) Act 1978, or

(v) by a person in the course of carrying on a care service which is registered under Chapter 3 of Part 5 of the Public Services Reform (Scotland) Act 2010 (asp 8); or

(d) the service is provided in Northern Ireland—

(i) in the course of the business of a hospital,

(ii) in a prison or other institution for the treatment of offenders, including a place mentioned in section 2 of the Treatment of Offenders Act (Northern Ireland) 1968 (c. 29 (N.I.)) and a juvenile justice centre within the meaning of the Criminal Justice (Children) (Northern Ireland) Order 1998 (S.I. 1998/1504 (N.I. 9)) (see Article 51(1) of that Order),

(iii) in a removal centre, short-term holding facility or pre-departure accommodation within the meaning of Part 8 of the Immigration and Asylum Act 1999 (see section 147 of that Act), or

(iv) by a person in the course of carrying on or managing an establishment in respect of which the person is registered under Part 3 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (S.I. 2003/431 (N.I. 9)).

(3) Condition B is met in respect of a pharmacy service if it has a chief pharmacist.

(4) A chief pharmacist, in relation to a pharmacy service, is a pharmacist who—

(a) plays a significant role (irrespective of whether other individuals also do so) in—

(i) the making of decisions about how the whole or a substantial part of the activities of the pharmacy service are to be managed or organised, or

(ii) the actual managing or organising of the whole or a substantial part of those activities,

(b) has the authority to make decisions that affect the running of the pharmacy service so far as concerns the sale or supply of medicinal products, and

(c) is responsible for securing that the pharmacy service is carried on safely and effectively.

(5) For the purposes of subsection (4)(c) a pharmacy service is carried on safely and effectively if it is carried on in ways that ensure its safe and effective running so far as concerns the sale or supply of medicinal products.**]**

Textual Amendments

F68 S. 67F inserted (1.12.2022) by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 (S.I. 2022/851), arts. 1(3), **9(1)** (with art. 3); S.I. 2022/1024, art. 2

F69 68 Disqualification on conviction of certain offences.

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Textual Amendments

F69 S. 68 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 III is up to date with all changes known to be in force on or before 21 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