



# Medicines Act 1968

## 1968 CHAPTER 67

An Act to make new provision with respect to medicinal products and related matters,  
and for purposes connected therewith. [25th October 1968]

### Modifications etc. (not altering text)

- C1** References to Ministers of Northern Ireland to be construed as references to heads of Northern Ireland departments: [Northern Ireland Constitution Act 1973 \(c. 36\)](#), [Sch. 5 para. 7](#)
- C2** Functions of Ministry of Home Affairs for Northern Ireland transferred to Department of Health and Social Services for Northern Ireland by S.R. & O. (N.I.) 1973 No. 504, [art. 5](#), [Sch. 2 Pt. I](#)
- C3** Functions exercisable by Ministers jointly under this Act (except s. 108(4)(7) now exercisable by those Ministers and Secretary of State for Wales jointly: [S.I. 1978/272](#), [art. 2\(3\)](#), [Sch. 1](#); references to Minister of Agriculture, Fisheries and Food amended (W.): *ibid.*, [art. 11\(6\)](#)
- C4** Act restricted by [S.I. 1985/273](#), [reg. 3\(3\)](#)
- C5** Act amended (N.I.) (1.4.1992) by [S.I. 1991/194 \(N.I. 1\)](#), [art. 7\(2\)](#), [Sch. 2 para. 5\(1\)](#); S.R. 1991/131, [art. 2\(e\)](#), [Sch. Pt. III](#)
- C6** Certain provisions of the Act extended and modified (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)
- C7** Act excluded in part (6.5.1998) by [S.I. 1998/1046](#), [reg. 43](#)  
Act excluded in part (6.5.1998) by [S.I. 1998/1047](#), [reg. 74](#)  
Act excluded in part (2.8.1999) by [S.I. 1999/1871](#), [reg. 92\(1\)](#)
- C8** Act: functions transferred (27.12.1999) by [S.I. 1999/3142](#), [art. 2\(1\)\(2\)](#) (with [art. 4](#))  
Act: functions transferred (27.3.2002) by [S.I. 2002/794](#), [art. 3\(1\)\(c\)\(2\)\(7\)](#) (with [art. 6](#))
- C9** Act excluded (30.10.2005) by [The Veterinary Medicines Regulations 2005 \(S.I. 2005/2745\)](#), [reg. 44\(1\)](#)
- C10** Act amendment to earlier affecting provision SI 1994/3144 reg. 10 Sch. 4 para. 10(b) (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 11\(b\)](#) (with [regs. 2\(4\), 3](#))
- C11** Act amendment to earlier affecting provision SI 1994/3144 reg. 10 Sch. 4 para. 9(b) (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 11\(a\)](#) (with [regs. 2\(4\), 3](#))

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**PART I**

**ADMINISTRATION**

**Modifications etc. (not altering text)**

**C12** Pt. I (ss. 1-5) modified (3.4.1992) by [S.I. 1992/605](#), **regs. 2(3)**, 3

**[<sup>F1</sup> 1 Ministers responsible for administration of Act.**

In this Act, “the Ministers” has the meaning given by regulation [6\(6\)](#) to (8) of the 2012 Regulations (but as if references in that regulation to those Regulations were references to this Act). ]

**Textual Amendments**

**F1** S. 1 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#) , **reg. 1(2)** , **Sch. 34 para. 2** (with [Sch. 32](#) )

**Modifications etc. (not altering text)**

**C13** Pt. I(ss. 1–5) extended by [S.I. 1984/187](#), **art. 2**  
**C14** S. 1 extended (3.4.1992) by [S.I. 1992/605](#), **regs. 2(4)**, 3

**<sup>F2</sup> 2 Establishment of Medicines Commission.**

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**Textual Amendments**

**F2** S. 2 repealed (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), **regs. 1(1)**, **2(2)**

**<sup>F3</sup> 2A. Establishment of the Commission on Human Medicines**

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**Textual Amendments**

**F3** 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](#))

**<sup>F3</sup> 3 Functions of the Commission**

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**Textual Amendments**

**F3** 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](#))

**F<sup>3</sup>4** **Establishment of committees.**

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**Textual Amendments**

**F3** 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](#))

**F<sup>3</sup>5** **Supplementary provisions as to Commission and committees.**

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**Textual Amendments**

**F3** 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](#))

**PART II**

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

*General provisions and exemptions*

**F<sup>3</sup>6** **The licensing authority.**

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**Textual Amendments**

**F3** 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](#))

**F<sup>3</sup>7** **General provisions as to dealing with medicinal products.**

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**Textual Amendments**

**F3** 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](#))

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**F3 8 Provisions as to manufacture and wholesale dealing.**

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**Textual Amendments**  
**F3** 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](#))

**F3 9 Exemptions for doctors and dentists**

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**Textual Amendments**  
**F3** 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) <sup>F4</sup> ... The restrictions imposed by [<sup>F5</sup>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 [<sup>F6</sup>, 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 [<sup>F7</sup>an appropriate practitioner], or
- (b) assembling a medicinal product [<sup>F8</sup>provided that where the assembling takes place in a registered pharmacy—
  - (i) it shall be in a registered pharmacy at [<sup>F9</sup>or from] 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 [<sup>F9</sup>or from] that registered pharmacy or at [<sup>F9</sup>or from] 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.

<sup>F10</sup>(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, <sup>F11</sup> ...

<sup>F11</sup>(b) .....

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(4) Without prejudice to the preceding subsections, the restrictions imposed by [F<sup>12</sup>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 [F<sup>13</sup>provided 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 [F<sup>14</sup>or from] that registered pharmacy or at [F<sup>14</sup>or from] 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.

[F<sup>15</sup>(5) Without prejudice to the preceding subsections, the restrictions imposed by [F<sup>16</sup>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 [F<sup>17</sup>or from] 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 [F<sup>18</sup>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 [F<sup>19</sup>or from] that registered pharmacy.

F<sup>20</sup>(6A) .....

F<sup>21</sup>(7) .....

[ The F<sup>23</sup> ... Ministers may make regulations prescribing conditions which must be F<sup>22</sup>(7A) 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.]

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- (8) For the purposes of this section “advertisement” shall have the meaning assigned to it by <sup>F24</sup>regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations].]
- <sup>F25</sup>(9) In subsection (1) of this section, “care home service” has the meaning given by <sup>F26</sup>paragraph 2 of schedule 12 to the Public Services Reform (Scotland) Act 2010 (asp 8) ]. ]

#### Textual Amendments

- F4** 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)
- 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(b)** (with Sch. 32)
- F6** 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)
- F7** 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)
- F8** Words added by S.I. 1971/1445, **art. 3(a)**
- F9** Words in s. 10(1)(b)(i) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 2(a)**; S.I. 2022/1023, art. 2
- F10** 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)
- F11** 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)
- F12** 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)
- F13** Words added by S.I. 1971/1445, **art. 3(b)**
- F14** Words in s. 10(4)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 2(b)**; S.I. 2022/1023, art. 2
- F15** S. 10(5)–(8) added by S.I. 1971/1445, **art. 3(c)**
- F16** 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)
- F17** Words in s. 10(5)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 2(c)**; S.I. 2022/1023, art. 2
- F18** 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)
- F19** Words in s. 10(6) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 2(d)**; S.I. 2022/1023, art. 2
- F20** 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)
- F21** S. 10(7) repealed (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)
- F22** S. 10(7A)–(7C) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 26(1)**, 83(1) (e)
- F23** 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)
- F24** 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)
- F25** 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)

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**F26** 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)**

**C15** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**

**C16** S. 10 amended (E.W.S.) (*prosp*) by [1954 c. 61](#), **s. 131(1)(b)** (as inserted (*prosp.*) by [1997 c. 19](#), ss. 1, 2(1), **Sch. para. 2**)

**F27** **11 Exemption for nurses and midwives.**

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**Textual Amendments**

**F27** 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**)

**F27** **12 Exemptions in respect of herbal remedies.**

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**Textual Amendments**

**F27** 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**)

**F27** **13 Exemptions for imports.**

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**Textual Amendments**

**F27** 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**)

**F27** **14 Exemption for re-exports.**

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**Textual Amendments**

**F27** 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.**

**F28** (1) .....

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<sup>F28</sup>(2) .....

(3) The <sup>F29</sup> ... Ministers may by order provide that any of the provisions of [<sup>F30</sup> 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.

**Textual Amendments**

**F28** S. 15(1)(2) repealed (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](#))

**F29** 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](#))

**F30** 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)**

**C17** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#) , [art. 3\(1\)](#)

<sup>F31</sup>**16 Transitional exemptions.**

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**Textual Amendments**

**F31** 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](#))

<sup>F31</sup>**17 Termination of transitional exemptions.**

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**Textual Amendments**

**F31** 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*

<sup>F31</sup>**18 Application for licence.**

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**Textual Amendments**

**F31** 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](#))

**F31 19 Factors relevant to determination of application for licence.**

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**Textual Amendments**

**F31** 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](#))

**F31 20 Grant or refusal of licence.**

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**Textual Amendments**

**F31** 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](#))

**F31 21 Procedure on reference to appropriate committee**

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**Textual Amendments**

**F31** 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](#))

**F31 22 Procedure in other cases.**

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**Textual Amendments**

**F31** 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](#))

**F31 22A Hearing before person appointed**

**22A .**

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**Textual Amendments**

**F31** 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](#))

**F31 23 Special provisions as to effect of manufacturer’s licence.**

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**Textual Amendments**

**F31** 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](#))

**F31 24 Duration and renewal of licence.**

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**Textual Amendments**

**F31** 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*

**F31 25 Entitlement to licence of right.**

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**Textual Amendments**

**F31** 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 26 Scope of licence of right in different cases.**

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**Textual Amendments**

**F32** S. 26 repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), [Sch. 1 Pt. 17](#) Group 7

**F31 27 Proceedings on application for licence of right.**

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**Textual Amendments**

**F31** 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*

**F31 28** **General power to suspend, revoke or vary licences.**

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**Textual Amendments**

**F31** 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](#))

**F31 29** **Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28.**

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**Textual Amendments**

**F31** 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](#))

**F31 30** **Variation of licence on application of holder.**

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**Textual Amendments**

**F31** 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*

**F33 31** **Clinical trials.**

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**Textual Amendments**

**F33** 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](#)

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**F34 32 Medicinal tests on animals.**

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**Textual Amendments**  
**F34** 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)

**F34 33 Exemptions in respect of medicinal tests on animals.**

.....

**Textual Amendments**  
**F34** 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)

**F34 34 Restrictions as to animals on which medicinal tests have been carried out.**

.....

**Textual Amendments**  
**F34** 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)

**F34 35 Supplementary provisions as to clinical trials and medicinal tests on animals.**

.....

**Textual Amendments**  
**F34** 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)

**F34 36 Application for, and issue of, certificate.**

.....

**Textual Amendments**  
**F34** 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)

**F35 37 Transitional provisions as to clinical trials and medicinal tests on animals.**

.....

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**Textual Amendments**

**F35** S. 37 repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), [Sch. 1 Pt. 17](#) Group 7

**F36** **38 Duration and renewal of certificate.**

.....

**Textual Amendments**

**F36** 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](#))

**F36** **39 Suspension, revocation or variation of certificate.**

.....

**Textual Amendments**

**F36** 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*

**F36** **40 Medicated animal feeding stuffs.**

.....

**Textual Amendments**

**F36** 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** ..... **F37**

**Textual Amendments**

**F37** 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*

**F31** **43 Extension of s. 7 to certain special circumstances.**

.....

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**Textual Amendments**

**F31** 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](#))

**F31 44 Provision of information to licensing authority.**

.....

**Textual Amendments**

**F31** 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](#))

**F31 45 Offences under Part II.**

.....

**Textual Amendments**

**F31** 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](#))

**F31 46 Special defences under s. 45.**

.....

**Textual Amendments**

**F31** 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](#))

**F31 47 Standard provisions for licences**

.....

**Textual Amendments**

**F31** 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](#))

**F31 48 Postponement of restrictions in relation to exports.**

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**Textual Amendments**

**F31** 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](#))

**<sup>F31</sup>49 Special provisions in respect of exporting certain products.**

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.....

**Textual Amendments**

**F31** 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](#))

**<sup>F38</sup>49A Special provisions in respect of exporting certain products to member States**

.....

.....

**Textual Amendments**

**F38** 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](#))

**<sup>F31</sup>49B. Special provisions in respect of exporting certain products to EEA State s**

.....

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**Textual Amendments**

**F31** 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](#))

**<sup>F31</sup>50 Certificates for exporters of medicinal products.**

.....

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**Textual Amendments**

**F31** 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](#))

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## PART III

### FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

#### Modifications etc. (not altering text)

- C18** Part III (ss.51-68) modified (1.1.1995) by [S.I. 1994/3144, reg. 9\(9\)](#)
- C19** 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*

#### <sup>F31</sup>**51** General sale lists.

.....

#### Textual Amendments

- F31** 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](#))

#### <sup>F31</sup>**52** Sale or supply of medicinal products not on general sale list.

.....

#### Textual Amendments

- F31** 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](#))

#### <sup>F31</sup>**53** Sale or supply of medicinal products on general sale list.

.....

#### Textual Amendments

- F31** 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](#))

#### <sup>F31</sup>**54** Sale of medicinal products from automatic machines.

.....

#### Textual Amendments

- F31** 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](#))



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*Exemptions from sections 52 and 53*

**F3155 Exemptions for doctors and dentists etc**

.....

**Textual Amendments**

**F31** 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](#))

**F3156 Exemptions in respect of herbal remedies.**

.....

**Textual Amendments**

**F31** 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](#))

**F3157 Power to extend or modify exemptions.**

.....

**Textual Amendments**

**F31** 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 [<sup>F39</sup>Ministers] may by order specify descriptions or classes of medicinal products [<sup>F40</sup>as prescription only medicines]

<sup>F41</sup>(1A) .....

<sup>F42</sup>(1ZA) .....

<sup>F43</sup>(1B) .....

<sup>F44</sup>(2) .....

<sup>F45</sup>(3) .....

(4) Without prejudice to [<sup>F46</sup> regulation 223(1) of the 2012 Regulations], any order made by the [<sup>F47</sup> Ministers ] for the purposes of this section may provide—

(a) that [<sup>F48</sup> regulation 214(1) or (2) of the 2012 Regulations] shall have effect subject to such exemptions as may be specified in the order [<sup>F49</sup>[<sup>F50</sup> or, in

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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 [<sup>F51</sup> 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.

[<sup>F52</sup>(4A) An order under this section may provide, in relation to [<sup>F53</sup>an 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.

<sup>F52</sup>( 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.

<sup>F52</sup>( 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 [<sup>F54</sup> regulation 214(1) or (2) of the 2012 Regulations] . ]

- (5) Any exemption conferred [<sup>F55</sup>or modification made] by an order in accordance with subsection (4)(a) of this section may be conferred [<sup>F56</sup>or made] subject to such conditions or limitations as may be specified in the order.

( 6 ) Before making an order under this section the [<sup>F57</sup> Ministers ] shall consult the appropriate committee <sup>F58</sup> ....

[<sup>F59</sup>(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

- F39** 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)
- F40** 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)
- F41** 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)
- F42** 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)
- F43** 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)
- F44** 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)

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- F45** 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)
- F46** 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)
- F47** 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)
- F48** 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)
- F49** 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**
- F50** 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)
- F51** 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)
- F52** 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)**
- F53** 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)
- F54** 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)
- F55** 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**
- F56** Words in s. 58(5) inserted (3.10.1994) by Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), s. **1(3)(b)**; S.I. 1994/2408, art. **2**
- F57** 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)
- F58** 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**
- F59** 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)**

- C20** 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**
- C21** 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)**
- C22** 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)**
- C23** S. 58(1) restricted (1.1.1995) by S.I. 1994/3144, reg. **8(4)**
- C24** 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)**

[<sup>F60</sup> **58A** [<sup>F61</sup> **Requirement to specify certain products as prescription-only products**]

- (1) The <sup>F62</sup> ... 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—
  - <sup>F63</sup>(a) .....
  - <sup>F63</sup>(b) .....
  - (c) to which subsection (2) of this section applies;  
[<sup>F64</sup>is specified as a prescription only medicine].
- (2) This subsection applies to any product which—

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- (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 <sup>F65</sup> ... 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 product 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 <sup>F66</sup> ... 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 <sup>F67</sup> ...—

“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 <sup>X1</sup>; and

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“the Psychotropic Substances Convention” means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971<sup>X2</sup>. ]

#### Editorial Information

- X1** The Convention, as amended by the Protocol, is published as Cmnd. 7466.  
**X2** Cmnd. 7330.

#### Textual Amendments

- F60** S. 58A inserted (1.1.1993) by [S.I. 1992/3271](#), [regs. 1\(1\)](#), 2  
**F61** 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](#)  
**F62** 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)  
**F63** 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](#))  
**F64** 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](#))  
**F65** 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)  
**F66** 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)  
**F67** 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)

- C22** 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\(12\)](#)  
**C25** S. 58A extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
**C26** 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](#)

<sup>F68</sup>**58B Requirement to specify certain products for veterinary use as prescription-only products.**

#### Textual Amendments

- F68** 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)

<sup>F69</sup>**59 Special provisions in relation to new medicinal products.**

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**Textual Amendments**

**F69** 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](#))

**F69 60 Restricted sale, supply and administration of certain medicinal products.**

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**Textual Amendments**

**F69** 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](#))

**F69 61 Special restrictions on persons to be supplied with medicinal products.**

.....

**Textual Amendments**

**F69** 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 <sup>F70</sup> ....**

- (1) Subject to the following provisions of this section, the <sup>F71</sup> ... 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;
  - <sup>F72</sup>(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 [<sup>F73</sup> Ministers ], unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health <sup>F74</sup> ..., shall consult the appropriate committee <sup>F75</sup> ....
- (4) Where an order is made under this section without prior consultation with the appropriate committee <sup>F76</sup> ... 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).

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(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 [<sup>F77</sup>Ministers] of their desire to be heard under this subsection, or have made representations in writing to [<sup>F78</sup>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 [<sup>F77</sup>Ministers] shall arrange for them to have an opportunity of appearing before, and being heard by, the [<sup>F79</sup>appropriate committee], or
- (b) if they have made representations in writing, the [<sup>F77</sup>Ministers] shall refer those representations to the [<sup>F79</sup>appropriate 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 [<sup>F77</sup>Ministers] and [<sup>F78</sup>the 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 <sup>F80</sup>... Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

[<sup>F81</sup>(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.]

[<sup>F82</sup>(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

- F70** 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)
- F71** 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)
- F72** 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)
- F73** 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)
- F74** 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)
- F75** 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\(2\)](#)
- F76** 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\(3\)](#)
- F77** 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)
- F78** 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)

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- F79** 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)**
- F80** 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)
- F81** 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)**
- F82** 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)**

- C27** S. 62 extended by S.I. 1984/187, **art. 2**
- C28** 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)**
- C29** 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)**
- C30** 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)**

- C31** Ss. 63–65 extended by S.I. 1984/187, **art. 2**
- C32** 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



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- (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 [<sup>F83</sup>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**

**F83** 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)**

**C33** Ss. 63–65 extended by [S.I. 1984/187](#), [art. 2](#)

<sup>F84</sup>**65 Compliance with standards specified in monographs in certain publications.**

.....

**Textual Amendments**

**F84** 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](#))

<sup>F84</sup>**66 Further powers to regulate dealings with medicinal products.**

.....

**Textual Amendments**

**F84** 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.

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<sup>F85</sup>(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 [<sup>F86</sup> 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 [<sup>F87</sup>63 and 64], or who contravenes <sup>F88</sup>... 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.

<sup>F89</sup>(3A) .....

(4) Any person guilty of an offence under [<sup>F90</sup>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.

<sup>F91</sup>(5) .....

<sup>F91</sup>(6) .....

#### Textual Amendments

- F85** 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)
- F86** 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)
- F87** 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)
- F88** 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)
- F89** 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)
- F90** 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)
- F91** 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)

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**Modifications etc. (not altering text)**

- C34** 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**

**[<sup>F92</sup>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—
- [<sup>F93</sup>(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—

    - [<sup>F94</sup>(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**

- F92** 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
- F93** 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
- F94** 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

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## **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—
  - [<sup>F95</sup>(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 [<sup>F96</sup>, 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—

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- (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 [<sup>F97</sup>, 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

- F92** 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
- F95** 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
- F96** 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
- F97** 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—
  - [<sup>F98</sup>(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

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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 [<sup>F99</sup>, 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 [<sup>F100</sup>, 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**

- F92** 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
- F98** 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
- F99** 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
- F100** 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.

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- (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 [<sup>F101</sup>or 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

- F92** 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
- F101** 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: [<sup>F102</sup>“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, [<sup>F103</sup>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 <sup>F104</sup>... maintained under articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 (SI 1976/1213 (NI 22)).]

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### Textual Amendments

- F92** 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
- F102** 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
- F103** 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)
- F104** 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)

### [<sup>F105</sup>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



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- (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**

**F105** 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

**F106** **68 Disqualification on conviction of certain offences.**

.....

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### Textual Amendments

- F106** S. 68 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

## PART IV

### PHARMACIES

#### Modifications etc. (not altering text)

- C35** Pt. IV: Power to amend conferred (N.I.) (2.4.2001) by [2001 c. 3 \(N.I.\)](#), s. 60, [Sch. 4 para. 2\(2\)](#); [S.R. 2001/128](#), art. 2(4), [Sch.](#)
- C36** Pt. IV 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\(12\)](#)
- C37** Pt. IV modified (E.W.S.) (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\)](#), art. 1(2)(3), [Sch. 2 para. 13\(7\)](#)
- C38** Pt. IV (except ss. 80-83): Power to amend conferred (15.3.2000) by [1999 c. 8](#), ss. 60(1)(2)(4), 67(1), [Sch. 3 para. 2\(3\)\(b\)](#); [S.I. 2000/779](#), art. 2

#### *Persons lawfully conducting retail pharmacy business*

### 69 General provisions.

- (1) Subject to the provisions of any order made under section 73 of this Act, a person carrying on a retail pharmacy business shall be taken to be a person lawfully conducting such a business if, not being disqualified by virtue of section 80 of this Act,—
- that person (or, if the business is carried on by a partnership, each, or, in Scotland, one or more, of the partners) is a pharmacist and the conditions specified in section 70 of this Act are fulfilled in relation to the business, or
  - that person is a body corporate and the conditions specified in section 71 of this Act are fulfilled in relation to the business, or
  - that person is a representative of a pharmacist (as defined by section 72 of this Act) and the conditions specified in subsection (2) of that section are fulfilled in relation to him and in relation to the business and the period applicable in accordance with subsection (3) of that section has not expired.

<sup>F107</sup>(1ZA) .....

[<sup>F108</sup>(2) For the purposes of the application of this Part of this Act to a business which—

- is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be also carried on elsewhere or not, or
- so far as concerns the retail sale of medicinal products, or the supply of such products in circumstances corresponding to retail sale, is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be carried on elsewhere or not,

each such part of that building shall be taken to be separate premises.

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(3) In this Part of this Act—

<sup>F109</sup>  
...

“the board”, in relation to a body corporate, means the body of persons controlling the body corporate, by whatever name called;

<sup>F110</sup>  
...

[<sup>F111</sup>“the register” means—

- (a) in relation to Great Britain, the register established and maintained under article 19 of the Pharmacy Order 2010; and
- (b) in relation to Northern Ireland, the register kept for the purposes of section 75;]

[<sup>F112</sup>“the registrar” means—

- (a) in relation to Great Britain, the person appointed under article 18 of the Pharmacy Order 2010 as registrar for the purposes of that Order; and
- (b) in relation to Northern Ireland, the person appointed under Article 9(1) of the Pharmacy (Northern Ireland) Order 1976 as registrar for the purposes of that Order;]

[<sup>F113</sup>“the relevant disciplinary committee” means—

- (a) in relation to Great Britain, the Fitness to Practise Committee established under article 4(6) of the Pharmacy Order 2010; and
- (b) in relation to Northern Ireland, the Statutory Committee appointed under Article 19 of the Pharmacy (Northern Ireland) Order 1976;]

“relevant European State ” means either an EEA State other than the United Kingdom or Switzerland.

<sup>F114</sup>  
...]

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**Textual Amendments**

**F107** S. 69(1ZA) 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. 4** (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)

**F108** Words in s. 69(1ZA) inserted (N.I.) (22.5.2008) by [The European Qualifications \(Pharmacy\) Regulations \(Northern Ireland\) 2008](#) (S.R. 2008/192), regs. 1(2), **13(a)**

**F109** Definition in s. 69(3) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt. XII**

**F110** Words in s. 69(3) omitted (27.9.2010) by virtue of [The Pharmacy Order 2010](#) (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(2)(b)(i)** (with Sch. 6 para. 1(1)); S.I. 2010/1621, art. 2(1), Sch.

**F111** Words in s. 69(3) inserted (27.9.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(2)(b)(ii)** (with Sch. 6 para. 1(1)); S.I. 2010/1621, art. 2(1), Sch.

**F112** Words in s. 69(3) substituted (27.9.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(2)(b)(iii)** (with Sch. 6 para. 1(1)); S.I. 2010/1621, art. 2(1), Sch.

**F113** Words in s. 69(3) substituted (27.9.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(2)(b)(iv)** (with Sch. 6 para. 1(1)); S.I. 2010/1621, art. 2(1), Sch.

**F114** Words in s. 69(3) omitted (coming into force in accordance with art. 1(2)(3)) by virtue of [Pharmacists and Pharmacy Technicians Order 2007](#) (S.I. 2007/289), art. 1(2)(3), **Sch. 1 para. 2(4)(c)**

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**Modifications etc. (not altering text)**

**C39** S. 69(3) amendment continued (11.2.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), art. 1(2)(c), **Sch. 6 para. 1(1)**

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**[<sup>F115</sup> 70 Business carried on by individual pharmacist or by partners.**

- (1) The conditions referred to in section 69(1)(a) of this Act are that subsections (2) and (3) of this section are both satisfied as respects each of the premises [<sup>F116</sup>at or from which] the retail pharmacy business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.
- (2) This subsection is satisfied if a responsible pharmacist who satisfies [<sup>F117</sup>the requirement of subsection (4)] of this section is in charge of [<sup>F118</sup>the business carried on at or from] those premises, so far as concerns—
- (a) the retail sale at [<sup>F119</sup>or from] those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at [<sup>F120</sup>or from] those premises of such products in circumstances corresponding to retail sale.
- (3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
- (a) the name of the responsible pharmacist for the time being,
  - [<sup>F121</sup>(b) the number of his registration under Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, under the Pharmacy (Northern Ireland) Order 1976, and]
  - (c) the fact that he is for the time being in charge of [<sup>F122</sup>the business carried on at or from] those premises.
- (4) The responsible pharmacist must be—
- (a) the person carrying on the business, or
  - [<sup>F123</sup>(b) if the business is carried on by a partnership, one of the partners or, in Scotland, one of the partners who is a person registered in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010 (pharmacists other than visiting practitioners), or]
  - (c) another pharmacist.

[<sup>F124</sup>(5) .....

[<sup>F124</sup>(6) .....]

**Textual Amendments**

**F115** S. 70 substituted (1.10.2009) by *Health Act 2006* (c. 28), **ss. 27(1)**, 83(7) (as amended by S.I. 2007/3101, regs. 1(2), **103(a)**); S.I. 2008/2714, **art. 2(a)**

**F116** Words in s. 70(1) substituted (1.12.2022) by *The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022* (S.I. 2022/849), art. 1(3), **Sch. 2 para. 3(a)**; S.I. 2022/1023, art. 2

**F117** Words in s. 70(2) substituted (4.11.2011) by *The Medicines Act 1968 (Pharmacy) Order 2011* (S.I. 2011/2647), arts. 1, **3(a)**; and (N.I.) (4.11.2011) by *The Medicines Act 1968 (Pharmacy) Order 2011* (S.R. 2011/442), arts. 1, **3(a)**

**F118** Words in s. 70(2) substituted (1.12.2022) by *The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022* (S.I. 2022/849), art. 1(3), **Sch. 2 para. 3(b)(i)**; S.I. 2022/1023, art. 2

**F119** Words in s. 70(2)(a) inserted (1.12.2022) by *The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022* (S.I. 2022/849), art. 1(3), **Sch. 2 para. 3(b)(ii)**; S.I. 2022/1023, art. 2

**F120** Words in s. 70(2)(b) inserted (1.12.2022) by *The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022* (S.I. 2022/849), art. 1(3), **Sch. 2 para. 3(b)(iii)**; S.I. 2022/1023, art. 2

**F121** S. 70(3)(b) substituted (27.9.2010) by *The Pharmacy Order 2010* (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(3)(a)**; S.I. 2010/1621, art. 2(1), Sch.

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- F122** Words in s. 70(3)(c) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 3(c)**; S.I. 2022/1023, art. 2
- F123** S. 70(4)(b) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(3)(b)**; S.I. 2010/1621, art. 2(1), Sch.
- F124** S. 70(5)(6) omitted (4.11.2011) by virtue of The Medicines Act 1968 (Pharmacy) Order 2011 (S.I. 2011/2647), arts. 1, **3(b)**; and (N.I.) (4.11.2011) by virtue of The Medicines Act 1968 (Pharmacy) Order 2011 (S.R. 2011/442), arts. 1, **3(b)**

## <sup>F125</sup> 71 Business carried on by body corporate

- (1) The conditions referred to in section 69(1)(b) of this Act are—
- <sup>F126</sup>(a) that there is a superintendent in relation to the retail pharmacy business in respect of whom the requirements specified in subsection (6) are fulfilled, and]
  - (b) that subsections (2) and (3) of this section are both satisfied as respects each of the premises <sup>F127</sup>at or from which] the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.
- (2) This subsection is satisfied if a responsible pharmacist who satisfies <sup>F128</sup>the requirement of subsection (4)] of this section is in charge of <sup>F129</sup>the business carried on at or from] the premises mentioned in subsection (1)(b) of this section, so far as concerns—
- (a) the retail sale at <sup>F130</sup>or from] those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at <sup>F131</sup>or from] those premises of such products in circumstances corresponding to retail sale.
- (3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
- (a) the name of the responsible pharmacist for the time being,
  - <sup>F132</sup>(b) the number of his registration under Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, under the Pharmacy (Northern Ireland) Order 1976, and]
  - (c) the fact that he is for the time being in charge of <sup>F133</sup>the business carried on at or from] those premises.
- (4) The responsible pharmacist must be—
- (a) the superintendent mentioned in subsection (1)(a) of this section, or
  - (b) a manager or assistant subject to the directions of the superintendent and who is a pharmacist.
- <sup>F134</sup>(5) .....
- <sup>F134</sup>(5A) .....
- (6) The requirements referred to in subsection (1)(a) of this section in relation to a superintendent are that—
- (a) he is a pharmacist,
  - <sup>F135</sup>(aa) he is a senior manager of the retail pharmacy business who has the authority to make decisions that affect the running of the retail pharmacy business so far as concerns—

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- (i) the retail sale of medicinal products (whether they are on a general sale list or not), and
- (ii) the supply of such products in circumstances corresponding to retail sale,
- and]
- (b) a statement in writing signed by him, and signed on behalf of the body corporate, specifying his name <sup>F136</sup>..., has been sent to the registrar <sup>F136</sup>...
- <sup>F137</sup>(c) .....
- <sup>F138</sup>(7) .....
- [<sup>F139</sup>(7A) For the purposes of subsection (6)(aa), a person is a senior manager of a retail pharmacy business if the person plays a significant role (irrespective of whether other individuals also do so) in—
- (a) the making of decisions about how the whole or a substantial part of its activities are to be managed or organised, or
- (b) the actual managing or organising of the whole or a substantial part of those activities.]
- [<sup>F140</sup>(8) [<sup>F141</sup>If a person who has been the superintendent in relation to a retail pharmacy business ceases to be the superintendent in relation to the business] (otherwise than by reason of death) the person must notify the registrar in writing of that fact within the period of 28 days beginning with the day on which the person ceases to [<sup>F142</sup>be the superintendent in relation to the business].]
- <sup>F143</sup>(9) .....

#### Textual Amendments

- F125** S. 71 substituted (1.10.2009) by Health Act 2006 (c. 28), ss. **28(1)**, 83(7) (as amended by S.I. 2007/3101, regs. 1(2), **103(b)** and S.R. 2008/192, regs. 1(2), **15**); S.I. 2008/2714, art. **2(a)**
- F126** S. 71(1)(a) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(a)**; S.I. 2022/1023, art. **2**
- F127** Words in s. 71(1)(b) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 4(a)**; S.I. 2022/1023, art. 2
- F128** Words in s. 71(2) substituted (4.11.2011) by The Medicines Act 1968 (Pharmacy) Order 2011 (S.I. 2011/2647), arts. 1, **4(a)**; and (N.I.) (4.11.2011) by The Medicines Act 1968 (Pharmacy) Order 2011 (S.R. 2011/442), arts. 1, **4(a)**
- F129** Words in s. 71(2) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 4(b)(i)**; S.I. 2022/1023, art. 2
- F130** Words in s. 71(2)(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 4(b)(ii)**; S.I. 2022/1023, art. 2
- F131** Words in s. 71(2)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 4(b)(iii)**; S.I. 2022/1023, art. 2
- F132** S. 71(3)(b) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(4)(a)**; S.I. 2010/1621, art. 2(1), Sch.
- F133** Words in s. 71(3)(c) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 4(c)**; S.I. 2022/1023, art. 2
- F134** S. 71(5)(5A) omitted (4.11.2011) by virtue of The Medicines Act 1968 (Pharmacy) Order 2011 (S.I. 2011/2647), arts. 1, **4(b)**; and (N.I.) (4.11.2011) by virtue of The Medicines Act 1968 (Pharmacy) Order 2011 (S.R. 2011/442), arts. 1, **4(b)**

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- F135** S. 71(6)(aa) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(b)(i)**; S.I. 2022/1023, art. 2
- F136** Words in s. 71(6)(b) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(b)(ii)**; S.I. 2022/1023, art. 2
- F137** S. 71(6)(c) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(b)(iii)**; S.I. 2022/1023, art. 2
- F138** S. 71(7) 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. 5** (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)
- F139** S. 71(7A) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(c)**; S.I. 2022/1023, art. 2
- F140** S. 71(8)(9) inserted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(4)(d)**; S.I. 2010/1621, art. 2(1), Sch.
- F141** Words in s. 71(8) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(d)(i)**; S.I. 2022/1023, art. 2
- F142** Words in s. 71(8) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(d)(ii)**; S.I. 2022/1023, art. 2
- F143** S. 71(9) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(1)(e)**; S.I. 2022/1023, art. 2

## 72 Representative of pharmacist in case of death or disability.

- (1) The provisions of this section shall have effect where a pharmacist carries on a retail pharmacy business and—
- (a) he dies, or
  - (b) he is adjudged bankrupt or enters into a composition or scheme or deed of arrangement with his creditors, or, in Scotland, sequestration of his estate is awarded or he makes a trust deed for behoof of his creditors or a composition contract, or
  - (c) [<sup>F144</sup>he becomes a person who lacks capacity (within the meaning of the Mental Capacity Act 2005) to carry on the business], or, in Scotland, a [<sup>F145</sup>guardian] or judicial factor is appointed for him on the ground that he suffers from mental disorder, or, in Northern Ireland, [<sup>F146</sup>a controller is appointed in his case under the Mental Health (Northern Ireland) Order 1986],
- and a representative of his thereafter carries on his business.
- [<sup>F147</sup>(1A) In subsection (1)(c), the reference to a person who lacks capacity to carry on the business is to a person—
- (a) in respect of whom there is a donee of an enduring power of attorney or lasting power of attorney (within the meaning of the Mental Capacity Act 2005), or
  - (b) for whom a deputy is appointed by the Court of Protection,
- and in relation to whom the donee or deputy has power for the purposes of this Act.]
- [<sup>F148</sup>(2) The conditions referred to in section 69(1)(c) of this Act are—
- (a) that the name and address of the representative, and the name of the pharmacist whose representative he is, have been notified to the registrar, and
  - (b) that subsections (2A) and (2B) of this section are both satisfied as respects each of the premises at [<sup>F149</sup>or from] which the business is carried on and

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medicinal products, other than medicinal products on a general sale list, are sold by retail.

- (2A) This subsection is satisfied if a responsible pharmacist is in charge of <sup>[F150]</sup>the business carried on at or from] the premises mentioned in subsection (2)(b) of this section, so far as concerns—
- (a) the retail sale at <sup>[F151]</sup>or from] those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at <sup>[F152]</sup>or from] those premises of such products in circumstances corresponding to retail sale.
- (2B) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
- (a) the name of the responsible pharmacist for the time being,
  - (b) <sup>[F153]</sup>the number of his registration under Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, under the Pharmacy (Northern Ireland) Order 1976, and]
  - (c) the fact that he is for the time being in charge of <sup>[F154]</sup>the business carried on at or from] those premises.]
- (3) The period referred to in section 69(1)(c) of this Act—
- (a) in the case of the death of a pharmacist, is a period of five years from the date of his death;
  - (b) in the case of the bankruptcy or sequestration of the estate of a pharmacist, is a period of three years from the date on which he is adjudged bankrupt or the date of the award of sequestration, as the case may be;
  - (c) in the case of a composition or scheme or deed of arrangement, or of a trust deed or composition contract, is a period of three years from the date on which the trustee appointed thereunder becomes entitled to carry on the business; and
  - (d) in a case falling within subsection (1)(c) of this section, is a period of three years from the date of the appointment of the <sup>[F155]</sup>deputy], <sup>[F156]</sup>curator bonis,] judicial factor, committee or guardian <sup>[F157]</sup>or from the date of registration of the instrument appointing the donee],
- or, in any such case, is such longer period as, on the application of the representative, <sup>[F158]</sup>the relevant disciplinary committee], having regard to all the circumstances of the case, may direct.
- (4) In this section “representative”—
- (a) in relation to a pharmacist who has died, means his executor or administrator and, in respect of a period of three months from the date of his death, if he has died leaving no executor who is entitled and willing to carry on the business, includes any person beneficially interested in his estate;
  - (b) in a case falling within paragraph (b) of subsection (1) of this section, means the trustee in bankruptcy or the trustee in the sequestration or any trustee appointed under the composition scheme, deed of arrangement, trust deed or composition contract; and
  - (c) in a case falling within paragraph (c) of that subsection, means the <sup>[F159]</sup>donee, deputy], <sup>[F156]</sup>curator bonis,] judicial factor, <sup>[F160]</sup>controller] or guardian <sup>[F161]</sup>; and in paragraph (b) above the reference to a trustee appointed under a composition, scheme or deed of arrangement includes a reference to the supervisor of a <sup>[F162]</sup>voluntary arrangement proposed for the purposes of, and



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approved under, Part VIII of the Insolvency Act 1986]<sup>F163</sup> or Chapter II of Part VIII of the Insolvency (Northern Ireland) Order 1989].]

### Textual Amendments

- F144** Words in s. 72(1)(c) substituted (1.10.2007) by Mental Capacity Act 2005 (c. 9), s. 68(1), **Sch. 6 para. 14(a)** (with ss. 27-29, 62); S.I. 2007/1897, art. 2(1)(d)
- F145** Words in s. 72(1) substituted (S.) (1.4.2002) by 2000 asp 4, s. 88(2), **Sch. 5 para. 12(a)**; S.S.I. 2001/81, art. 3, **Sch. 2**
- F146** Words in s. 72(1)(c) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 10(a)** (with Sch. 32)
- F147** S. 72(1A) inserted (1.10.2007) by Mental Capacity Act 2005 (c. 9), s. 68(1), **Sch. 6 para. 14(b)** (with ss. 27-29, 62); S.I. 2007/1897, art. 2(1)(d)
- F148** S. 72(2)-(2B) substituted for s. 72(2) (1.10.2009) by Health Act 2006 (c. 28), ss. 29, 83(7); S.I. 2008/2714, art. 2(a)
- F149** Words in s. 72(2)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 5(a)**; S.I. 2022/1023, art. 2
- F150** Words in s. 72(2A) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 5(b)(i)**; S.I. 2022/1023, art. 2
- F151** Words in s. 72(2A)(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 5(b)(ii)**; S.I. 2022/1023, art. 2
- F152** Words in s. 72(2A)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 5(b)(iii)**; S.I. 2022/1023, art. 2
- F153** S. 72(2B)(b) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(5)**; S.I. 2010/1621, art. 2(1), Sch.
- F154** Words in s. 72(2B)(c) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 5(c)**; S.I. 2022/1023, art. 2
- F155** Word in s. 72(3)(d) substituted (1.10.2007) by Mental Capacity Act 2005 (c. 9), s. 68(1), **Sch. 6 para. 14(c)(i)** (with ss. 27-29, 62); S.I. 2007/1897, art. 2(1)(d)
- F156** Words in s. 72(3)(d)(4)(c) repealed (S.) (1.4.2002) by 2000 asp 4, s. 88(2)(3), Sch. 5 para. 12(b), **Sch. 6**; S.S.I. 2001/81, art. 3, **Sch. 2**
- F157** Words in s. 72(3)(d) inserted (1.10.2007) by Mental Capacity Act 2005 (c. 9), s. 68(1), **Sch. 6 para. 14(c)(ii)** (with ss. 27-29, 62); S.I. 2007/1897, art. 2(1)(d)
- F158** Words in s. 72(3) substituted (coming into force in accordance with art. 1(2)(3)) by Pharmacists and Pharmacy Technicians Order 2007 (S.I. 2007/289), art. 1(2)(3), **Sch. 1 para. 2(9)(b)**
- F159** Words in s. 72(4)(c) substituted (1.10.2007) by Mental Capacity Act 2005 (c. 9), s. 68(1), **Sch. 6 para. 14(d)** (with ss. 27-29, 62); S.I. 2007/1897, art. 2(1)(d)
- F160** Word in s. 72(4)(c) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 10(b)** (with Sch. 32)
- F161** Words inserted by Insolvency Act 1985 (c. 65, SIF 66), s. 235, Sch. 8 para. 15, **Sch. 9 para. 11(2)**
- F162** Words substituted by Insolvency Act 1986 (c. 45, SIF 66), s. 439(2), **Sch. 14**
- F163** Words in s. 72(4) added (N.I.) (1.10.1991) by S.I. 1989/2405 (N.I. 19), art. 381, **Sch. 9 Pt. II para. 24**; S.R. 1991/411, art. 2

### Modifications etc. (not altering text)

- C40** S. 72(3) amendments continued (11.2.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(2)(c), **Sch. 6 para. 1(2)(a)**

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**[<sup>F164</sup>72A The responsible pharmacist**

[ Nothing in this Part is to be taken as requiring there to be a responsible pharmacist in <sup>F165</sup>(A1) respect of premises at or from which a retail pharmacy business is carried on at a time when no medicinal products (whether they are on a general sale list or not) are being—  
(a) offered or exposed for sale by retail or supply in circumstances corresponding to retail sale at or from the premises, or  
(b) assembled, prepared or dispensed at or from the premises with a view to such sale or supply.]

(1) It is the duty of the responsible pharmacist mentioned in sections 70, 71 and 72 of this Act to secure the safe and effective running of the pharmacy [<sup>F166</sup>business carried on at or from] the premises in question so far as concerns—  
(a) the retail sale at [<sup>F167</sup>or from] those premises of medicinal products (whether they are on a general sale list or not), and  
(b) the supply at [<sup>F168</sup>or from] those premises of such products in circumstances corresponding to retail sale.

(2) A person may not be the responsible pharmacist in respect of more than one set of premises at the same time, except in circumstances specified by [<sup>F169</sup>the General Pharmaceutical Council in rules in relation to premises in Great Britain or the Council of the Pharmaceutical Society of Northern Ireland in regulations in relation to premises in Northern Ireland], and then only if such conditions as may be so specified are complied with.

<sup>F170</sup>(3) .....

<sup>F170</sup>(4) .....

<sup>F170</sup>(5) .....

[<sup>F171</sup>(6) The General Pharmaceutical Council may make further provision in rules in relation to the responsible pharmacist in respect of premises in Great Britain, and the Council of the Pharmaceutical Society of Northern Ireland may make further provision in regulations in relation to the responsible pharmacist in respect of premises in Northern Ireland.

(6A) In making any such provision, the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland must have regard to the principle that the burdens imposed on businesses by rules or regulations should be the minimum necessary to secure the benefits, considered in general terms, which are expected to result from the rules or regulations.

(7) The rules and regulations mentioned in subsection (6) may (amongst other things)—  
(a) make further provision about the matters mentioned in subsection (1);  
(b) make provision about the responsible pharmacist’s absence from the premises.

(7A) If such rules or regulations make provision about the responsible pharmacist’s absence from the premises, they must also provide that the retail sale of medicinal products on a general sale list may continue at or from the premises during any period in which the responsible pharmacist is absent from the premises.]

<sup>F172</sup>(8) .....]

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**Textual Amendments**

- F164** Ss. 72A, 72B inserted (19.7.2006 for specified purposes) by [Health Act 2006 \(c. 28\)](#), **ss. 30(1)**, 83(1)(e)
- F165** [S. 72A\(A1\)](#) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **5(2)**; S.I. 2022/1023, art. 2
- F166** Words in [s. 72A\(1\)](#) substituted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 2 para. 6(a)**; S.I. 2022/1023, art. 2
- F167** Words in [s. 72A\(1\)\(a\)](#) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 2 para. 6(b)**; S.I. 2022/1023, art. 2
- F168** Words in [s. 72A\(1\)\(b\)](#) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 2 para. 6(c)**; S.I. 2022/1023, art. 2
- F169** Words in [s. 72A\(2\)](#) substituted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **5(3)**; S.I. 2022/1023, art. 2
- F170** [S. 72A\(3\)-\(5\)](#) omitted (1.12.2022) by virtue of [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **5(4)** (with art. 8(2)); S.I. 2022/1023, art. 2
- F171** [S. 72A\(6\)-\(7A\)](#) substituted for [s. 72A\(6\)\(7\)](#) (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **5(5)**; S.I. 2022/1023, **art. 2**
- F172** [S. 72A\(8\)](#) omitted (1.12.2022) by virtue of [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **5(6)**; S.I. 2022/1023, art. 2

**[<sup>F173</sup>72AA] The superintendent**

It is the duty of the superintendent in relation to a retail pharmacy business to secure that the business is at all times carried on in ways that ensure its safe and effective running so far as concerns—

- (a) the retail sale of medicinal products (whether they are on a general sale list or not), and
- (b) the supply of such products in circumstances corresponding to retail sale.]

**Textual Amendments**

- F173** [S. 72AA](#) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), arts. 1(3), **6(2)**; S.I. 2022/1023, art. 2

**[<sup>F164</sup>72B [<sup>F174</sup>Sections 72A and 72AA: supplementary]**

<sup>F175</sup>(1) The failure by a person to comply with any requirements of [<sup>F176</sup>section 72A or 72AA of this Act, or of rules or regulations made under section 72A,] may constitute misconduct for the purposes of section 80 of this Act, article 51(1)(a) of the Pharmacy Order 2010 and Article 20 of the Pharmacy (Northern Ireland) Order 1976 and the relevant disciplinary committee may deal with such a failure accordingly.]

<sup>F177</sup>(2) .....

(3) Subsection (4) of this section applies if a person—

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- (a) fails to comply with the requirements of subsection (2) of section 72A of this Act, or of <sup>F178</sup>rules or] regulations made under that subsection,
  - (b) fails to comply with any requirements as to absence from the premises contained in <sup>F179</sup>rules or] regulations made by virtue of <sup>F180</sup>subsection (7)] of that section.
- (4) If this subsection applies, the person in question is not to be considered while the failure continues as being in charge of <sup>F181</sup>the business carried on at or from] the premises in question (or in a subsection (3)(a) case at any of them) for the purposes of sections 70 to 72 of this Act.]

#### Textual Amendments

- F164** Ss. 72A, 72B inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 30(1)**, 83(1) (e)
- F174** S. 72B heading substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 2**; S.I. 2022/1023, art. 2
- F175** S. 72B(1) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(6)**; S.I. 2010/1621, art. 2(1), Sch.
- F176** Words in s. 72B(1) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 3(a)**; S.I. 2022/1023, art. 2
- F177** S. 72B(2) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 3(b)**; S.I. 2022/1023, art. 2
- F178** Words in s. 72B(3)(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 3(c)(i)**; S.I. 2022/1023, art. 2
- F179** Words in s. 72B(3)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 3(c)(ii)**; S.I. 2022/1023, art. 2
- F180** Words in s. 72B(3)(b) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 3(c)(ii)**; S.I. 2022/1023, art. 2
- F181** Words in s. 72B(4) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 7**; S.I. 2022/1023, art. 2

### 73 Power to extend or modify conditions.

- (1) The <sup>F182</sup>... Ministers may by order add to, revoke or vary any of the provisions of sections 70 to 72 of this Act, so as either—
- (a) to modify, or provide new conditions in substitution for, the conditions referred to in any of the paragraphs of section 69(1) of this Act, or
  - (b) for the purposes of any of those paragraphs, to provide alternative conditions compliance with which is to have the like effect as compliance with the conditions referred to in that paragraph.
- (2) Any provision made by an order in accordance with subsection (1) of this section may be made either generally or in relation to any particular circumstances specified in the order.

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- (3) Any order made under this section may direct that subsection (1) or subsection (2) of section 69 of this Act shall have effect subject to such exceptions or modifications as appear to the <sup>F183</sup>... Ministers to be necessary or expedient in consequence of the provision made by the order in accordance with subsection (1) of this section.
- (4) Where an order under this section is for the time being in force, any reference to section 69 of this Act in any other enactment as amended by this Act shall be construed as a reference to that section as modified by the order.
- (5) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

#### Textual Amendments

**F182** Word in s. 73(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 39\(a\)](#) (with regs. 2(4), 3)

**F183** Word in s. 73(3) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 39\(b\)](#) (with regs. 2(4), 3)

### Registration of pharmacies

#### 74 Meaning of “registered pharmacy”.

- (1) <sup>F184</sup> . . . In this Act “registered pharmacy” means premises for the time being entered in the register <sup>F185</sup> ....
- <sup>F186</sup>(1A) If the entry of a registered pharmacy in the register is suspended under [<sup>F187</sup>paragraph (4)(b) of article 14][<sup>F187</sup>section 82A of this Act, paragraph 8 of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976 or article 14(4)(b) or 56] of the Pharmacy Order 2010 then, except for such purposes [<sup>F188</sup>of that Order] as the General Pharmaceutical Council may prescribe by rules [<sup>F189</sup>in relation to Great Britain or the Council of the Pharmaceutical Society of Northern Ireland may prescribe by regulations in relation to Northern Ireland], that registered pharmacy must be treated as not being entered in the register notwithstanding that the register still includes the address of that pharmacy.]
- <sup>F186</sup>(1B) Accordingly, premises whose entry in the register is suspended are not to be treated as a registered pharmacy for the purposes of this Act or any other enactment [<sup>F190</sup>apart from that Order][<sup>F190</sup>except for a purpose prescribed by the rules or regulations mentioned in subsection (1A)] .]
- <sup>F191</sup>(2) . . . . .
- <sup>F192</sup>(3) . . . . .
- <sup>F191</sup>(4) . . . . .

#### Textual Amendments

**F184** Words in s. 74(1) repealed (5.11.1993) by [1993 c. 50, s. 1\(1\)](#), [Sch. 1Pt. XII](#)

**F185** Words in s. 74(1) omitted (27.9.2010) by virtue of [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(7\)\(a\)](#); [S.I. 2010/1621](#), art. 2(1), Sch.

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- F186** S. 74(1A)(1B) inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(7)(b)**; S.I. 2010/1621, art. 2(1), Sch.
- F187** Words in s. 74(1A) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **5(2)(a)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F188** Words in s. 74(1A) omitted (24.5.2018 for E.W.S.) by virtue of The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **5(2)(b)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F189** Words in s. 74(1A) inserted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **5(2)(c)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F190** Words in s. 74(1B) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **5(3)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F191** S. 74(2)(4) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt. XII**
- F192** S. 74(3) omitted (27.9.2010) by virtue of The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(7)(c)**; S.I. 2010/1621, art. 2(1), Sch.

#### [<sup>F193</sup>74A.Registration of premises: Great Britain

- (1) This section applies in relation to premises in Great Britain.
- (2) If the registrar is satisfied that the conditions in section 74B are met in relation to premises that are not entered in the register, the registrar must enter the premises in Part 3 of the register unless the registrar considers that doing so would prejudice the health, safety or well-being of members of the public.
- (3) Subject to subsection (5) and to section 74H, the entry of premises entered in Part 3 of the register under subsection (2) is valid for the period of one year beginning with the date on which the entry was made.
- (4) If the registrar is satisfied that the conditions in section 74B are met in relation to premises entered in Part 3 of the register under subsection (2), the registrar must renew the entry of the premises unless the registrar considers that doing so would prejudice the health, safety or well-being of members of the public.
- (5) Subject to subsection (7) and to section 74H, each renewal of the entry of premises entered in Part 3 of the register under subsection (2) extends the validity of the entry for the period of one year beginning with the day on which the entry would otherwise have ceased to be valid.
- (6) The registrar may, except in such circumstances as may be prescribed by the General Pharmaceutical Council in rules, renew the entry of premises in Part 3 of the register for a period exceeding one year beginning with the day on which the entry would otherwise have ceased to be valid in which case the renewal of the entry of premises entered in that part of the register under subsection (2) extends the validity of the entry for that period.
- (7) If the entry of premises entered in Part 3 of the register under this section ceases to be valid then, except in such circumstances as may be prescribed by the General Pharmaceutical Council in rules, the premises are to be treated for all purposes as no longer being entered in Part 3 of the register and accordingly the registrar must remove the entry from that part of the register.]

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### Textual Amendments

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.

### [<sup>F193</sup>74B. Conditions for registration: Great Britain

- (1) The conditions referred to in section 74A are as follows.
- (2) Condition A is that an application for the entry of the premises in Part 3 of the register or, as the case may be, for the renewal of the entry of the premises in Part 3 of the register is made—
  - (a) in such form and manner as is prescribed in rules made by the General Pharmaceutical Council; and
  - (b) if the application is an application for renewal, by such time prior to the entry ceasing to be valid as is so prescribed.
- (3) Condition B is that the appropriate fee prescribed in rules made by the General Pharmaceutical Council under article 36(1) of the Pharmacy Order 2010 is paid.
- (4) Condition C—
  - (a) if the application is an application for the entry of the premises in Part 3 of the register, is that either—
    - (i) the applicant is lawfully conducting a retail pharmacy business, or
    - (ii) if the premises are entered in Part 3 of the register, and the applicant begins to carry on a retail pharmacy business at [<sup>F194</sup>or from] the premises, the applicant will, from the time the applicant begins to do so, be a person lawfully conducting a retail pharmacy business; or
  - (b) if the application is an application for the renewal of the entry of the premises in Part 3 of the register, is that the applicant is lawfully conducting a retail pharmacy business at [<sup>F195</sup>or from] the premises.
- (5) Condition D—
  - (a) if the application is an application for the entry of the premises in Part 3 of the register, is that the standards that are [<sup>F196</sup>provided for in rules made][<sup>F196</sup>set] under article 7(1) of the Pharmacy Order 2010 are met, or are capable of being met, in connection with the carrying on of a retail pharmacy business at [<sup>F197</sup>or from] the premises; or
  - (b) if the application is an application for the renewal of the entry of the premises in Part 3 of the register, is—
    - (i) that the standards that are [<sup>F198</sup>provided for in rules made][<sup>F198</sup>set] under article 7(1) of the Pharmacy Order 2010 are met in connection with the carrying on of a retail pharmacy business at [<sup>F199</sup>or from] the premises, and
    - (ii) that the requirements of rules [<sup>F200</sup>(if any)] made under article 7(4) of that Order are met by the person carrying on a retail pharmacy business at [<sup>F201</sup>or from] the premises.]

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### Textual Amendments

- F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.
- F194** Words in s. 74B(4)(a)(ii) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 8(a)(i)**; S.I. 2022/1023, art. 2
- F195** Words in s. 74B(4)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 8(a)(ii)**; S.I. 2022/1023, art. 2
- F196** Word in s. 74B(5)(a) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **6(a)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F197** Words in s. 74B(5)(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 8(b)(i)**; S.I. 2022/1023, art. 2
- F198** Word in s. 74B(5)(b)(i) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **6(b)(i)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F199** Words in s. 74B(5)(b)(i) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 8(b)(ii)**; S.I. 2022/1023, art. 2
- F200** Words in s. 74B(5)(b)(ii) inserted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **6(b)(ii)**; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F201** Words in s. 74B(5)(b)(ii) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 8(b)(ii)**; S.I. 2022/1023, art. 2

### [<sup>F193</sup>74C. Supplementary provision in respect of registration of premises: Great Britain

- (1) The registrar may restore to Part 3 of the register the entry of premises removed from that part of the register by virtue of section 74A(7) if an application is made to the registrar in accordance with this section.
- (2) An entry restored under this section to Part 3 of the register—
  - (a) is still to be treated as having been entered in that part of the register under section 74A;
  - (b) is valid for the period of one year beginning with the day on which the entry would otherwise have ceased to be valid by virtue of section 74A(7) or is valid for such longer period beginning with that day as the registrar may in any particular case allow; and
  - (c) may be subject to the same conditions as those to which the entry was subject immediately before it was removed from Part 3 of the register by virtue of section 74A(7) or may be subject to such other conditions as the registrar may impose under section 74D(1).
- (3) An application for restoration may be made to the registrar by the person who is the owner of the retail pharmacy business previously carried on at [<sup>F202</sup>or from] the premises and that person must be—



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- (a) a person who is lawfully conducting a retail pharmacy business; or
  - (b) a person who, if the entry of the premises is restored to Part 3 of the register and the person begins to carry on a retail pharmacy business at [<sup>F203</sup>or from] the premises, will, from the time the person begins to do so, be a person lawfully conducting a retail pharmacy business.
- (4) The General Pharmaceutical Council may make rules in connection with applications under this section.
- (5) Rules under subsection (4) may, in particular, include provision—
- (a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the General Pharmaceutical Council may determine from time to time);
  - (b) about the information to be provided in respect of applications; and
  - (c) about the circumstances in which applications must or, as the case may be, may be refused (including where an application for renewal under this section was not received by the registrar by the time prescribed by the General Pharmaceutical Council in rules under section 74B(2)(b)).
- (6) Where the registrar restores the entry of premises to Part 3 of the register pursuant to an application under this section, the registrar must give notice in writing of that restoration to the applicant.
- (7) The notice under subsection (6) must specify—
- (a) the period for which the entry restored to Part 3 of the register is valid;
  - (b) any conditions to which that entry is subject by virtue of subsection (2)(c).
- (8) The notice under subsection (6) must be sent—
- (a) where the retail pharmacy business was carried on by an individual, to that individual at that individual’s home address in the register;
  - (b) where the retail pharmacy business was carried on by a partnership, to that partnership at its principal office;
  - (c) where the retail pharmacy business was carried on by a body corporate, to that body corporate at its registered or principal office.]

#### Textual Amendments

- F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.
- F202** Words in s. 74C(3) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 9(a)**; S.I. 2022/1023, art. 2
- F203** Words in s. 74C(3)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 9(b)**; S.I. 2022/1023, art. 2

#### [<sup>F193</sup>74D. Conditional registration: Great Britain

- (1) The registrar may make the entry of premises entered in Part 3 of the register under section 74A subject to such conditions as the registrar considers it necessary to impose

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for the purpose of securing the safe and effective practice of pharmacy [F204 in the course of the business carried on at or from] those premises.

- (2) The power under subsection (1)—
- (a) may be exercised on the making of the entry or subsequently (whether on a renewal of the entry or otherwise);
  - (b) includes power to vary the conditions to which the entry of the premises in Part 3 of the register is subject, including by adding to the conditions or revoking any of them.
- (3) Except as provided in subsection (4), the registrar may not under subsection (1)—
- (a) impose a new condition in respect of premises already entered in Part 3 of the register; or
  - (b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,

unless the registrar has given reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition, to the person carrying on the retail pharmacy business at [F205 or from] the premises and of the date from which that condition, variation or revocation is to have effect.

- (4) The registrar may, with immediate effect—
- (a) impose a new condition in respect of premises already entered in Part 3 of the register; or
  - (b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,

if, in the registrar's opinion, the giving of reasonable notice as required by subsection (3) would prejudice the health, safety or well-being of members of the public.

- (5) The registrar must give notice in writing of any decision under subsection (4) to the person carrying on a retail pharmacy business at [F206 or from] the premises.
- (6) The notice under subsection (5) must be sent—
- (a) where the retail pharmacy business is carried on by an individual, to that individual at that individual's home address in the register;
  - (b) where the retail pharmacy business is carried on by a partnership, to that partnership at its principal office; or
  - (c) where the retail pharmacy business is carried on by a body corporate, to that body corporate at its registered or principal office.

- (7) Where premises are entered in the register because condition C in section 74B is met by virtue of subsection (4)(a)(ii) of that section, the registrar may, on making the entry of the premises in the register, also make that entry subject to a condition that the applicant for registration will be a person lawfully conducting a retail pharmacy business within such period as the registrar reasonably determines beginning with the date on which the entry is made.]

#### Textual Amendments

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(8\)](#) (with [Sch. 5 para. 10](#)); [S.I. 2010/1621](#), art. 2(1), [Sch.](#)

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- F204** Words in s. 74D(1) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 10(a)**; S.I. 2022/1023, art. 2
- F205** Words in s. 74D(3) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 10(b)**; S.I. 2022/1023, art. 2
- F206** Words in s. 74D(5) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 10(c)**; S.I. 2022/1023, art. 2

### [<sup>F193</sup>74E. Supplementary provision in respect of conditional registration: Great Britain

- (1) Where the entry of premises entered in Part 3 of the register is subject to conditions imposed under section 74D(1), the person carrying on the business at [<sup>F207</sup>or from] the premises may apply to the registrar for any of the conditions imposed to be varied or revoked.
- (2) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).
- (3) Rules under subsection (2) may, in particular, include provision—
  - (a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the General Pharmaceutical Council may determine from time to time);
  - (b) about the information to be provided in respect of applications;
  - (c) about the circumstances in which applications may be refused by the registrar;
  - (d) about the giving of notice of the decision in respect of the application to the applicant by the registrar.
- (4) The registrar may vary a condition imposed under section 74D(7) by extending the period within which the applicant for registration must become a person lawfully conducting a retail pharmacy business.
- (5) Where premises are entered in the register subject to a condition imposed under subsection (7) of section 74D, the registrar may remove the entry if the applicant is not a person lawfully conducting a retail pharmacy business at [<sup>F208</sup>or from] the premises within the period determined by the registrar in accordance with that subsection or within such longer period as the registrar may, by virtue of subsection (4), allow.
- (6) Where the registrar—
  - (a) varies a condition under subsection (5); or
  - (b) removes an entry of premises in Part 3 of the register under subsection (4),the registrar must send to the person who applied for registration a statement in writing giving that person notice of the decision and the reasons for it.
- (7) The notice under subsection (6) must be sent—
  - (a) where the person who applied for registration is an individual, to that individual at that individual's home address in the register;
  - (b) where that person is a partnership, to that partnership at its principal office;
  - (c) where that person is a body corporate, to that body corporate at its registered or principal office.]

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### Textual Amendments

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.

**F207** Words in s. 74E(1) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 11(a)**; S.I. 2022/1023, art. 2

**F208** Words in s. 74E(5) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 11(b)**; S.I. 2022/1023, art. 2

### [<sup>F193</sup>74F. Giving of notice by registrar: Great Britain

- (1) Where, in pursuance of an application, the registrar enters premises in Part 3 of the register under section 74A, the registrar must give to the applicant a written confirmation of the entry.
- (2) The written confirmation under subsection (1) must include—
  - (a) the number of the entry;
  - (b) the date on which the entry was made;
  - (c) the period for which the entry is valid; and
  - (d) details of any conditions to which the entry is subject by virtue of section 74D.
- (3) Where, in pursuance of an application, the registrar renews the entry of premises in Part 3 of the register under section 74A, the registrar must give to the applicant a written confirmation of the renewal.
- (4) The written confirmation under subsection (3) must include—
  - (a) the number of the entry;
  - (b) the date on which the renewal of the entry was made;
  - (c) the period for which the renewal of the entry is valid; and
  - (d) details of any conditions to which the renewal of the entry is subject by virtue of section 74D.
- (5) Where the registrar refuses an application for the entry of premises in Part 3 of the register under section 74A, or for the renewal of an entry of premises in the register under that section, the registrar must give to the applicant written notice of that refusal and the reasons for it and of the right of appeal to the Appeals Committee under article 40 of the Pharmacy Order 2010.
- (6) Where, under section 74J, the registrar enters premises or a group of premises in Part 3 of the register, the registrar must give written confirmation of the entry to the person who will be carrying on a retail pharmacy business at [<sup>F209</sup>or from the premises, or at or from] each set of premises in the group of premises.
- (7) The written confirmation under subsection (6) must include—
  - (a) the number of the entry;
  - (b) the date on which the entry was made; and
  - (c) details of any conditions to which the entry is subject by virtue of section 74J(4).]

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#### Textual Amendments

- F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.
- F209** Words in s. 74F(6) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 12**; S.I. 2022/1023, art. 2

#### [<sup>F193</sup>74G.] Voluntary removal from the register: Great Britain

- (1) An application may be made to the registrar by the person carrying on a retail pharmacy business at [<sup>F210</sup>or from] any premises entered in Part 3 of the register under section 74A or 74J for the premises to be removed from the register.
- (2) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).
- (3) Rules under subsection (2) may, in particular, include provision—
  - (a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
  - (b) about the information to be provided by the applicant;
  - (c) about the circumstances in which applications may be refused; and
  - (d) for written notice of the outcome of the application to be given to the applicant by the registrar.]

#### Textual Amendments

- F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.
- F210** Words in s. 74G(1) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 13**; S.I. 2022/1023, art. 2

- [<sup>F193</sup>74H.] Subject to subsection (2), where a change occurs in the ownership of a retail pharmacy business carried on at [<sup>F211</sup>or from] premises entered in Part 3 of the register under section 74A, the entry of the premises in the register ceases to be valid at the end of the relevant period unless the registrar is notified in writing of the change prior to the end of the relevant period by the person who, as a result of the change, will be the person carrying on the business at [<sup>F212</sup>or from] the premises.
- (2) Subsection (1) only applies if the relevant period is shorter than the period for which the entry would otherwise have remained valid under section 74A.
  - (3) Where, before the end of the relevant period, the registrar is notified of a change in the ownership of a retail pharmacy business carried on at [<sup>F213</sup>or from] premises entered in Part 3 of the register, the registrar must, on receipt of a fee of the amount prescribed in rules under article 36(1)(c) of the Pharmacy Order 2010, amend the entry relating to the premises in Part 3 of the Register to record the name and address of the person who, as a result of the change, will be the person carrying on the retail pharmacy business at [<sup>F214</sup>or from] the premises.

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- (4) For the purposes of subsections (1) to (3), the relevant period—
- (a) if the change occurs on the death of the person carrying on the business or, in the case of a partnership, on the death of one of the partners, means the period of three months beginning with the date of death; and
  - (b) in any other case, means the period of 28 days beginning with the date on which the change occurred.
- (5) If the entry of premises entered in Part 3 of the register under section 74A ceases to be valid under this section, the premises are to be treated for all purposes as no longer being entered in the register and accordingly the registrar must remove the entry from the register.
- (6) The registrar must restore the entry of the premises to Part 3 of the register if—
- (a) an application for restoration is made to the registrar in accordance with section 74I(1) and with rules made under section 74I(3);
  - (b) a fee of an amount prescribed in rules under article 36(1)(b) of the Pharmacy Order 2010 (fees in connection with entry) is paid; and
  - (c) the registrar is satisfied that the standards that are [F215 provided for in rules made][F215 set] under article 7(1) of the Pharmacy Order 2010 are met in connection with the carrying on of a retail pharmacy business at [F216 or from] the premises.
- (7) Subject to subsection (8), an entry restored to the register under subsection (6)—
- (a) is still to be treated as having been entered in Part 3 of the register under section 74A;
  - (b) is subject to the same conditions as those to which the entry was subject immediately before it was removed from Part 3 of the register by virtue of subsection (5);
  - (c) is valid for the same period as the period for which the entry would have been valid under section 74A had it not been removed from Part 3 of the register by virtue of subsection (5) of this section.
- (8) Where an entry of premises in Part 3 of the register is restored by the registrar under subsection (6) and the applicant is a person falling within section 74I(2)(b), the registrar may—
- (a) on restoring the entry of the premises to the register, make that entry subject to a condition that the applicant for restoration will be a person lawfully conducting a retail pharmacy business within such period as the registrar reasonably determines beginning with the date on which the entry is restored; and
  - (b) subsequently remove the entry of the premises from Part 3 of the register if the applicant is not a person lawfully conducting a retail pharmacy business within the period determined by the registrar in accordance with paragraph (a).
- (9) Where under subsection (8)(b) the registrar removes an entry of premises from Part 3 of the register, the registrar must give to the person who was carrying on a retail pharmacy business at [F217 or from] the premises immediately prior to the removal written notice of the removal and the reasons for it.
- (10) The notice under subsection (9) must be sent—
- (a) where the retail pharmacy business is carried on by an individual, to that individual at that individual's home address in the register;

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- (b) where the retail pharmacy business is carried on by a partnership, to the principal office of that partnership;
- (c) where the retail pharmacy business is carried on by a body corporate, to the registered or principal office of that body corporate.]

#### Textual Amendments

- F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(3), **Sch. 4 para. 1(8)** (with Sch. 5 para. 10); S.I. 2010/1621, art. 2(1), Sch.
- F211** Words in s. 74H(1) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(a)(i)**; S.I. 2022/1023, art. 2
- F212** Words in s. 74H(1) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(a)(ii)**; S.I. 2022/1023, art. 2
- F213** Words in s. 74H(3) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(a)(i)**; S.I. 2022/1023, art. 2
- F214** Words in s. 74H(3) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(a)(ii)**; S.I. 2022/1023, art. 2
- F215** Word in s. 74H(6)(c) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), 7; S.I. 2018/512, art. 2(1)(a)(i)(2)
- F216** Words in s. 74H(6)(c) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(b)**; S.I. 2022/1023, art. 2
- F217** Words in s. 74H(9) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 14(c)**; S.I. 2022/1023, art. 2

#### [<sup>F193</sup>74I. Supplementary provision in respect of change of ownership of retail pharmacy business: Great Britain

- (1) An application may be made to the registrar for the entry of premises removed from Part 3 of the register by virtue of section 74H(5) to be restored to the register.
- (2) An application under subsection (1) must be made by the person who, in consequence of the change of ownership, has become the owner of the business and that person must be—
  - (a) a person who is lawfully conducting a retail pharmacy business; or
  - (b) a person who, if the entry of the premises is restored to Part 3 of the register and the person begins to carry on a retail pharmacy business at [<sup>F218</sup>or from] those premises, will, from the time the person begins to do so, be a person lawfully conducting a retail pharmacy business.
- (3) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).
- (4) Rules under subsection (3) may, in particular, include provision—
  - (a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
  - (b) about the information to be provided in respect of applications;
  - (c) about the circumstances in which an application for restoration under subsection (1) may be treated by the registrar as an application for the renewal of registration under section 74A(4) as well as an application for restoration.

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- (5) Where the registrar restores the entry of premises to Part 3 of the register pursuant to an application under subsection (1), the registrar must send to the applicant for restoration a statement in writing giving the applicant notice of the restoration.
- (6) The notice given by the registrar under subsection (5) must specify—
  - (a) the period for which the entry restored to Part 3 of the register is valid;
  - (b) any conditions to which the entry of the premises restored to Part 3 of the register is subject.
- (7) Where the registrar refuses an application under this section for the restoration to Part 3 of the register of an entry relating to any premises, the registrar must send to the applicant for restoration a statement in writing giving the applicant notice of the decision and the reasons for it.
- (8) The notice under subsections (5) and (7) must be sent—
  - (a) where the applicant is an individual, to that individual at that individual’s home address in the register;
  - (b) where the applicant is a partnership, to the principal office of that partnership;
  - (c) where the applicant is a body corporate, to the registered or principal office of that body corporate.]

#### Textual Amendments

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(8\)](#) (with [Sch. 5 para. 10](#)); [S.I. 2010/1621](#), art. 2(1), [Sch.](#)

**F218** Words in s. 74I(2)(b) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 2 para. 15](#); [S.I. 2022/1023](#), art. 2

#### [<sup>F193</sup>74J. Temporary registration with regard to emergencies involving loss of human life or human illness etc.

- (1) This section applies in relation to premises in Great Britain.
- (2) If the Secretary of State advises the registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this section, the registrar may under this section enter in Part 3 of the register—
  - (a) premises; or
  - (b) premises comprising a specified group of premises,
 with regard to the emergency.
- (3) The registrar may enter in Part 3 of the register by virtue of subsection (2)(b) all of the premises in a specified group of premises without first identifying each set of premises in the group.
- (4) The registrar may make the entry of premises entered in Part 3 of the register under this section subject to such conditions as the registrar considers necessary to impose for the purpose of securing the safe and effective practice of pharmacy [<sup>F219</sup> in the course of the business carried on at or from] those premises.
- (5) The power in subsection (4)—



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- (a) may be exercised on the making of the entry or subsequently;
  - (b) includes power to vary the conditions to which the entry of the premises in Part 3 of the register is subject, including by adding to the conditions or revoking any of them.
- (6) The entry of premises entered in Part 3 of the register under this section by virtue of subsection (2)(b) as one of a specified group may be subject to the same conditions as the entry of the other premises in the group or it may be subject to different conditions.
- (7) The conditions to which the entry of premises entered in Part 3 of the register under this section is subject may include conditions relating to their physical state, safety and security and the conditions in which medicinal products (including controlled drugs) are stored at those premises.
- (8) The registrar may not under subsection (4)—
- (a) impose a new condition in respect of the entry of premises already entered in Part 3 of the register; or
  - (b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,
- unless the registrar has given reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition, to the person carrying on a retail pharmacy business at [<sup>F220</sup>or from] the premises and of the date from which that condition, variation or revocation is to have effect.
- (9) The entry of premises entered in Part 3 of the register under this section may be removed by the registrar, which—
- (a) the registrar must do if the Secretary of State advises the registrar that the circumstances that led the Secretary of State to advise the registrar as mentioned in subsection (2) no longer exist;
  - (b) the registrar may do for any other reason at any time including where the registrar has grounds for suspecting that there is a failure to comply with any conditions to which the entry of the premises in Part 3 of the register is subject.
- (10) The entry of premises entered in Part 3 of the register under this section by virtue of subsection (2)(b) as one of a specified group of premises may be removed without removing the entries of the other premises in the group, or it may be removed by virtue of a decision to remove the entries of all of the premises in the group.
- (11) In this section, and in section 74K, “emergency” means an emergency of the type described in subsection (1)(a) of section 19 of the Civil Contingencies Act 2004 (meaning of “emergency”), read with subsection (2)(a) and (b) of that section.]

#### Textual Amendments

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(8\)](#) (with [Sch. 5 para. 10](#)); [S.I. 2010/1621](#), art. 2(1), [Sch.](#)

**F219** Words in s. 74J(4) substituted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 2 para. 16\(a\)](#); [S.I. 2022/1023](#), art. 2

**F220** Words in s. 74J(8) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 2 para. 16\(b\)](#); [S.I. 2022/1023](#), art. 2

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[<sup>F193</sup>**74K. Temporary annotations with regard to emergencies involving loss of human life or human illness etc.**

- (1) If the Secretary of State advises the registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this section, the registrar may annotate—
  - (a) the entry of a registered pharmacy entered in Part 3 of the register under section 74J to designate that pharmacy as a pharmacy from which drugs, medicines and appliances may be ordered in a specified capacity; or
  - (b) the entries of a specified group of registered pharmacies entered in Part 3 of the register under section 74J to designate that group as a group of pharmacies from which drugs, medicines and appliances may be ordered in a specified capacity.
- (2) The registrar may make an annotation, by virtue of subsection (1), to the entry of a registered pharmacy entered in Part 3 of the register under section 74J in such a way as to distinguish that annotation from an annotation in respect of a registered pharmacy made otherwise than by virtue of subsection (1).
- (3) Annotations made by virtue of subsection (1)—
  - (a) must be removed by the registrar if the Secretary of State advises the registrar that the circumstances that led the Secretary of State to advise the registrar as mentioned in subsection (1) no longer exist;
  - (b) may be removed by the registrar for any other reason at any time.
- (4) An annotation of the entry of a registered pharmacy made by virtue of subsection (1) (b) as one of a specified group may be removed without removing the annotations of the entries of the other registered pharmacies in the group, or it may be removed by virtue of a decision to remove the annotations of the entries of all the registered pharmacies in the group.]

**Textual Amendments**

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(8\)](#) (with [Sch. 5 para. 10](#)); [S.I. 2010/1621](#), art. 2(1), [Sch.](#)

[<sup>F193</sup>**74L. Evidence of registration: Great Britain**

A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises in Great Britain were, or were not, entered in Part 3 of the register (whether under section 74A or section 74J) is admissible in any proceedings as evidence (or in Scotland, as sufficient evidence) that those premises were, or were not, entered in the register on that date.]

**Textual Amendments**

**F193** Ss. 74A-74L inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(8\)](#) (with [Sch. 5 para. 10](#)); [S.I. 2010/1621](#), art. 2(1), [Sch.](#)

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## 75 Registration of premises<sup>[F221]</sup>: Northern Ireland].

<sup>[F222]</sup>(A1) This section applies in relation to premises in Northern Ireland.]

- (1) It shall be the duty of the registrar to keep a register for the purposes of this section <sup>F223</sup>... and, subject to the following provisions of this section, on payment of the prescribed fee to enter in the register any premises in respect of which an application is made under this section.
- (2) Any application for the registration of premises under this section shall be made in the prescribed manner and shall specify the premises to which the application relates and shall contain such other particulars as may be prescribed.
- (3) On the making of any such application the registrar shall notify the appropriate Minister, specifying the premises to which the application relates and the date on which the application was made, and shall not enter those premises in the register before the end of the period of two months from that date, unless before the end of that period the appropriate Minister consents to his doing so.
- (4) If it appears to the appropriate Minister that in a material respect the premises do not comply with the requirements of regulations made under section 66 of this Act which are for the time being in force, and accordingly he proposes to certify that the premises are unsuitable for registration under this section, he shall, before the end of the period referred to in subsection (3) of this section, serve on the applicant a notice stating his proposals and the reasons for them, and shall serve a copy of that notice on the registrar; and, where a copy of such a notice is served on him, the registrar shall not enter the premises in the register except where required to do so in accordance with the following provisions of this section.
- (5) If, within the time allowed after the service on him of a notice under subsection (4) of this section, the applicant gives notice to the appropriate Minister of his desire to be heard with respect to the proposals, or makes representations in writing to the appropriate Minister with respect to the proposals, then, before determining whether to issue a certificate under this section in respect of the premises,—
  - (a) if the applicant has given notice of his desire to be heard, the appropriate Minister shall afford to him an opportunity of appearing before, and being heard by, a person appointed by that Minister for the purpose, or
  - (b) if he has made representations in writing, that Minister shall consider those representations.
- (6) Where the appropriate Minister has served a notice under subsection (4) of this section, then—
  - (a) if he determines not to issue a certificate certifying that the premises are unsuitable for registration under this section, he shall notify the applicant and the registrar of his decision and (subject to subsection (7) of this section) the registrar shall forthwith enter the premises in the register;
  - (b) if the appropriate Minister issues such a certificate, he shall transmit the certificate to the registrar and shall notify the applicant that he has done so, and, if so required by the applicant, shall inform him of the reasons for his decision to issue such a certificate.
- (7) Notwithstanding anything in the preceding provisions of this section, the registrar shall not enter any premises in the register in pursuance of an application under this section unless it is shown to his reasonable satisfaction either—

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- (a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or
- (b) that, if the premises are entered in the register, and the applicant begins to carry on a retail pharmacy business at [<sup>F224</sup>or from] those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business.
- (8) In this section “the appropriate Minister”—
- <sup>F225</sup>(a) .....
- <sup>F225</sup>(b) .....
- (c) <sup>F226</sup>... means the Minister of Health and Social Services for Northern Ireland, and “the time allowed” means the period of twenty-eight days or such extended period as the appropriate Minister may in any particular case allow.

#### Textual Amendments

- F221** Words in s. 75 heading inserted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(9\)\(a\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F222** S. 75(A1) inserted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(9\)\(b\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F223** Words in s. 75(1) omitted (27.9.2010) by virtue of [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(9\)\(c\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F224** Words in s. 75(7)(b) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 2 para. 17](#); S.I. 2022/1023, art. 2
- F225** S. 75(8)(a)(b) omitted (27.9.2010) by virtue of [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(9\)\(d\)\(i\)](#); S.I. 2010/1621, art. 2(1), Sch.; S.I. 2010/1621, art. 2(1), Sch.
- F226** Words in s. 75(8)(c) omitted (27.9.2010) by virtue of [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(9\)\(d\)\(iii\)](#); S.I. 2010/1621, art. 2(1), Sch.

#### Modifications etc. (not altering text)

- C41** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: [S.I. 1969/388](#), [art. 2\(1\)](#)

## 76 Supplementary provisions as to registration of premises<sup>F227</sup>: Northern Ireland].

- (1) Where any premises have been entered in the register [<sup>F228</sup>under section 75], then, in respect of each year subsequent to the year in which the premises were so entered, a further fee (in this section referred to as a “retention fee”) of the prescribed amount shall be payable by the person carrying on a retail pharmacy business at [<sup>F229</sup>or from] those premises.
- (2) If, on demand being made to him in the prescribed manner, the person carrying on a retail pharmacy business at [<sup>F230</sup>or from] any premises entered in the register [<sup>F231</sup>under section 75] fails to pay a retention fee in respect of those premises within two months from the date on which the demand is made, [<sup>F232</sup>the appropriate Minister] may direct the registrar to remove the premises from the register; but if, before the end of the year in respect of which the retention fee is payable or such longer period as in any particular case [<sup>F232</sup>the appropriate Minister] may allow, the person carrying on the business pays to the registrar the retention fee in respect of that year, together with such additional sum (if any) by way of penalty as may be prescribed,—
- (a) the registrar shall restore the premises to the register, and

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- (b) if [<sup>F232</sup>the appropriate Minister] so [<sup>F233</sup>directs], the restoration shall be deemed to have had effect as from the date on which the premises were removed from the register.
- (3) Where a change occurs in the ownership of a retail pharmacy business carried on at [<sup>F234</sup>or from] any premises registered under section 75 of this Act, the registration of the premises under that section—
- (a) if the change occurs on the death of the person carrying on the business, or, in the case of a partnership, on the death of one of the partners, shall become void at the end of the period of three months from the date of the death, and
- (b) in any other case, shall become void at the end of the period of twenty-eight days from the date on which the change occurs.
- <sup>F235</sup>(4) .....
- (5) Where the registration of any premises under section 75 of this Act in respect of a business becomes void by virtue of subsection (3) of this section, an application for the premises to be restored to the register may be made by the person who, in consequence of the change of ownership, has become the owner of the business; and where such an application is made, and it is shown to the reasonable satisfaction of the registrar either—
- (a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or
- (b) that, if the premises are restored to the register, and the applicant thereafter carries on a retail pharmacy business at [<sup>F236</sup>or from] those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business,
- and (in a case where, if the registration had not become void, a retention fee would have become payable) a fee equal to a retention fee has been paid, the registrar shall restore the premises to the register.
- <sup>F237</sup>(6) .....
- (7) A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises [<sup>F238</sup>in Northern Ireland] were, or were not, entered in the register shall be admissible in any proceedings as evidence (and, in Scotland, shall be sufficient evidence) that those premises were, or were not, entered in the register on that date.
- <sup>F239</sup>(8) .....
- [<sup>F240</sup>(9) In this section—
- “the appropriate Minister” means the Minister of Health, Social Services and Public Safety for Northern Ireland;
- “year” means a period of 12 months beginning with such date as the appropriate Minister may from time to time determine.]

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**Textual Amendments**

**F227** Words in s. 76 heading inserted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(10\)\(a\)](#); S.I. 2010/1621, art. 2(1), Sch.

**F228** Words in s. 76(1) inserted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(10\)\(b\)](#); S.I. 2010/1621, art. 2(1), Sch.

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- F229** Words in s. 76(1) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 18(a)**; S.I. 2022/1023, art. 2
- F230** Words in s. 76(2) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 18(a)**; S.I. 2022/1023, art. 2
- F231** Words in s. 76(2) inserted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(c)(i)**; S.I. 2010/1621, art. 2(1), Sch.
- F232** Words in s. 76(2) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(c)(ii)**; S.I. 2010/1621, art. 2(1), Sch.
- F233** Word in s. 76(2)(b) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(c)(iii)**; S.I. 2010/1621, art. 2(1), Sch.
- F234** Words in s. 76(3) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 18(b)**; S.I. 2022/1023, art. 2
- F235** S. 76(4) repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1Pt. XII**
- F236** Words in s. 76(5)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 18(c)**; S.I. 2022/1023, art. 2
- F237** S. 76(6) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 40** (with regs. 2(4), 3)
- F238** Words in s. 76(7) inserted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(d)**; S.I. 2010/1621, art. 2(1), Sch.
- F239** S. 76(8) omitted (27.9.2010) by virtue of The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(e)**; S.I. 2010/1621, art. 2(1), Sch.
- F240** S. 76(9) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(10)(f)**; S.I. 2010/1621, art. 2(1), Sch.

## 77 Annual return of premises to registrar.

Every person who carried on a retail pharmacy business [<sup>F241</sup>at [<sup>F242</sup>or from] premises in Northern Ireland] shall, in the month of January in each year, send to the registrar—

- (a) a list of all [<sup>F243</sup>such] premises at [<sup>F244</sup>or from] which his business, so far as it consists of the retail sale of medicinal products, is carried on, and
- <sup>F245</sup>(b) .....

### Textual Amendments

- F241** Words in s. 77 inserted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(11)(a)**; S.I. 2010/1621, art. 2(1), Sch.
- F242** Words in s. 77 inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 19(a)**; S.I. 2022/1023, art. 2
- F243** Word in s. 77(a) inserted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(11)(b)**; S.I. 2010/1621, art. 2(1), Sch.
- F244** Words in s. 77(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 19(b)**; S.I. 2022/1023, art. 2
- F245** S. 77(b) repealed (1.10.2009) by Health Act 2006 (c. 28), ss. 30(2), 83(7), **Sch. 9**; S.I. 2008/2714, art. 2(b)(c)

*Provisions as to use of certain titles, descriptions and emblems*

## 78 Restrictions on use of titles, descriptions and emblems.

- (1) The provisions of this section shall have effect subject to section 79 of this Act.

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- (2) <sup>F246</sup>... No person shall—
- (a) take or use any of the following titles, that is to say, chemist and druggist, druggist, dispensing chemist, and dispensing druggist, or
  - (b) take or use the title of chemist in connection with the sale of any goods by retail or the supply of any goods in circumstances corresponding to retail sale, unless the conditions specified in the next following subsection are fulfilled.
- (3) Those conditions are—
- (a) in the case of an individual, that he is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership) and that he does not take or use the title in question in connection with any premises at [<sup>F247</sup>or from] which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and
  - (b) in the case of a body corporate, that the body is a person lawfully conducting a retail pharmacy business and that the title in question is not taken or used by that body in connection with any premises at [<sup>F248</sup>or from] which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy <sup>F249</sup>....
- (4) <sup>F246</sup>... No person shall, in connection with a business carried on by him which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, use the description “pharmacy” except in respect of a registered pharmacy or in respect of the pharmaceutical department of a hospital or a health centre.
- [<sup>F250</sup>(5) A person who is not registered in the register of pharmaceutical chemists for Northern Ireland <sup>F251</sup>... made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 may not—
- (a) take or use the title pharmaceutical chemist, pharmacist, pharmacist, member of the Pharmaceutical Society of Northern Ireland or Fellow of the Pharmaceutical Society of Northern Ireland; or
  - (b) take or use any of the titles mentioned in paragraph (a) in connection with a business carried on (whether by him or by some other person) at [<sup>F252</sup>or from] any premises which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, unless those premises are a registered pharmacy or a hospital or health centre.
- (5A) A person who is not registered as a pharmacist in Part 1 <sup>F253</sup>... of the register maintained under article 19 of the Pharmacy Order 2010 may not take or use the title pharmacist or fferyllydd (its equivalent in the Welsh language) in connection with a business carried on (whether by him or by some other person) at [<sup>F254</sup>or from] any premises which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, unless those premises are a registered pharmacy or a hospital or health centre.
- (5B) Subsection (5) extends to Northern Ireland only; and subsection (5A) does not extend there.]
- (6) <sup>F246</sup>... No person shall, in connection with any business, use any title, description or emblem likely to suggest—
- (a) that he possesses any qualification with respect to the sale, manufacture or assembly of medicinal products which he does not in fact possess, or

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- (b) that any person employed in the business possesses any such qualification which that person does not in fact possess.
- (7) For the purposes of the last preceding subsection the use of the description “pharmacy”, in connection with a business carried on at [<sup>F255</sup>or from] any premises, shall be taken to be likely to suggest that the person carrying on the business (where that person is not a body corporate) is a pharmacist and that any other person, [<sup>F256</sup>who is in charge of [<sup>F257</sup>the business carried on at or from] those premises (so far as concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale) is also a pharmacist].
- (8) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in section 69(1)(c) of this Act, subsections (5) to (7) of this section shall not have effect so as to prevent the representative from taking or using, in connection with that business, any title, description or emblem which the pharmacist himself could have used in accordance with those subsections.

#### Textual Amendments

- F246** Words in s. 78 repealed (5.11.1993) by 1993 c. 50, s. 1(1), **Sch. 1 Pt. XII**
- F247** Words in s. 78(3)(a) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(a)**; S.I. 2022/1023, art. 2
- F248** Words in s. 78(3)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(a)**; S.I. 2022/1023, art. 2
- F249** Words in s. 78(3)(b) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), arts. 1(3), **6(3)**; S.I. 2022/1023, art. 2
- F250** S. 78(5)-(5B) substituted for s. 78(5) (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(12)**; S.I. 2010/1621, art. 2(1), Sch.
- F251** Words in s. 78(5) 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. 6(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)
- F252** Words in s. 78(5)(b) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(b)**; S.I. 2022/1023, art. 2
- F253** Words in s. 78(5A) 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. 6(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)
- F254** Words in s. 78(5A) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(c)**; S.I. 2022/1023, art. 2
- F255** Words in s. 78(7) inserted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(d)(i)**; S.I. 2022/1023, art. 2
- F256** Words in s. 78(7) substituted (1.10.2009) by Health Act 2006 (c. 28), **ss. 27(2)**, 83(7); S.I. 2008/2714, art. 2(a)
- F257** Words in s. 78(7) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 2 para. 20(d)(ii)**; S.I. 2022/1023, art. 2



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## 79 Provision for modifying or extending restrictions under s. 78.

- (1) The <sup>F258</sup>... Ministers may by order provide that any of the restrictions imposed by section 78 of this Act shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the order.
- (2) Without prejudice to the preceding subsection, regulations made by the <sup>F259</sup>... Ministers may (in addition to the restrictions for the time being having effect by virtue of section 78 of this Act) impose such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified in the regulations.
- (3) Without prejudice to the application of section 129(6) of this Act, before making any order or regulations under this section the <sup>F260</sup>... Ministers shall consult [<sup>F261</sup>the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland].
- (4) Regulations made under this section shall be of no effect unless a draft of the regulations has been laid before Parliament and approved by a resolution of each House of Parliament.

### Textual Amendments

- F258** Word in s. 79(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 41\(a\)](#) (with regs. 2(4), 3)
- F259** Word in s. 79(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 41\(b\)](#) (with regs. 2(4), 3)
- F260** Word in s. 79(3) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 41\(c\)](#) (with regs. 2(4), 3)
- F261** Words in s. 79(3) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(13\)](#); S.I. 2010/1621, art. 2(1), Sch.

### *Disqualification, and removal of premises from register*

## 80 Power for [<sup>F262</sup>relevant disciplinary committee] to disqualify and direct removal from register.

- [<sup>F263</sup>(1) Where a body corporate carries on a retail pharmacy business and—
- (a) that body is convicted of an offence under one of the relevant Acts;
  - (b) any member of the board or any officer of, or person employed by, that body is convicted of an offence, or has been guilty of misconduct, and the offence or misconduct is such as in the opinion of the relevant disciplinary committee renders him, or would if he were a pharmacist, render him unfit to be a pharmacist; or
  - (c) in respect of premises [<sup>F264</sup>in Great Britain] that are entered in the register as premises at [<sup>F265</sup>or from] which the body corporate carries on that business, there is a failure to meet the standards that are [<sup>F266</sup>provided for in rules made under][<sup>F266</sup>set under Article 5A(1) of the Pharmacy (Northern Ireland) Order 1976 or] article 7(1) of the Pharmacy Order 2010 in connection with the carrying on of the business at [<sup>F267</sup>or from] those premises,

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then, subject to the following provisions of this Part of this Act, the relevant disciplinary committee, after inquiring into the case, may direct that the body corporate is to be disqualified for the purposes of this Part of this Act.]

[<sup>F268</sup>(1A) Where—

- (a) a pharmacist or partnership carries on a retail pharmacy business, and
- (b) in respect of premises that are entered in the register as premises at or from which that pharmacist or partnership carries on that business, there is a failure to meet the standards that are set under Article 5A(1) of the Pharmacy (Northern Ireland) Order 1976 or article 7(1) of the Pharmacy Order 2010 in connection with the carrying on of the business at or from those premises,

then, subject to the following provisions of this Part of this Act, the relevant disciplinary committee, after inquiring into the case, may direct that the pharmacist or partnership is to be disqualified for the purposes of this Part of this Act.

(1B) But, in a case falling within subsection (1)(c) or (1A), the relevant disciplinary committee may only give a direction under the subsection in question if they are satisfied that the body corporate, the pharmacist or the partnership is unfit to carry on a retail pharmacy business safely and effectively, so far as concerns—

- (a) the retail sale of medicinal products (whether they are on a general sale list or not), or
- (b) the supply of such products in circumstances corresponding to retail sale.]

(2) In any case falling [<sup>F269</sup>within the preceding subsection][<sup>F269</sup>within subsection (1) or (1A)] —

- (a) if the [<sup>F270</sup>the relevant disciplinary committee] give a direction under [<sup>F271</sup>that subsection][<sup>F271</sup>the subsection in question], they shall direct the registrar to remove from the register all premises entered in the register as being premises at [<sup>F272</sup>or from] which the body corporate[<sup>F273</sup>, the pharmacist or the partnership] carries on a retail pharmacy business;
- (b) if the [<sup>F270</sup>the relevant disciplinary committee] do not give a direction under [<sup>F274</sup>the preceding subsection][<sup>F274</sup>the subsection in question], they may, if they think fit, direct the registrar to remove from the register all those premises, or such of them as may be specified in the direction under this paragraph.

[<sup>F275</sup>(2A) But, in a case falling within subsection (1)(c) or (1A), the relevant disciplinary committee may only direct the registrar under subsection (2)(b) to remove premises from the register if they are satisfied that the body corporate, the pharmacist or the partnership is unfit to carry on a retail pharmacy business safely and effectively at or from those premises, so far as concerns—

- (a) the retail sale of medicinal products (whether they are on a general sale list or not), or
- (b) the supply of such products in circumstances corresponding to retail sale.]

(3) Directions under subsection (1) [<sup>F276</sup>or (1A)] of this section and under paragraph (a) of [<sup>F277</sup>the last preceding subsection][<sup>F277</sup>subsection (2)], and any direction under paragraph (b) of [<sup>F277</sup>the last preceding subsection][<sup>F277</sup>subsection (2)], may, if the [<sup>F278</sup>the relevant disciplinary committee] think fit, be given so as to have effect for a limited period; and in that case the registrar, at the end of that period, shall restore to the register any premises removed from it in compliance with the direction given under paragraph (a) or paragraph (b) of [<sup>F277</sup>the last preceding subsection][<sup>F277</sup>subsection (2)].

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- (4) Where, in any such case as is mentioned in subsection (1) of section 72 of this Act, a representative, or a person employed by a representative in the business referred to in that subsection,—
- (a) is convicted of an offence, or
  - (b) has been guilty of misconduct,
- and the offence or misconduct is such as in the opinion of the [<sup>F279</sup>the relevant disciplinary committee] renders him, or would if he were a pharmacist render him, unfit to be a pharmacist, then, subject to the following provisions of this Part of this Act, the [<sup>F279</sup>the relevant disciplinary committee], after inquiring into the case, may direct that the representative shall be disqualified for the purposes of this Part of this Act.
- (5) In this and the next following section “the relevant Acts” means [<sup>F280</sup>the Pharmacy Act 1954, this Act, the Misuse of Drugs Act 1971, the Pharmacy (Northern Ireland) Order 1976, the Pharmacists and Pharmacy Technicians Order 2007 and the Pharmacy Order 2010], and “representative” has the same meaning as in section 72 of this Act.

#### Textual Amendments

- F262** Words in heading substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\)](#), art. 1(2)(3), **Sch. 1 para. 2(12)**
- F263** S. 80(1) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), **Sch. 4 para. 1(14)(a)**; S.I. 2010/1621, art. 2(1), Sch.
- F264** Words in s. 80(1)(c) omitted (24.5.2018 for E.W.S.) by virtue of [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(2)(a)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F265** Words in s. 80(1)(c) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(2)(b)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F266** Words in s. 80(1)(c) substituted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(2)(c)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F267** Words in s. 80(1)(c) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(2)(d)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F268** S. 80(1A)(1B) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(3)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F269** Words in s. 80(2) substituted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(4)(a)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F270** Words in s. 80(2) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\)](#), art. 1(2)(3), **Sch. 1 para. 2(12)(a)**
- F271** Words in s. 80(2)(a) substituted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(4)(b)(i)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F272** Words in s. 80(2)(a) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(4)(b)(ii)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F273** Words in s. 80(2)(a) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **9(4)(b)(iii)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)

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- F274** Words in s. 80(2)(b) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **9(4)(c)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F275** S. 80(2A) inserted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **9(5)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F276** Words in s. 80(3) inserted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **9(6)(a)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F277** Words in s. 80(3) substituted (24.5.2018 for E.W.S.) by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (S.I. 2016/372), arts. 1(3), **9(6)(b)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F278** Words in s. 80(3) substituted (coming into force in accordance with art. 1(2)(3)) by Pharmacists and Pharmacy Technicians Order 2007 (S.I. 2007/289), art. 1(2)(3), **Sch. 1 para. 2(12)(a)**
- F279** Words in s. 80(4) substituted (coming into force in accordance with art. 1(2)(3)) by Pharmacists and Pharmacy Technicians Order 2007 (S.I. 2007/289), art. 1(2)(3), **Sch. 1 para. 2(12)(a)**
- F280** Words in s. 80(5) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(14)(b)**; S.I. 2010/1621, art. 2(1), Sch.

#### Modifications etc. (not altering text)

- C42** S. 80 heading; amendments continued (11.2.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(2)(c), **Sch. 6 para. 1(2)(b)**
- C43** S. 80: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), **Sch. 3 para. 2(3)(a)**; S.I. 2000/779, **art. 2(1)**
- C44** S. 80(2)(3)(4) amendments continued (11.2.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(2)(c), **Sch. 6 para. 1(2)(c)**

## 81 Grounds for disqualification in certain cases.

[<sup>F281</sup>(1) Unless the conditions specified in subsection (1A) are satisfied, the relevant disciplinary committee may not do any of the following—

- (a) give a direction under subsection (1) of section 80 of this Act—
  - (i) in a case falling within paragraph (b) of that subsection, or
  - (ii) in a case falling within paragraph (c) of that subsection, where the failure in question is by a member of the board or any officer of, or person employed by, the body in question; or
- (b) give a direction under subsection (4) of that section.

(1A) The conditions are that—

- (a) one or more of the facts specified in subsection (2) are proved to the satisfaction of the relevant disciplinary committee; and
- (b) the committee are of the opinion, having regard to those facts, that the board of the body corporate or, as the case may be, the representative, is to be regarded as responsible for the offence, misconduct or failure in question.]

(2) [<sup>F282</sup>The facts referred to in subsection (1A)(a) of this section are]

- (a) that [<sup>F283</sup>the offence, misconduct or failure in question] was instigated or connived at by the board or by a member of the board, or by the representative, as the case may be;

- [<sup>F284</sup>(b) that, in the case of a body corporate, a member of the board, or an officer of, or person employed by, the body corporate had, at some time within the twelve months immediately preceding the date on which the offence, misconduct or failure occurred, been guilty of a similar offence or failure or of similar

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- misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence, misconduct or failure;]
- (c) that, in the case of the representative, he or a person employed by him had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and (where it was a similar offence or similar misconduct on the part of an employee) that the representative had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;
  - (d) if [<sup>F285</sup>offence, misconduct or failure in question is a continuing offence or failure or is continuing misconduct], that the board, or the representative, had, or with the exercise of reasonable care would have had, knowledge of its continuance;
  - (e) in the case of an offence in respect of a contravention of an enactment contained in any of the relevant Acts, that the board, or the representative, had not exercised reasonable care to secure that the enactment was complied with.

#### Textual Amendments

- F281** S. 81(1)(1A) substituted for s. 81(1) (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(15\)\(a\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F282** Words in s. 81(2) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(15\)\(b\)\(i\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F283** Words in s. 81(2)(a) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(15\)\(b\)\(ii\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F284** S. 81(2)(b) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(15\)\(b\)\(iii\)](#); S.I. 2010/1621, art. 2(1), Sch.
- F285** Words in s. 81(2)(d) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(15\)\(b\)\(iv\)](#); S.I. 2010/1621, art. 2(1), Sch.

#### Modifications etc. (not altering text)

- C45** S. 81: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), [Sch. 3 para. 2\(3\)\(a\)](#); S.I. 2000/779, [art. 2\(1\)](#)

## 82 Procedure relating to disqualification.

- (1) [<sup>F286</sup>The relevant disciplinary committee] shall not give a direction under section 80 of this Act except with the assent of the chairman of the Committee.
- (2) A direction under that section shall not take effect until the end of the period of three months from the date on which notice of the direction is given to the body corporate [<sup>F287</sup>, pharmacist, partnership] or other person to whom it relates, and, if an appeal against the direction is brought under this section, shall not take effect until that appeal has been determined or withdrawn.
- (3) Where any such direction is given, the body corporate [<sup>F288</sup>, pharmacist, partnership] or other person to whom it relates may, at any time before the end of the period of three months specified in subsection (2) of this section, appeal against the direction to the High Court.
- (4) The [<sup>F289</sup>General Pharmaceutical Council or, in Northern Ireland, the Pharmaceutical Society of Northern Ireland] may appear as respondent on any such appeal; and, for

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the purpose of enabling directions to be given as to costs on any such appeal, the [<sup>F290</sup>Council or the Society] shall be deemed to be a respondent to the appeal whether they appear on the hearing of the appeal or not.

- (5) On any such appeal, the High Court may give such directions in the matter as appear to the Court to be appropriate; and it shall be the duty of [<sup>F291</sup>the relevant disciplinary committee] to comply with any such directions and (where appropriate) of the registrar to make such alterations in the register as are necessary to give effect to them.
- (6) No appeal shall lie from any decision of the High Court under this section.
- (7) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session, and any reference to costs shall be construed as a reference to expenses.
- (8) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the [<sup>F292</sup>Court of Judicature ] of Northern Ireland.

#### Textual Amendments

- F286** Words in s. 82(1) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\)](#), art. 1(2)(3), **Sch. 1 para. 2(14)**
- F287** Words in s. 82(2) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **10(a)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F288** Words in s. 82(3) inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **10(b)**; S.I. 2018/512, art. 2(1)(a)(ii)(2)
- F289** Words in s. 82(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 11(a)** (with Sch. 32)
- F290** Words in s. 82(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 11(b)** (with Sch. 32)
- F291** Words in s. 82(5) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\)](#), art. 1(2)(3), **Sch. 1 para. 2(14)**
- F292** Words in Act substituted (1.10.2009) by [Constitutional Reform Act 2005 \(c. 4\)](#), s. 148(1), **Sch. 11 para. 6**; S.I. 2009/1604, art. 2(d)

#### Modifications etc. (not altering text)

- C42** S. 80 heading; amendments continued (11.2.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(2)(c), **Sch. 6 para. 1(2)(b)**
- C46** s. 82: Power to amend conferred (15.3.2000) by 1999 c. 8, s. 60(1)(2)(4), **Sch. 3 para. 2(3)(a)**; S.I. 2000/779, **art. 2(1)**
- C47** S. 82(1) amendments continued (11.2.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(2)(c), **Sch. 6 para. 1(2)(d)**
- C48** S. 82(5) amendments continued (11.2.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(2)(c), **Sch. 6 para. 1(2)(d)**

#### <sup>F293</sup>82A. Interim measures

- (1) Subsection (2) applies where—
  - (a) the relevant disciplinary committee have given a direction (“the principal direction”) under section 80(1), (1A) or (2) in relation to a body corporate, pharmacist or partnership; and
  - (b) the direction has not yet taken effect.

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- (2) Where the committee are satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest, the committee may direct the registrar to suspend from the register, until the principal direction takes effect or an appeal under section 82(3) against the principal direction is successful—
  - (a) all entries of premises entered in the register as premises at or from which the body corporate, pharmacist or partnership carries on a retail pharmacy business; or
  - (b) entries of such of those premises as may be specified in the direction under this subsection.
- (3) Where the committee give a direction under subsection (2), the registrar must send to the body corporate, pharmacist or partnership to whom the direction relates a statement in writing giving that person notice of—
  - (a) the contents of the direction; and
  - (b) the right of appeal under subsection (5).
- (4) The statement must be sent—
  - (a) in the case of a body corporate, to the body corporate at its registered or principal office;
  - (b) in the case of a pharmacist, to the pharmacist at the pharmacist's home address in the register;
  - (c) in the case of a partnership, to the partnership at its principal office.
- (5) A body corporate, pharmacist or partnership to whom a direction under subsection (2) relates may appeal against the direction to the High Court.
- (6) Subsections (4) to (6) of section 82 apply in relation to an appeal under subsection (5) as they apply in relation to an appeal under section 82(3).
- (7) Subsections (7) and (8) of section 82 apply in the application of this section to Scotland or Northern Ireland as they apply in the application of section 82 to Scotland or Northern Ireland.]

#### Textual Amendments

**F293** S. 82A inserted (24.5.2018 for E.W.S.) by [The Pharmacy \(Premises Standards, Information Obligations, etc.\) Order 2016 \(S.I. 2016/372\)](#), arts. 1(3), **11**; S.I. 2018/512, art. 2(1)(a)(ii)(2)

### 83 Revocation of disqualification.

- (1) At any time while a direction under section 80 of this Act is in force [<sup>F294</sup>the relevant disciplinary committee], either on the application of the person to whom it relates or without any such application, may revoke the direction.
- (2) If, on an application to [<sup>F295</sup>the relevant disciplinary committee] to revoke such a direction, [<sup>F296</sup>the committee] refuse to revoke it, the applicant, at any time before the end of the period of three months from the date on which notice of the refusal is given to him, may appeal to the High Court against the refusal.
- (3) Subsections (4) to (6) of section 82 of this Act shall have effect in relation to any appeal under this section as they have effect in relation to appeals under that section.

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- (4) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session; and in the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the [F292 Court of Judicature ] of Northern Ireland.

#### Textual Amendments

- F292** Words in Act substituted (1.10.2009) by [Constitutional Reform Act 2005 \(c. 4\), s. 148\(1\), Sch. 11 para. 6](#); [S.I. 2009/1604, art. 2\(d\)](#)
- F294** Words in s. 83(1) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\), art. 1\(2\)\(3\), Sch. 1 para. 2\(15\)\(a\)](#)
- F295** Words in s. 83(2) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\), art. 1\(2\)\(3\), Sch. 1 para. 2\(15\)\(a\)](#)
- F296** Words in s. 83(2) substituted (coming into force in accordance with art. 1(2)(3)) by [Pharmacists and Pharmacy Technicians Order 2007 \(S.I. 2007/289\), art. 1\(2\)\(3\), Sch. 1 para. 2\(15\)\(b\)](#)

#### Modifications etc. (not altering text)

- C42** S. 80 heading; amendments continued (11.2.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\), art. 1\(2\)\(c\), Sch. 6 para. 1\(2\)\(b\)](#)
- C49** S. 83: Power to amend conferred (15.3.2000) by [1999 c. 8, s. 60\(1\)\(2\)\(4\), Sch. 3 para. 2\(3\)\(a\)](#); [S.I. 2000/779, art. 2\(1\)](#)
- C50** S. 83(1)(2) amendments continued (11.2.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\), art. 1\(2\)\(c\), Sch. 6 para. 1\(2\)\(e\)](#)

### Supplementary provisions

#### 84 Offences under Part IV.

<sup>F297</sup>(A1) .....

- (1) Any person who contravenes section 77 of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F298</sup>level 3 on the standard scale].
- (2) Any person who contravenes section 78 of this Act or who contravenes any regulations made under section 79(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding [<sup>F299</sup>level 3 on the standard scale].

#### Textual Amendments

- F297** S. 84(A1) omitted (1.12.2022) by virtue of [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\), art. 1\(3\), Sch. 1 para. 4](#) (with art. 8(2)); [S.I. 2022/1023, art. 2](#)
- F298** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\), ss. 38, 46](#), (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\), ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\), arts. 5, 6](#)
- F299** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c.48, SIF 39:1\), ss. 38, 46](#), (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\), ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\), arts. 5, 6](#)



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## [<sup>F300</sup>84A.Rules by the General Pharmaceutical Council

- (1) The General Pharmaceutical Council may make such provision as it considers appropriate in rules for any purpose for which rules are authorised or required to be made by it under Part 4 of this Act.
- (2) Article 66 of the Pharmacy Order 2010 (rules) applies to the making of rules by the General Pharmaceutical Council under [<sup>F301</sup>any provision of Part 4 of this Act other than section 72A] as it applies to the making of rules by the General Pharmaceutical Council under Part 3 of that Order (registered pharmacies: standards in retail pharmacies).]
- [<sup>F302</sup>(3) The power of the General Pharmaceutical Council to make rules under section 72A may be exercised so as to make different provision for different areas or in relation to different cases or different circumstances to which the power is applicable, and to make any such provision subject to such exceptions, limitations and conditions (if any) as the General Pharmaceutical Council considers necessary or expedient.
- (4) Before making rules under section 72A, the General Pharmaceutical Council must publish draft rules and invite representations to be made to it about the draft by—
  - (a) the Secretary of State, the Scottish Ministers and the Welsh Ministers, and
  - (b) any other persons appearing to it appropriate to consult about the draft.
- (5) No rules made under section 72A by the General Pharmaceutical Council are to come into force until approved by order of the Privy Council.
- (6) The power vested in the Privy Council to make an order under subsection (5) may be exercised by any two or more members of the Privy Council.
- (7) The making of an order under subsection (5) is sufficiently signified by an instrument signed by the Clerk of the Privy Council.
- (8) Where an order under subsection (5) is signified by an instrument purporting to be signed by the Clerk of the Privy Council, that is evidence and in Scotland sufficient evidence of—
  - (a) the fact that the order was duly made, and
  - (b) the order's terms.]

### Textual Amendments

- F300** S. 84A inserted (10.2.2010 for specified purposes, 27.9.2010 in so far as not already in force) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(3), [Sch. 4 para. 1\(16\)](#); S.I. 2010/1621, art. 2(1), [Sch. 2022/1023](#), art. 2
- F301** Words in s. 84A(2) substituted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 1 para. 5\(a\)](#); S.I. 2022/1023, art. 2
- F302** S. 84A(3)-(8) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), [Sch. 1 para. 5\(b\)](#); S.I. 2022/1023, art. 2

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## PART V

### CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

#### <sup>F303</sup>85 Labelling and marking of containers and packages.

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##### Textual Amendments

**F303** S. 86 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

#### <sup>F303</sup>86 Leaflets.

.....

##### Textual Amendments

**F303** S. 86 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

#### 87 Requirements as to containers.

- (1) The <sup>F304</sup>... Ministers may make regulations prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as [<sup>F305</sup>the Ministers] consider necessary or expedient for any of the purposes specified in [<sup>F306</sup>subsection (3)], or for the purpose of preserving the quality of the products, and in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed.
- (2) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.
- [<sup>F307</sup>(3) The purposes mentioned in subsection (1) are—
- (a) securing that medicinal products are correctly described and readily identifiable;
  - (b) securing that any appropriate warning or other appropriate instruction or information is given, and that false or misleading information is not given, with respect to medicinal products;
  - (c) promoting safety in relation to medicinal products.]

##### Textual Amendments

- F304** Word in s. 87(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 44\(a\)](#) (with regs. 2(4), 3)
- F305** Words in s. 87(1) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 44\(b\)](#) (with regs. 2(4), 3)

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- F306** Words in s. 87(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 12(a)** (with Sch. 32)
- F307** S. 87(3) inserted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 12(b)** (with Sch. 32)

**Modifications etc. (not altering text)**

- C51** Pt. V (ss. 85–91) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**
- C52** Ss. 85–88, 91 extended by [S.I. 1984/187](#), **art. 2**

**88 Distinctive colours, shapes and markings of medicinal products.**

- (1) Regulations made by the <sup>F308</sup>... Ministers may impose such requirements as, for any of the purposes specified in [<sup>F309</sup>section 87(3)] of this Act, [<sup>F310</sup>the Ministers] consider necessary or expedient with respect to any one or more of the following matters, that is to say—
- (a) the colour of the products;
  - (b) the shape of the products; and
  - (c) distinctive marks to be displayed on the products.
- (2) Regulations made under this section may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations shall not except in such circumstances (if any) as may be so specified, be of any such colour or shape, or display any such mark, as may be so specified.
- (3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by regulations under this section.

**Textual Amendments**

- F308** Word in s. 88(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 45(a)** (with regs. 2(4), 3)
- F309** Words in s. 88(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 13** (with Sch. 32)
- F310** Words in s. 88(1) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 45(b)** (with regs. 2(4), 3)

**Modifications etc. (not altering text)**

- C53** Pt. V (ss. 85–91) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**
- C54** Ss. 85–88, 91 extended by [S.I. 1984/187](#), **art. 2**

<sup>F311</sup>**89 Display of information on automatic machines.**

**Textual Amendments**

- F311** S. 89 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 35** (with Sch. 32)

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**Modifications etc. (not altering text)**

**C55** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**<sup>F312</sup>90 Provisions as to medicated animal feeding stuffs.**

.....

**Textual Amendments**

**F312** S. 90 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 47** (with regs. 2(4), 3)

**Modifications etc. (not altering text)**

**C56** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**91 Offences under Part V, and supplementary provisions.**

**<sup>F313</sup>(1)** .....

- (2) Any regulations made under this Part of this Act may provide that any person who contravenes the regulations, or who contravenes the provisions of <sup>F314</sup>... section 87(2) of this Act <sup>F315</sup>..., shall be guilty of an offence and—
- (a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and
  - (b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.
- (3) Without prejudice to the application of section 129(5) of this Act, any power to make regulations conferred by [<sup>F316</sup>section] 87 of this Act may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations <sup>F317</sup>....
- (4) In this Part of this Act “requirements” includes restrictions.

**Textual Amendments**

**F313** S. 91(1) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 14(a)**, **Sch. 35** (with Sch. 32)

**F314** Words in s. 91(2) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 14(b)** (with Sch. 32)

**F315** Words in s. 91(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 48(b)** (with regs. 2(4), 3)

**F316** Word in s. 91(3) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 14(c)** (with Sch. 32)

**F317** Words in s. 91(3) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 48(c)** (with regs. 2(4), 3)

**Modifications etc. (not altering text)**

**C57** Pt. V (ss. 85–91) extended with modifications by S.I. 1985/1403, **art. 3(1)**

**C58** Ss. 85–88, 91 extended by S.I. 1984/187, **art. 2**

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- C59** S. 91 applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**
- C60** Criminal Justice Act 1982 (c. 48, SIF 39:1), **ss. 38** (increase of fines) and 46 (substitution of references to levels on the standard scale) apply (E.W.) and Criminal Procedure (Scotland) Act 1975 (c. 21, SIF 39:1), **ss. 289F, 289G** (increase of fines and substitution of references to levels on the standard scale) apply (S.) and S.I. 1984/703 (N.I. 3), **art. 5** (substitution of references to levels on the standard scale) and art. 6 (increase of fines) apply (N.I.)

## PART VI

### PROMOTION OF SALES OF MEDICINAL PRODUCTS

#### <sup>F318</sup>92 Scope of Part VI.

.....

##### Textual Amendments

- F318** Ss. 92-103 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

#### <sup>F318</sup>93 False or misleading advertisements and representations.

.....

##### Textual Amendments

- F318** Ss. 92-103 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

#### <sup>F318</sup>94 Advertisements requiring consent of holder of product licence.

.....

##### Textual Amendments

- F318** Ss. 92-103 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

#### <sup>F318</sup>95 Powers to regulate advertisements and representations.

.....

##### Textual Amendments

- F318** Ss. 92-103 repealed (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 35** (with Sch. 32)

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**F318 96 Advertisements and representations directed to practitioners.**

.....

**Textual Amendments**  
**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**F318 97 Power for licensing authority to require copies of advertisements.**

.....

**Textual Amendments**  
**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**PART VII**

BRITISH PHARMACOPOEIA AND OTHER PUBLICATIONS

**98** ..... **F319**

**Textual Amendments**  
**F319** S. 98 repealed by [Copyright, Designs and Patents Act 1988 \(c. 48, SIF 67A\)](#), s. 303(2), [Sch. 8](#)

**F318 99 New editions of British Pharmacopoeia, and other compendia.**

.....

**Textual Amendments**  
**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**F318 100 Lists of names.**

.....

**Textual Amendments**  
**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

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**F318 101 Other publications.**

.....

**Textual Amendments**

**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**F318 102 Supplementary provisions.**

.....

**Textual Amendments**

**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**F318 103 Construction of references to specified publications.**

.....

**Textual Amendments**

**F318** Ss. 92-103 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**PART VIII**

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

**Modifications etc. (not altering text)**

**C61** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**104 Application of [<sup>F320</sup>the 2012 Regulations] to certain articles and substances.**

- (1) The Ministers<sup>F321</sup>... may by order specify any description or class of articles or substances appearing to them to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and may by the order direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of [<sup>F322</sup>the 2012 Regulations]<sup>F323</sup>, or the Clinical Trials Regulations,] as may be so specified (including provisions so specified which relate to offences or penalties) shall have effect in relation to articles or substances of that description or class as those provisions have effect in relation to medicinal products.

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- (2) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

#### Textual Amendments

- F320** Words in s. 104 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 15(a)** (with Sch. 32)
- F321** Words in s. 104(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 54** (with regs. 2(4), 3)
- F322** Words in s. 104(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 15(b)** (with Sch. 32)
- F323** Words in s. 104(1) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 17**

#### Modifications etc. (not altering text)

- C62** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

### 105 Application of [<sup>F324</sup>the 2012 Regulations] to certain other substances which are not medicinal products.

- (1) The Ministers may by order specify any substance appearing to the Ministers to be a substance which is not itself a medicinal product but—
- is used as an ingredient in the manufacture of medicinal products, or
  - if used without proper safeguards, is capable of causing danger to the health of the community<sup>F325</sup> ...,
- and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of [<sup>F326</sup>the 2012 Regulations][<sup>F327</sup>, or the Clinical Trials Regulations.] as may be so specified (including any provisions so specified which relate to offences or penalties) shall have effect in relation to that substance as those provisions have effect in relation to medicinal products.
- (2) The power conferred by the preceding subsection may be exercised in relation to a class of substances if it appears to the Ministers that the conditions specified in paragraph (a) or paragraph (b) of that subsection are fulfilled in relation to all substances falling within that class.
- (3) No order shall be made under this section—
- in relation to a substance as being a substance in respect of which the condition specified in subsection (1)(b) of this section is fulfilled, or
  - in relation to a class of substances as being substances in respect of which that condition is fulfilled,
- unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

#### Textual Amendments

- F324** Words in s. 105 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 16(a)** (with Sch. 32)



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- F325** Words in s. 105(1)(b) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 55** (with regs. 2(4), 3)
- F326** Words in s. 105(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 16(b)** (with Sch. 32)
- F327** Words in s. 105(1) inserted (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), reg. 1, **Sch. 10 para. 18**

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**Modifications etc. (not altering text)**

- C63** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

## **106 Extension of references to carrying on business.**

- (1) The Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if in those provisions any reference to a business included a reference to an activity (other than a business) of a description specified in the order.
- (2) Without prejudice to the preceding subsection, the Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if, in such circumstances as may be so specified, a business carried on by a person's employer were a business carried on by that person.

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**Modifications etc. (not altering text)**

- C64** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C65** Commentary missing

## **107 Validity of decisions and proceedings relating thereto.**

- (1) Except as provided by the following provisions of this section, the validity of any decision <sup>F328</sup>... of a Minister under section 75 of this Act, and the validity of any [<sup>F329</sup>certificate issued] or other thing done in pursuance of any such decision, shall not be questioned in any legal proceedings.
- (2) If the person to whom such a decision relates desires to question the validity of the decision on the grounds—
  - (a) that it is not within the powers of this Act, or
  - (b) that any of the requirements of this Act or of any regulations made under this Act, which are applicable to the matter to which the decision relates, have not been complied with,that person may, at any time within the period of three months from the date on which notice of the decision is served on him, make an application to the High Court under this section.
- (3) On any application under this section the High Court—

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- (a) may by interim order suspend the operation of the decision to which the application relates until the final determination of the proceedings;
  - (b) if satisfied that the decision is not within the powers of this Act, or that the interests of the person making the application have been substantially prejudiced by a failure to comply with any of the requirements mentioned in subsection (2)(b) of this section, may quash the decision.
- (4) Where a decision to [<sup>F330</sup>issue a certificate] is quashed under this section, any [<sup>F331</sup>certificate issued] in pursuance of that decision shall be void, and any proceedings on the application for the [<sup>F332</sup>issue of the] certificate may be continued as if no such decision had been made.
- (5) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session.
- (6) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the High Court <sup>F333</sup>... in Northern Ireland.

#### Textual Amendments

- F328** Words in s. 107(1) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(a\)\(i\)](#) (with Sch. 32)
- F329** Words in s. 107(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(a\)\(ii\)](#) (with Sch. 32)
- F330** Words in s. 107(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(b\)\(i\)](#) (with Sch. 32)
- F331** Words in s. 107(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(b\)\(ii\)](#) (with Sch. 32)
- F332** Words in s. 107(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(b\)\(iii\)](#) (with Sch. 32)
- F333** Words in s. 107(6) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 17\(c\)](#) (with Sch. 32)

#### Modifications etc. (not altering text)

- C66** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C67** S. 107 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), [Sch. 4](#)  
S. 107 extended (with modifications)(14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)  
S. 107 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)  
S. 107 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)
- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [regs. 1, 47](#), [Schs. 9](#)
- C69** Ss. 107-109 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with Sch. 6)
- C70** Ss. 107-116 amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9 \(29.8.2006\)](#) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), [regs. 1\(1\), 32](#)

## 108 Enforcement in England and Wales.

- (1) [<sup>F334</sup>Subject to the provisions of subsection (6C) of this section,] it shall be the duty of the appropriate Minister to enforce in England and Wales, or to secure the enforcement

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in England and Wales of, the provisions of this Act and any regulations and orders made under it.

- (2) For the purpose of performing that duty in relation to—
- (a) the provisions of any order made under paragraph (a) of section 62(1) of this Act and of section 63(b), [F335 section 64 and sections 87(2) and 88(3)] of this Act, in the application of any of those provisions to the retail sale, offer or exposure for retail sale, or possession for the purpose of retail sale, of medicinal products and to the supply, offer or exposure for supply, or possession for the purpose of supply, of medicinal products in circumstances corresponding to retail sale;

F336(b) .....

F336(c) .....

the appropriate Minister shall, in respect of each area for which there is a [F337 drugs authority] make arrangements or give directions whereby [F338 the General Pharmaceutical Council], or the [F337 drugs authority] for that area, or both [F339 the Council] and that authority, to such extent as, in the case of [F340 that Council] or authority, the arrangements or directions may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in [F341 paragraph (a)] of this subsection, in their application as mentioned in [F342 that paragraph] F343 ....

F344(3) .....

F344(4) .....

F344(5) .....

- (6) [F345 the General Pharmaceutical Council] shall be under a duty, concurrently with the appropriate Minister,—

F346(a) .....

- (b) to enforce the provisions of any regulations made under section 60 F347 ... of this Act in their application to premises in England and Wales at which medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale; and

- (c) to enforce the provisions of [F348 section 78] of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.

F349 [F350 (6A) .....

- (6B) [F351 the General Pharmaceutical Council] shall be under a duty to enforce [F352 the provisions of sections 72A and 72AA of this Act, and any rules made under section 72A,] in their application to England and Wales.

- (6C) The appropriate Minister shall be under no duty to enforce [F353 those provisions, or any rules made under section 72A,] in their application to England and Wales.

- (6D) Notwithstanding subsection (6C) of this section the appropriate Minister is to be treated for the purposes of sections 111 to 114 of this Act—

- (a) as empowered by this section to enforce [F354 those provisions, or any rules made under section 72A,] in their application to England and Wales, and

- (b) to that extent as an enforcement authority in relation to [F355 those provisions or those rules] in their application to England and Wales.]

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<sup>F356</sup>(7) .....

<sup>F357</sup>(8) .....

(9) Notwithstanding anything in subsections [<sup>F358</sup>(2) to [<sup>F359</sup>(6D)]] of this section, no duty or power conferred or imposed by or under any of those subsections shall be performed or be exercisable in relation to—

- (a) any hospital [<sup>F360</sup>(except in relation to so much of the hospital premises as is a registered pharmacy)], or
- (b) so much of any premises as is used by a practitioner for carrying on his practice, or
- (c) so much of any premises (not falling within either of the preceding paragraphs) as is used for veterinary medicine or veterinary surgery for the purposes of any institution.

(10) If the appropriate Minister is satisfied, after making such inquiry as he thinks fit, that [<sup>F361</sup>the General Pharmaceutical Council][<sup>F362</sup>has in relation to any matter failed to perform a duty imposed on it by][<sup>F363</sup>subsection (6B) to enforce any provisions or rules mentioned in that subsection, and that the public interest requires that the provisions or rules in question should be enforced in relation to it, the appropriate Minister may enforce those provisions or rules in relation to that matter.]

(11) In this section “the appropriate Minister” —

- <sup>F364</sup>(a) .....
- (b) <sup>F365</sup>... means the [<sup>F366</sup>Secretary of State].

<sup>F367</sup>(12) In this section “ drugs authority ” means—

- <sup>F368</sup>(a) in relation to an area in England other than the City of London, the council of a non-metropolitan county, metropolitan district or London borough;
- (b) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London; and
- (c) in relation to an area in Wales, the council of a county or county borough.]]

#### Textual Amendments

**F334** Words in s. 108(1) inserted (1.10.2009) by [Health Act 2006 \(c. 28\)](#), **ss. 31(1)(a)**, 83(7); S.I. 2008/2714, art. 2(a)

**F335** Words in s. 108(2)(a) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(a)** (with Sch. 32)

**F336** S. 108(2)(b)(c) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(b)** (with Sch. 32)

**F337** Words substituted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), ss. 54, 59(1), **Sch. 3 para. 8(a)**

**F338** Words in s. 108(2) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(c)(i)** (with Sch. 32)

**F339** Words in s. 108(2) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(c)(ii)** (with Sch. 32)

**F340** Words in s. 108(2) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(c)(iii)** (with Sch. 32)

**F341** Words in s. 108(2) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), **reg. 1(2)**, **Sch. 34 para. 18(2)(c)(iv)** (with Sch. 32)

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- F342** Words in s. 108(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(2)(c)(v)** (with Sch. 32)
- F343** Words in s. 108(2) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(2)(c)(vi)** (with Sch. 32)
- F344** S. 108(3)-(5) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 18(3), **Sch. 35** (with Sch. 32)
- F345** Words in s. 108(6) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(4)(a)** (with Sch. 32)
- F346** S. 108(6)(a) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(4)(b)** (with Sch. 32)
- F347** Words in s. 108(6)(b) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(4)(c)** (with Sch. 32)
- F348** Words in s. 108(6)(c) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(17)**; S.I. 2010/1621, art. 2(1), Sch.
- F349** S. 108(6A) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(a)**; S.I. 2022/1023, art. 2
- F350** S. 108(6A)-(6D) inserted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(1)(b)**, 83(7); S.I. 2008/2714, art. 2(a)
- F351** Words in s. 108(6A)(6B) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(5)** (with Sch. 32)
- F352** Words in s. 108(6B) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(b)** (with art. 8(3)); S.I. 2022/1023, art. 2
- F353** Words in s. 108(6C) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(c)** (with art. 8(3)); S.I. 2022/1023, art. 2
- F354** Words in s. 108(6D)(a) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(d)(i)** (with art. 8(3)); S.I. 2022/1023, art. 2
- F355** Words in s. 108(6D)(b) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(d)(ii)** (with art. 8(3)); S.I. 2022/1023, art. 2
- F356** S. 108(7) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 18(6), **Sch. 35** (with Sch. 32)
- F357** S. 108(8) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 56(b)** (with regs. 2(4), 3)
- F358** Words in s. 108(9) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 56(c)** (with regs. 2(4), 3)
- F359** Word in s. 108(9) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(7)** (with Sch. 32)
- F360** Words in s. 108(9)(a) inserted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(1)(c)**, 83(7); S.I. 2008/2714, art. 2(a)
- F361** Words in s. 108(10) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(8)(i)** (with Sch. 32)
- F362** Words in s. 108(10) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(8)(ii)** (with Sch. 32)
- F363** Words in s. 108(10) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 6(e)** (with art. 8(3)); S.I. 2022/1023, art. 2
- F364** S. 108(11)(a) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 56(e)(i)** (with regs. 2(4), 3)
- F365** Words in s. 108(11)(b) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 56(e)(ii)** (with regs. 2(4), 3)

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- F366** Words substituted by virtue of S.I. 1968/1699, **arts. 2, 5(4)(a)**
- F367** S. 108(12) inserted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 8(b)**
- F368** S. 108(12)(a)-(c) substituted for s. 108(12)(a)(b) (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 18(9)** (with Sch. 32)

**Modifications etc. (not altering text)**

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), regs. 1, 47, **Schs. 9**
- C69** Ss. 107-109 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **32**
- C71** Power to modify s. 108(8)(W.) conferred by Local Government Act 1972 (c. 70), **s. 200(3)**
- C72** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: S.I. 1969/388, **art. 2(1)**
- C73** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**
- C74** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg. 12.**
- C75** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**  
Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, reg. 11(c)(ii)(aa)
- C76** S. 108 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**  
S. 108 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**  
S. 108 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
s. 108 extended (1.1.1995) by S.I. 1994/3142, **reg. 18(7)**  
S. 108 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**  
S. 108 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**  
Ss. 108-110 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C77** S. 108: Functions transferred (W.) (1.7.1999) by virtue of S.I. 1999/672, art. 2, **Sch. 1**

**109 Enforcement in Scotland.**

- (1) <sup>F369</sup> Subject to the provisions of section 108(6C) of this Act as applied by subsection (2) of this section, [It shall be the duty of the Secretary of State to enforce in Scotland, or to secure the enforcement in Scotland of, the provisions of this Act and of any regulations and orders made under it.
- (2) Subsections <sup>F370</sup>(2), (6) to (6D), (9) and (10)] of section 108 of this Act shall have effect in relation to Scotland as if—
  - (a) any reference to the appropriate Minister <sup>F371</sup>... were a reference to the Secretary of State;
  - (b) any reference to England and Wales were a reference to Scotland; and
  - <sup>F372</sup>[  
<sup>F373</sup>(c) references to a food and drugs authority and to the area of any such authority were references respectively to a local authority as defined by section 26(4) of the <sup>M1</sup> Food and Drugs (Scotland) Act 1956 and to the area of such an authority; and ]
  - <sup>F374</sup>( d )] .....
- <sup>F375</sup>(2A) Subsection (12) of section 108 of this Act shall have effect in relation to Scotland as if for paragraphs (a) and (b) there were substituted the words <sup>F376</sup>“ a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 ” ]]

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F377(3) .....

(4) Nothing in this section shall be construed as authorising an enforcement authority to institute proceedings for any offence.

#### Textual Amendments

- F369** Words in s. 109(1) inserted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(2)**, 83(7); S.I. 2008/2714, art. 2(a)
- F370** Words in s. 109(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 19(a)(i)** (with Sch. 32)
- F371** Words in s. 109(2)(a) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 19(a)(ii)** (with Sch. 32)
- F372** S. 109(2)(c)(d) substituted (S.) for s. 109(2)(c) by Local Government (Scotland) Act 1973 (c. 65), **Sch. 27 Pt. II para. 191**
- F373** S. 109(2)(c) repealed (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 9(a)**
- F374** S. 109(2)(d) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 57** (with regs. 2(4), 3)
- F375** S. 109(2A) inserted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 9(b)**
- F376** Words in s. 109(2A) substituted (S.) (1.4.1996) by 1994 c. 39, s. 180(1), **Sch. 13 para. 79(b)**; S.I. 1996/323, **art. 4(1)(c)**
- F377** S. 109(3) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 19(b), **Sch. 35** (with Sch. 32)

#### Modifications etc. (not altering text)

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), regs. 1, 47, **Schs. 9**
- C69** Ss. 107-109 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **32**
- C78** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**
- C79** S. 109 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**  
S. 109 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch. 4**  
S. 109 extended (1.1.1995) by S.I. 1994/3142, **reg. 18(7)**  
S. 109 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
S. 109 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**  
S. 109 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**  
Ss. 108-110 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C80** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg. 12**.
- C81** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3)**, 3  
Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**
- C82** S. 109: Functions transferred (S.) (1.7.1999) by S.I. 1999/1750, art. 2, **Sch. 1** (with art. 7)
- C83** S. 109(1): power to transfer functions conferred (1.5.2000) by S.I. 2000/745, art. 2(1), **Sch. para. 1**

#### Marginal Citations

- M1** 1956 c. 30.

*Changes to legislation: Medicines Act 1968 is up to date with all changes known to be in force on or before 08 May 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. (See end of Document for details) View outstanding changes*

## 110 Enforcement in Northern Ireland.

- (1) Subject to the provisions of [<sup>F378</sup>subsections (3C) and (4)] of this section, it shall be the duty of the [<sup>F379</sup>Minister for Health, Social Services and Public Safety] (in this section referred to as “the Minister”) to enforce in Northern Ireland, or to secure the enforcement in Northern Ireland of, the provisions of this Act and of any regulations and orders made under it.
- (2) For the purpose of performing that duty in relation to the provisions specified in [<sup>F380</sup>paragraph (a)] of subsection (2) of section 108 of this Act in their application as mentioned in [<sup>F381</sup>that paragraph], within the [<sup>F382</sup>district] of any [<sup>F383</sup>district council], the Minister may make arrangements or give directions whereby the [<sup>F383</sup>district council], to such extent as the arrangements or directions may provide, shall have power concurrently with the Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in the said [<sup>F380</sup>paragraph (a)] in their application as so mentioned <sup>F384</sup>....
- <sup>F385</sup>(3) .....
- <sup>F386</sup>[<sup>F387</sup>(3A) .....
- (3B) The Pharmaceutical Society [<sup>F388</sup>of Northern Ireland] shall be under a duty to enforce [<sup>F389</sup>the provisions of sections 72A and 72AA of this Act, and any regulations made under section 72A,] in their application to Northern Ireland.
- (3C) The Minister shall be under no duty to enforce [<sup>F390</sup>those provisions, or any regulations made under section 72A,] in their application to Northern Ireland.
- (3D) Notwithstanding subsection (3C) of this section the Minister is to be treated for the purposes of sections 111 to 114 of this Act—
- (a) as empowered by this section to enforce [<sup>F391</sup>those provisions, or any regulations made under section 72A,] in their application to Northern Ireland, and
- (b) to that extent as an enforcement authority in relation to those <sup>F392</sup>... provisions or those regulations in their application to Northern Ireland.]
- <sup>F393</sup>(4) .....
- (5) [<sup>F394</sup>Subsection (9)] of section 108 of this Act shall have effect in relation to Northern Ireland as if—
- (a) in the said subsection (9) the reference to subsections [<sup>F395</sup>(2) to (6D)] of that section were a reference to subsections (2) [<sup>F396</sup>to (3D)] of this section; <sup>F397</sup>...
- <sup>F397</sup>(b) .....
- <sup>F398</sup>(6) .....
- [<sup>F399</sup>(8) In this section “district council” means a council established under the Local Government Act (Northern Ireland) 1972.]

### Textual Amendments

**F378** Words in s. 110(1) substituted (1.10.2009) by [Health Act 2006 \(c. 28\), ss. 31\(3\)\(a\), 83\(7\); S.I. 2008/2714, art. 2\(a\)](#)

**F379** Words in s. 110(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\), reg. 1\(2\), Sch. 34 para. 20\(a\)](#) (with Sch. 32)



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- F380** Words in s. 110(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(i)** (with Sch. 32)
- F381** Words in s. 110(2) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(ii)** (with Sch. 32)
- F382** Word in s. 110(2) substituted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(iii)** (with Sch. 32)
- F383** Words in s. 110(2) substituted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(iv)** (with Sch. 32)
- F384** Words in s. 110(2) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(v)** (with Sch. 32)
- F385** S. 110(3) repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 20(c), **Sch. 35** (with Sch. 32)
- F386** S. 110(3A) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 7(a)**; S.I. 2022/1023, art. 2
- F387** S. 110(3A)-(3D) inserted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(3)(b)**, 83(7); S.I. 2008/2714, art. 2(a)
- F388** Words in s. 110(3A)(3B) inserted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(d)** (with Sch. 32)
- F389** Words in s. 110(3B) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 7(b)**; S.I. 2022/1023, art. 2
- F390** Words in s. 110(3C) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 7(c)**; S.I. 2022/1023, art. 2
- F391** Words in s. 110(3D)(a) substituted (1.12.2022) by The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 7(d)(i)**; S.I. 2022/1023, art. 2
- F392** Word in s. 110(3D)(b) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 7(d)(ii)**; S.I. 2022/1023, art. 2
- F393** S. 110(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 58(b)** (with regs. 2(4), 3)
- F394** Words in s. 110(5) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(e)(i)** (with Sch. 32)
- F395** Words in s. 110(5)(a) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(e)(ii)** (with Sch. 32)
- F396** Words in s. 110(5)(a) substituted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(3)(c)**, 83(7); S.I. 2008/2714, art. 2(a)
- F397** S. 110(5)(b) and word omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(e)(iii)** (with Sch. 32)
- F398** S. 110(6)(7) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(f)** (with Sch. 32)
- F399** S. 110(8) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(g)** (with Sch. 32)

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**Modifications etc. (not altering text)**

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), regs. 1, 47, **Schs. 9**
- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **32**
- C84** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

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- C85** S. 110 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**  
 S. 110 extended (with modifications) (14.2.1994) by S.I. 1994/105, **reg. 19, Sch.4**  
 S. 110 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
 S. 110 applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch.5**  
 S. 110 extended (1.1.1995) by S.I.1994/ 3142, **reg. 18(7)**  
 S. 110 (except (4)) applied (with modifications) (1.1.1995) by S.I. 1994/3144 , **reg.10**  
 Ss. 108-110 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C86** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12.**
- C87** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**  
 Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**
- C88** S. 110 applied in part (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), **regs. 1(a), 11, Schs. 4** (with Sch. 6)

## 111 Rights of entry.

- (1) Subject to the following provisions of this section, any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises—
- (a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce,<sup>F400</sup> ...
- [<sup>F401</sup>(aa) <sup>F402</sup>... or ]
- (b) generally for the purposes of the performance by the authority of their functions under this Act or under any such regulations or order.
- (2) Any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time—
- <sup>F403</sup>(a) .....
- (b) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship, for any purpose for which under subsection (1) of this section the person so authorised would have a right to enter any premises.
- <sup>F404</sup>(3) .....
- (4) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of the preceding provisions of this section unless twenty-four hours' notice of the intended entry has been given to the occupier.
- (5) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entering any premises for any purpose for which a person authorised by an enforcement authority has a right to enter them in accordance with the preceding provisions of this section, and is also satisfied—
- (a) that admission to the premises has been refused, or that a refusal is apprehended, and (in either case) that notice of the intention to apply for a warrant has been given to the occupier, or
- (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or
- (c) that the case is one of urgency, or
- (d) that the premises are unoccupied or the occupier is temporarily absent,

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the justice may by warrant under his hand authorise the enforcement authority, or any person duly authorised by them, to enter the premises, if need be by force.

- (6) The last preceding subsection shall have effect in relation to entering any ship,<sup>F405</sup> ... vehicle, stall or place which may be entered under subsection (2) of this section as it has effect in relation to entering any premises, as if in the last preceding subsection any reference to the occupier were a reference to the master<sup>F406</sup> ... or other person in charge of the ship,<sup>F405</sup> ... vehicle, stall or place.
- (7) Any warrant granted under this section shall continue in force for a period of one month.
- (8) In this section “home-going ship” means a ship plying exclusively in inland waters or engaged exclusively in coastal voyages; and for the purposes of this subsection “inland waters” means any canal, river, lake, loch, navigation or estuary and “coastal voyage” means a voyage which starts and ends in the United Kingdom and does not involve calling at any place outside the United Kingdom.

- [<sup>F407</sup>(9) References in this section to a justice of the peace—
- (a) in relation to England, include a reference to a district judge (magistrates’ courts);
  - (b) in relation to Scotland, are to be read as references to a sheriff, stipendiary magistrate or justice of the peace, and
  - (c) in relation to Northern Ireland, are to be read as references to a lay magistrate or a district judge (magistrates’ courts).]

#### Textual Amendments

- F400** Word in s. 111(1)(a) 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. 9\(a\)](#) (with Sch. 6)
- F401** S. 111(1)(aa) 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. 9\(b\)](#) (with Sch. 6)
- F402** Words in s. 111(1)(aa) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(a\)](#) (with Sch. 32)
- F403** S. 111(2)(a) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(b\)](#) (with Sch. 32)
- F404** S. 111(3) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(c\)](#), [Sch. 35](#) (with Sch. 32)
- F405** Word in s. 111(6) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(d\)\(i\)](#) (with Sch. 32)
- F406** Word in s. 111(6) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(d\)\(ii\)](#) (with Sch. 32)
- F407** S. 111(9) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 21\(e\)](#) (with Sch. 32)

#### Modifications etc. (not altering text)

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)
- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), [32](#)

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- C89** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C90** S. 111 modified (30.1.1992) by [S.I. 1992/32, reg. 12\(1\)\(2\)](#)  
S. 111 extended (with modifications) (14.2.1994) by [S.I. 1994/105, reg. 19, Sch.4](#)  
S. 111 applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)  
S. 111 applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)  
S. 111 applied (with modifications) (1.1.1995) by [S.I. 1994/3144, reg.10, Sch. 4](#)  
S. 111 (other than s. 111(3)) applied (1.2.2000) by [S.I. 2000/7, reg. 5](#)
- C91** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520, reg.12](#).
- C92** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605, regs. 2\(3\), 3](#)  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328, reg. 11\(c\)](#)
- C93** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#) , regs. 1(a) , 11 , [Schs. 4](#) (with [Sch. 6](#) )

## 112 Power to inspect, take samples and seize goods and documents.

- (1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act an enforcement authority is required or empowered to enforce, any person duly authorised in writing by that authority shall have a right to inspect—
- (a) any substance or article appearing to him to be a medicinal product;
  - (b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or
  - (c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.
- (2) Where for the purpose specified in the preceding subsection a person authorised as mentioned in that subsection requires a sample of any substance or article appearing to him to be—
- (a) a medicinal product sold or supplied or intended to be sold or supplied, or
  - (b) a substance or article used or intended to be used in the manufacture of a medicinal product,
- he shall (if he does not obtain the sample by purchase) have a right to take a sample of that substance or article.
- (3) For the purpose specified in subsection (1) of this section, any person authorised as mentioned in that subsection shall have a right—
- (a) to require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control;
  - (b) to take copies of, or of any entry in, any book or document produced in pursuance of the preceding paragraph.
- (4) Any person so authorised shall have a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to

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which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) For the purpose of exercising any such right as is specified in subsection (4) of this section the person having that right may, so far as is reasonably necessary in order to secure that the provisions of this Act and any regulations or order made thereunder are duly observed, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so.

(6) Where a person seizes any substance or article (including any document) in the exercise of such a right as is specified in subsection (4) of this section, he shall inform the person from whom it is seized, and, in the case of anything seized from a vending machine, the person whose name and address are stated on the machine as being those of the owner of the machine, or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.

<sup>F408</sup>(7) . . . . .

(8) Notwithstanding anything in the preceding provisions of this section, where a person claiming to exercise a right by virtue of this section is required to produce his credentials, the right shall not be exercisable by him except on production of those credentials.

(9) The provisions of Schedule 3 to this Act shall have effect with respect to samples obtained on behalf of enforcement authorities for the purposes of this Act.

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**Textual Amendments**

**F408** S. 112(7) repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 35](#) (with [Sch. 32](#))

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**Modifications etc. (not altering text)**

**C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [regs. 1, 47](#), [Schs. 9](#)

**C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), [regs. 1\(1\), 32](#)

**C93** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with [Sch. 6](#))

**C94** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**C95** S. 112 modified by [S.I. 1985/273](#), [reg. 2](#), [Sch. 1 Pt. I](#)

**C96** S. 112 restricted by [S.I. 1985/273](#), [reg. 3\(3\)](#)

**C97** S. 112 modified (30.1.1992) by [S.I. 1992/32](#), [reg. 12\(1\)\(2\)](#)

S. 112 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)

S. 112 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)

S. 112 applied (with modifications) (1.1.1994) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)

S. 112 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)

S. 112 (other than s. 112(7)) applied (1.2.2000) by [S.I. 2000/7](#), [reg. 5](#)

**C98** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520](#), [reg. 12](#).

**C99** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\), 3](#)

Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), [reg. 11\(c\)](#)

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### 113 Application of sampling procedure to substance or article seized under s. 112.

- (1) The provisions of this section shall have effect where a person (in this section referred to as an “authorised officer”) seizes a substance or article (other than a document) in the exercise of such a right as is specified in subsection (4) of section 112 of this Act  
F409  
....
- (2) If any person who in accordance with subsection (6) of that section is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then, subject to the next following subsection, the authorised officer shall either—
- (a) set aside a sample of the substance or article seized, or
  - (b) treat that substance or article as a sample,
- whichever he considers more appropriate having regard to the nature of that substance or article.
- (3) An authorised officer shall not be required by virtue of subsection (2) of this section to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.
- (4) Where in accordance with subsection (2) of this section an authorised officer sets aside a sample, or treats a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one part of it to the person who made the request under subsection (2) of this section.
- (5) Paragraphs 10, 11 and 12 and paragraphs 15 to 27 of Schedule 3 to this Act shall have effect in relation to a sample set aside, or a substance or article treated as a sample, in accordance with subsection (2) of this section as they have effect in relation to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if in those paragraphs—
- (a) any reference to a sampling officer were a reference to an authorised officer;
  - (b) any reference to a sample included a reference to a substance or article treated as a sample;
  - (c) any reference to the preceding provisions of that Schedule were a reference to the preceding provisions of this section; and
  - (d) any reference to the relevant enforcement authority were a reference to the authority by whom the authorised officer is authorised for the purposes of section 112 of this Act,
- and as if in paragraph 24(1) of that Schedule the reference to a substance or article obtained as mentioned in paragraph 1 of that Schedule were a reference to a substance or article of which a sample has been set aside, or which has been treated as a sample, in accordance with subsection (2) of this section.

#### Textual Amendments

**F409** Words in s. 113(1) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 22](#) (with [Sch. 32](#))

#### Modifications etc. (not altering text)

**C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)

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- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **32**
- C93** Ss. 111-116 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750) , regs. 1(a) , 11 , **Schs. 4** (with Sch. 6 )
- C100** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**
- C101** S. 113 modified by S.I. 1985/273, reg. 2, **Sch. 1 Pt. I**
- C102** S. 113 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**  
S. 113 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**  
S. 113 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**  
S. 113 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**  
S. 113 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C103** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12.**
- C104** Ss. 108-115 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**  
Ss. 108-115 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**

#### **114 Supplementary provisions as to rights of entry and related rights.**

- (1) Any person entering any property (that is to say, any premises, ship,<sup>F410</sup> ... vehicle, stall or place) by virtue of section 111 of this Act (whether in pursuance of a warrant or not) may take with him such other persons and such equipment as may appear to him to be necessary; and on leaving any such property which he has entered in pursuance of a warrant under that section he shall, if the property is unoccupied or the occupier (or, in the case of a ship,<sup>F410</sup> ... vehicle, stall or place, the master<sup>F411</sup> ... or other person in charge of it) is temporarily absent, leave it as effectively secured against trespass as he found it.
- (2) Any person who—
- (a) wilfully obstructs a person acting in pursuance of this Act and duly authorised so to act by an enforcement authority, or
  - (b) wilfully fails to comply with any requirement properly made to him by a person so acting under section 112 of this Act, or
  - (c) without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him for the purpose of the performance of his functions under this Act,
- shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding [<sup>F412</sup>level 3 on the standard scale]
- (3) If any person, in giving any such information as is mentioned in subsection (2)(c) of this section, makes any statement which he knows to be false, he shall be guilty of an offence and 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.
- (4) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or (where that person is [<sup>F413</sup> married or a civil partner] the spouse or civil partner ) of that person.

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#### Textual Amendments

- F410** Word in s. 114(1) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 23\(a\)](#) (with [Sch. 32](#))
- F411** Word in s. 114(1) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 23\(b\)](#) (with [Sch. 32](#))
- F412** Words substituted by virtue of (E.W.) [Criminal Justice Act 1982 \(c. 48, SIF 39:1\)](#), [ss. 38, 46](#) and (S.) [Criminal Procedure \(Scotland\) Act 1975 \(c.21, SIF 39:1\)](#), [ss. 289F, 289G](#) and (N.I.) [S.I. 1984/703 \(N.I. 3\)](#), [arts. 5, 6](#)
- F413** Words in s. 114(4) substituted (5.12.2005) by [Civil Partnership Act 2004 \(c. 33\)](#), s. 263(10)(b), [Sch. 27 para. 32](#); [S.I. 2005/3175](#), art. 2(2)

#### Modifications etc. (not altering text)

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [regs. 1, 47](#), [Schs. 9](#)
- C70** Ss. 107-116 amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9 \(29.8.2006\)](#) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), [regs. 1\(1\), 32](#)
- C93** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with [Sch. 6](#))
- C105** Pt. VIII (ss. 104–136) extended by S.I.s [1982/425](#), art. 3, [1984/187](#) art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C106** S. 114 modified (30.1.1992) by [S.I. 1992/32](#), [reg. 12\(1\)\(2\)](#)  
S. 114 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 114 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg.10](#), [Sch. 4](#)  
S. 114 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)  
S. 114 applied (1.2.2000) by [S.I. 2000/7](#), [reg. 5](#)
- C107** Ss. 108-114 applied (with modifications) (1.7.1992) by [S.I. 1992/1520](#), [reg.12.](#)
- C108** Ss. 108-115 modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\), 3](#)  
Ss. 108-115 applied (3.10.1994) by [S.I. 1994/2328](#), [reg. 11\(c\)](#)

#### <sup>F414</sup>115 Analysis of samples in other cases.

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#### Textual Amendments

- F414** Ss. 115, 116 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 35](#) (with [Sch. 32](#))

#### <sup>F415</sup>115A Facilities for microbiological examinations.

A drugs authority or the council of a non-metropolitan district may provide facilities for microbiological examinations of drugs. ]

#### Textual Amendments

- F415** S. 115A inserted (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\)](#), [ss. 54, 59\(1\)](#), [Sch. 3 para. 10](#)



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**Modifications etc. (not altering text)**

- C68** Ss. 107-116 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C70** Ss. 107-116 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**
- C93** Ss. 111-116 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C109** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C110** S. 115A applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg.10, **Sch. 4**

<sup>F414</sup>**116 Liability to forfeiture under Customs and Excise Act 1952.**

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**Textual Amendments**

- F414** Ss. 115, 116 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 35** (with Sch. 32)

<sup>F416</sup>**117 Special enforcement and sampling provisions relating to animal feeding stuffs.**

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**Textual Amendments**

- F416** S. 117 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 60** (with regs. 2(4), 3)

**Modifications etc. (not altering text)**

- C111** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**

**118 Restrictions on disclosure of information.**

- (1) If any person discloses to any other person—
- (a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 111 of this Act, or
  - (b) any information obtained by or furnished to him in pursuance of this Act, he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

[<sup>F417</sup>(1A) Subsection (1) of this section does not apply if—

- (a) the person making the disclosure is, or is acting on behalf of a person who is, a public authority for the purposes of the Freedom of Information Act 2000 [<sup>F418</sup>or a Scottish public authority for the purposes of the Freedom of Information (Scotland) Act 2002], and

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- (b) the information is not held by the authority on behalf of another person.]
- (2) Any person guilty of an offence under 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.

#### Textual Amendments

- F417** S. 118(1A) inserted (1.1.2005) by [Freedom of Information \(Removal and Relaxation of Statutory Prohibitions on Disclosure of Information\) Order 2004 \(S.I. 2004/3363\)](#), arts. 1, 4
- F418** Words in s. 118(1A)(a) inserted (S.) (13.10.2008) by [Freedom of Information \(Relaxation of Statutory Prohibitions on Disclosure of Information\) \(Scotland\) Order 2008 \(S.S.I. 2008/339\)](#), arts. 1, 4

#### Modifications etc. (not altering text)

- C112** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), art. 3(1)
- C113** S. 118 modified (3.4.1992) by [S.I. 1992/605](#), regs. 2(3), 3  
S. 118 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, Sch. 4  
S. 118 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg. 10, Sch. 4
- C114** S. 118 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, Schs. 9
- C115** S. 118 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, Schs. 4 (with Sch. 6)
- C116** S. 118 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), 32

### 119 Protection for officers of enforcement authorities.

- (1) An officer of an enforcement authority shall not be personally liable in respect of any act done by him in the execution or purported execution of this Act and within the scope of his employment if he did it in the honest belief that his duty under this Act required or entitled him to do it.
- (2) Where an action has been brought against an officer of an enforcement authority in respect of an act done by him in the execution or purported execution of this Act, and the circumstances are such that he is not legally entitled to require the enforcement authority to indemnify him, the authority may nevertheless indemnify him against the whole or part of the damages and costs or expenses which he may have been ordered to pay or may have incurred, if they are satisfied that he honestly believed that his duty under this Act required or entitled him to do it.
- (3) In this section any reference to an officer of an enforcement authority shall be construed as including a reference to any person who, not being an officer of the authority, is authorised to act in pursuance of this Act by such an authority; and in relation to any such person any reference in this section to the scope of his employment shall be construed as a reference to the scope of the authorisation under which he acts.

#### Modifications etc. (not altering text)

- C117** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), art. 3(1)

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- C118** S. 119 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3), 3**
- C119** S. 119 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**
- C120** S. 119 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**
  - S. 119 extended (with modifications) (14.2.1994) by S.I. 1994/105, **reg. 19, Sch.4**
  - S. 119 applied (3.10.1994) by S.I. 1994/2328, **reg. 11(c)**
  - S. 119 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
  - S. 119 applied (with modifications) (1.1.1995) by S.I. 1994/3144, **reg.10, Sch. 4**
  - S. 119 applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch.5**
  - S. 119 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C121** S. 119 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), **regs. 1, 47, Schs. 9**
- C122** S. 119 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), **regs. 1(a), 11, Schs. 4** (with Sch. 6)
- C123** S. 119 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), **regs. 1(1), 32**

**F419 120 Compensation for loss of employment or loss or diminution of emoluments.**

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**Textual Amendments**

**F419** S. 120 repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), **Sch. 1 Pt. 17** Group 7

**Modifications etc. (not altering text)**

**C124** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

**121 Contravention due to default of other person.**

- (1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Act, and is due to an act or default of another person, then, whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence, and shall be liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had been convicted of the offence.
- (2) Where a person who is charged with an offence under this Act in respect of a contravention of a provision to which this section applies proves to the satisfaction of the court—
  - (a) that he exercised all due diligence to secure that the provision in question would not be contravened, and
  - (b) that the contravention was due to the act or default of another person,the first-mentioned person shall, subject to the next following subsection, be acquitted of the offence.
- (3) A person shall not, without the leave of the court, be entitled to rely on the defence provided by subsection (2) of this section unless, not later than seven clear days before the date of the hearing, he has served on the prosecutor a notice in writing giving such information identifying, or assisting in the identification of, the other person in question as was then in his possession.

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- (4) This section applies to the following provisions, that is to say, sections [F420 63, 64, 87 and 88], and the provisions of any regulations made under any of those sections.

#### Textual Amendments

**F420** Words in s. 121(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 24** (with Sch. 32)

#### Modifications etc. (not altering text)

- C125** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), art. 3(1)
- C126** S. 121 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), reg. 2(1)(2), Sch. S. 121 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch. 4** S. 121 applied (1.1.1995) by [S.I. 1994/3142](#), reg. 18(2) S. 121 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg. 10, **Sch. 4** S. 121 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**
- C127** Ss. 121–125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C128** Ss. 121–127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C129** Ss. 121–125 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**

## 122 Warranty as defence.

- (1) Subject to the following provisions of this section, in any proceedings for an offence under this Act in respect of a contravention of a provision to which this section applies, it shall be a defence for the defendant to prove—
- that he purchased the substance or article to which the contravention relates in the United Kingdom as being a substance or article which could be lawfully sold, supplied, or offered or exposed for sale, or could be lawfully sold, supplied, or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty to that effect;
  - that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and
  - that the substance or article was then in the same state as when he purchased it.
- (2) This section applies to the following provisions, that is to say, [F421 sections 63(b), 64, 87 and 88] F422 ... and the provisions of any regulations made under any of those sections.
- (3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than three clear days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it, and has also sent a like notice to that person.
- (4) Where the defendant is a servant of the person who purchased the substance or article under the warranty, he shall be entitled to rely on the provisions of this section in the same way as his employer would have been entitled to do if he had been the defendant.

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- (5) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing and to give evidence, and the court may, if it thinks fit, adjourn the hearing to enable him to do so.
- (6) For the purposes of this section a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description by any person without contravening any provision to which this section applies.
- (7) In the application of this and the next following section to Scotland, any reference to the defendant shall be construed as a reference to the accused.

#### Textual Amendments

- F421** Words in s. 122(2) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 25** (with Sch. 32)
- F422** Words in s. 122(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 62** (with regs. 2(4), 3)

#### Modifications etc. (not altering text)

- C127** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C129** Ss. 121-125 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**
- C130** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- S. 122 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.
- S. 122 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch.4**
- S. 122 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**
- S. 122 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg.10, **Sch. 4**
- S. 122 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch.5**

## 123 Offences in relation to warranties and certificates of analysis.

- (1) If a defendant in any such proceedings as are mentioned in section 122(1) of this Act wilfully applies to any substance or article—
  - (a) a warranty given in relation to a different substance or article, or
  - (b) a certificate issued under <sup>F423</sup> ... paragraph 19 of Schedule 3 to this Act, which relates to a sample of a different substance or article,he shall be guilty of an offence.
- (2) A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 122 of this Act, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

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- (3) Where the defendant in any such proceedings as are mentioned in section 122(1) of this Act relies successfully on a warranty given to him or to his employer, any proceedings for an offence under subsection (2) of this section in respect of the warranty may, at the option of the prosecutor, be taken either before a court having jurisdiction in the place where a sample of the substance or article to which the warranty relates was procured, or before a court having jurisdiction in the place where the warranty was given.
- (4) Any person guilty of an offence under 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.

#### Textual Amendments

**F423** Words in s. 123(1)(b) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 26](#) (with [Sch. 32](#))

#### Modifications etc. (not altering text)

**C127** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, [Schs. 9](#)

**C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, [Schs. 4](#) (with [Sch. 6](#))

**C129** Ss. 121-125 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), [32](#)

**C131** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**C132** S. 123 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)

S. 123 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)

S. 123 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)

## 124 Offences by bodies corporate.

- (1) Where an offence under this Act which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.
- (2) In relation to a body corporate carrying on a retail pharmacy business as mentioned in subsection (1) of section 71 of this Act, the preceding subsection shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in the preceding subsection)—
- (a) is the superintendent referred to in subsection (1) of that section, or
  - (b) <sup>F424</sup>in respect of any premises at or from which] the business is carried on, is the pharmacist referred to in <sup>F425</sup>subsection (4)(b)] of that section who acts under the directions of the superintendent,
- as if he were such an officer of the body corporate as is mentioned in the preceding subsection.

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- (3) In this section “director”, in relation to a body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

#### Textual Amendments

- F424** Words in s. 124(2)(b) substituted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 2 para. 21**; S.I. 2022/1023, art. 2
- F425** Words in s. 124(2)(b) substituted (1.10.2009) by [Health Act 2006 \(c. 28\)](#), **ss. 28(2)**, 83(7); S.I. 2008/2714, art. 2(a)

#### Modifications etc. (not altering text)

- C127** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C129** Ss. 121-125 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**
- C133** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C134** S. 124 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch. 4**  
S. 124 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 124 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), reg. 10, **Sch. 4**  
S. 124 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**
- C135** S. 124(1)(3) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**, Sch.

## 125 Prosecutions.

- (1) Notwithstanding anything in <sup>F426</sup>section 127(1) of the Magistrates’ Courts Act 1980], a magistrates’ court in England or Wales may try an information for an offence under this Act if the information was laid at any time within twelve months from the commission of the offence.
- (2) Notwithstanding anything in <sup>F427</sup>section 331 of the <sup>M2</sup>Criminal Procedure (Scotland) Act 1975] (limitation of time for proceedings in statutory offences) summary proceedings in Scotland for an offence under this Act may be commenced at any time within twelve months from the time when the offence was committed, and <sup>F427</sup>subsection 3 of the said section 331] shall apply for the purposes of this subsection as it applies for the purposes of that section.
- (3) Notwithstanding anything in <sup>F428</sup>section 34 of the <sup>M3</sup>Magistrates’ Courts Act (Northern Ireland) 1964]]<sup>F428</sup>Article 19(1) of the Magistrates’ Courts (Northern Ireland) Order 1981], a magistrates’ court in Northern Ireland may hear and determine a complaint for an offence <sup>F429</sup>punishable under this Act upon summary conviction other than an offence which is also triable upon indictment] if the complaint was made at any time within twelve months from the commission of the offence.
- (4) Neither <sup>F430</sup>the General Pharmaceutical Council] nor any other body referred to in subsection (2) <sup>F431</sup>... of section 108 of this Act shall institute proceedings for an offence

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under this Act in respect of a contravention of a provision which, by virtue of <sup>F432</sup>that subsection], <sup>F433</sup>the Council] or body have a power or duty to enforce, unless they have given to the appropriate Minister not less than twenty-eight days' notice of their intention to institute proceedings, together with a summary of the facts upon which the charges are founded.

- (5) For the purposes of subsection (4) of this section the appropriate Minister, in relation to a contravention of any provision, is the Minister who in accordance with section 108 of this Act has a concurrent duty to enforce that provision.
- (6) <sup>F434</sup>A district council] (as defined by section 110 of this Act) shall not prosecute for an offence under this Act in respect of a contravention of any provision which, by virtue of subsection (2) of that section, the authority have a power or duty to enforce, unless the authority have given to the <sup>F435</sup>Minister for Health, Social Services and Public Safety] not less than twenty-eight days' notice of their intention to begin the prosecution, together with a summary of the facts upon which the charges are founded.
- (7) A certificate of the Minister who is the appropriate Minister for the purposes of subsection (4) of this section that the requirements of that subsection have been complied with in relation to any proceedings, and a certificate of the <sup>F435</sup>Minister for Health, Social Services and Public Safety] that the requirements of subsection (6) of this section have been complied with in relation to any prosecution, shall be conclusive evidence that those requirements have been so complied with; and any document purporting to be such a certificate and to be signed by or on behalf of that Minister shall be presumed to be such a certificate unless the contrary is proved.

#### Textual Amendments

- F426** Words substituted by [Magistrates' Courts Act 1980 \(c. 43, SIF 82\)](#), s. 154, **Sch. 7 para. 76**
- F427** Words substituted by virtue of [Criminal Procedure \(Scotland\) Act 1975 \(c. 21\)](#), s. 460(1)(b)
- F428** Words substituted(N.I.) by [S.I. 1981/1675 \(N.I. 26\)](#), **Sch. 6 Pt. I para. 15**
- F429** Words substituted by [S.I. 1980/704](#), **Sch. 1 Pt. II para. 50**
- F430** Words in s. 125(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 27(a)(i)** (with Sch. 32)
- F431** Words in s. 125(4) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 63(a)** (with regs. 2(4), 3)
- F432** Words in s. 125(4) substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 63(b)** (with regs. 2(4), 3)
- F433** Words in s. 125(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 27(a)(ii)** (with Sch. 32)
- F434** Words substituted by [S.R. &O. \(N.I.\) 1973 No. 211](#), **Sch.**
- F435** Words in s. 125(6)(7) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 27(b)** (with Sch. 32)

#### Modifications etc. (not altering text)

- C127** Ss. 121-125 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C129** Ss. 121-125 amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9 \(29.8.2006\)](#) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**



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**C136** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

**C137** S. 125 modified (3.4.1992) by [S.I. 1992/605, regs. 2\(3\), 3](#)

S. 125 applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)

S. 125 applied (with modifications) (1.1.1995) by [S.I. 1994/3144, reg. 10, Sch. 4](#)

S. 125 applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch. 5](#)

#### Marginal Citations

**M2** 1975 c. 21.

**M3** 1964 c. 21 (N.I.)

## 126 Presumptions.

(1) For the purposes of any proceedings under this Act for an offence consisting of—

<sup>F436</sup>(a) .....

<sup>F437</sup>(b) .....

(c) offering a medicinal product for sale in contravention of section 63(b) of this Act,

where it is proved that the <sup>F438</sup>... medicinal product in question was found on a vehicle from which <sup>F439</sup>... medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that <sup>F438</sup>... medicinal product for sale and, in a case falling within paragraph (b) of this subsection, that he offered it for sale by retail.

(2) For the purposes of any proceedings under this Act for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person's having any medicinal product <sup>F440</sup>... in his possession for the purpose of sale or supply, where it is proved that the medicinal product <sup>F440</sup>... in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products <sup>F441</sup>..., it shall be presumed, unless the contrary is proved, that he had that medicinal product or animal feeding stuff in his possession for the purpose of sale or supply.

(3) Subsection (2) of this section applies to the following provisions of this Act, that is to say, section 63(b), <sup>F442</sup>... subsection (2) of section 87 and subsection (3) of section 88<sup>F443</sup>... as applied by subsection (1) of section 90, and to subsection (2) of section 90 except in so far as it relates to leaflets.

<sup>F444</sup>(4) .....

#### Textual Amendments

**F436** S. 126(1)(a) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\), reg. 1, Sch. 8 para. 64\(a\)\(i\)](#) (with regs. 2(4), 3)

**F437** S. 126(1)(b) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\), reg. 1\(2\), Sch. 34 para. 28\(a\)](#) (with Sch. 32)

**F438** Words in s. 126(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\), reg. 1, Sch. 8 para. 64\(a\)\(ii\)](#) (with regs. 2(4), 3)

**F439** Words in s. 126(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\), reg. 1, Sch. 8 para. 64\(a\)\(iii\)](#) (with regs. 2(4), 3)

**F440** Words in s. 126(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\), reg. 1, Sch. 8 para. 64\(b\)\(i\)](#) (with regs. 2(4), 3)

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- F441** Words in s. 126(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 64\(b\)\(ii\)](#) (with [regs. 2\(4\), 3](#))
- F442** Words in s. 126(3) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 28\(b\)](#) (with [Sch. 32](#))
- F443** Words in s. 126(3) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 64\(c\)](#) (with [regs. 2\(4\), 3](#))
- F444** S. 126(4) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 28\(c\)](#) [Sch. 35](#) (with [Sch. 32](#))

#### Modifications etc. (not altering text)

- C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with [Sch. 6](#))
- C138** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, [art. 3](#), 1984/187 [art. 2](#); and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C139** S. 126 extended (with modifications) (14.2.1994) by [S.I.1994/105](#), [reg. 19](#), [Sch.4](#)  
S. 126 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 126 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg.10](#), [Sch. 4](#)  
S. 126 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)
- C140** S. 126(4) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#),[Sch.](#)

## 127 Service of documents.

Any notice or other document required or authorised by any provision of this Act to be served on any person, or to be given or sent to any person, may be served, given or sent—

- (a) by delivering it to him; or
- (b) by sending it by post to him at his usual or last-known residence or place of business in the United Kingdom; or
- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office.

#### Modifications etc. (not altering text)

- C128** Ss. 121-127 applied (with modifications) (30.10.2005) by [Medicines \(Traditional Herbal Medicinal Products for Human Use\) Regulations 2005 \(S.I. 2005/2750\)](#), [regs. 1\(a\), 11](#), [Schs. 4](#) (with [Sch. 6](#))
- C141** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, [art. 3](#), 1984/187 [art. 2](#); and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)
- C142** S. 127 applied by [S.I. 1986/1180](#), [art. 2\(2\)](#) and [S.I. 1984/673](#), [art. 2\(2\)](#)
- C143** S. 127 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#),[Sch.](#)  
S. 127 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch.4](#)  
S. 127 applied (1.1.1995) by [S.I. 1994/3142](#), [reg. 18\(2\)](#)  
S. 127 applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg.10](#), [Sch. 4](#)  
S. 127 applied (8.12.1995) by [S.I. 1995/2808](#), [art. 2\(2\)](#)  
S. 127 applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch.5](#)
- C144** S. 127 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), [regs. 1, 47](#), [Schs. 9](#)
- C145** S. 127 amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9](#) (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), [regs. 1\(1\)](#), [32](#)

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## 128 Financial provisions.

- (1) Any expenses incurred in consequence of this Act by [<sup>F445</sup>either of the Ministers], other than expenses so incurred exclusively in respect of executing this Act in Northern Ireland, shall be defrayed out of moneys provided by Parliament.
- (2) There shall be defrayed out of moneys provided by Parliament any increase attributable to the provisions of this Act in—
  - (a) the sums payable out of moneys so provided in respect of rate support grants to local authorities in England and Wales which may arise from the inclusion, in the expenditure relevant to the fixing of the aggregate amount of those grants, of expenditure under this Act, or
  - (b) the sums payable out of moneys so provided under any enactment relating to local government in Scotland.
- (3) ..... <sup>F446</sup>
- (4) Where [<sup>F447</sup>the General Pharmaceutical Council or (as the case may be) the Pharmaceutical Society of Northern Ireland] or any other body enforces any provision of this Act or of any regulations or order made thereunder in the performance of a duty imposed, or the exercise of a power conferred, under section 108(2) or section 110(2) of this Act, the Minister who has a concurrent duty to enforce that provision shall pay to the Society or other body such charges as they may reasonably require to be paid in respect of expenses incurred by them in the enforcement of that provision.
- (5) Where under subsection (10) of section 108 of this Act (or under that subsection as modified in relation to Northern Ireland by section 110(5) of this Act) [<sup>F448</sup>either of the Ministers] makes a determination in respect of the enforcement of any provision in relation to a particular matter, he shall be entitled to recover from [<sup>F447</sup>the General Pharmaceutical Council or (as the case may be) the Pharmaceutical Society of Northern Ireland] or other body who were under a duty to enforce that provision in relation to that matter any expenses reasonably incurred by that Minister in taking steps to enforce that provision in relation to that matter.
- (6) Any fees and other sums received by virtue of this Act by [<sup>F449</sup>the Secretary of State], shall be paid into the Exchequer.
- (7) Such sums paid out of the Exchequer of the United Kingdom in connection with the execution of this Act as may be determined by the Joint Exchequer Board to be properly payable by the Government of Northern Ireland shall be made good by means of deductions from the Northern Ireland residuary share of reserved taxes.

### Textual Amendments

- F445** Words in s. 128(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 29\(a\)](#) (with Sch. 32)
- F446** S. 128(3) repealed by [Medicines Act 1971 \(c. 69\)](#), [s. 1\(4\)](#)
- F447** Words in s. 128(4)(5) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 29\(b\)](#) (with Sch. 32)
- F448** Words in s. 128(5) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 29\(c\)](#) (with Sch. 32)
- F449** Words in s. 128(6) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 29\(d\)](#) (with Sch. 32)

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**Modifications etc. (not altering text)**

- C146 Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, art. 3(1)
- C147 S. 128 applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), Sch.
- C148 S. 128(1)(6)(7) extended by Medicines Act 1971 (c. 69), s. 1(3)(a)

**129 Orders and regulations.**

- (1) The Ministers may make regulations for any purpose for which regulations are authorised or required to be made under this Act, other than any purpose for which any provision of this Act authorises or requires regulations to be made otherwise than by the Ministers.
- (2) Any power to make orders or regulations under this Act (other than any order made by a court or judge or any order or regulations made in relation to Northern Ireland under [F450 section 72A of this Act or] paragraph 1 F451 ... or paragraph 6 of Schedule 4 to this Act F452 ...) shall be exercisable by statutory instrument.
- (3) Any statutory instrument consisting of—
  - (a) an order made under any of the following provisions of this Act, that is to say, sections [F453 58, 62, 79 [F454, 84A(5)] and 106] and paragraph 27 of Schedule 3, or
  - F455(b) .....
  - (c) any regulations made under any provision, other than section 79, of this Act, shall be subject to annulment in pursuance of a resolution of either House of Parliament.
- (4) Any power to make an order under any provision F456 ... of this Act shall include power to revoke or vary the order by a subsequent order made under that provision.
- (5) Any power to make [F457 an order or ] regulations under this Act may be exercised so as to make different provision for different areas or in relation to different cases or different circumstances to which the power is applicable, and to make any such provision subject to such exceptions, limitations and conditions (if any) as the authority making the [F458 order or ] regulations considers necessary or expedient.
- (6) Before making any regulations under this Act and before making any order under this Act (except an order made in accordance with any provision of this Act under which, in case of urgency, an order can be made with immediate effect) the Ministers proposing to make the regulations or order shall consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order.

F459(6A) .....

- (7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III, F460 ... of this Act, or under section 104 or section 105 of this Act, and they consult [F461 an expert committee appointed by themselves, or by one of them acting alone], or the Commission, with respect to that proposal, they shall take the advice of the committee or of the Commission into account before proceeding with those proposals.

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### Textual Amendments

- F450** Words in s. 129(2) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 1 para. 8(a)**; S.I. 2022/1023, art. 2
- F451** Words in s. 129(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 65(a)** (with regs. 2(4), 3)
- F452** Words in s. 129(2) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(a)** (with Sch. 32)
- F453** Words in s. 129(3)(a) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(b)(i)** (with Sch. 32)
- F454** Word in s. 129(3)(a) inserted (1.12.2022) by [The Pharmacy \(Responsible Pharmacists, Superintendent Pharmacists etc.\) Order 2022 \(S.I. 2022/849\)](#), art. 1(3), **Sch. 1 para. 8(b)**; S.I. 2022/1023, art. 2
- F455** S. 129(3)(b) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(b)(ii)** (with Sch. 32)
- F456** Words in s. 129(4) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(c)** (with Sch. 32)
- F457** Words in s. 129(5) inserted (19.7.2006 for specified purposes) by [Health Act 2006 \(c. 28\)](#), **ss. 32(a)**, 83(1)(e)
- F458** Words in s. 129(5) inserted (19.7.2006 for specified purposes) by [Health Act 2006 \(c. 28\)](#), **ss. 32(b)**, 83(1)(e)
- F459** S. 129(6A) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 65(c)** (with regs. 2(4), 3)
- F460** Words in s. 129(7) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(d)(i)** (with Sch. 32)
- F461** Words in s. 129(7) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 30(d)(ii)** (with Sch. 32)

### Modifications etc. (not altering text)

- C149** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C150** S. 129 modified (1.1.1995) by [S.I. 1994/3144](#), **reg. 9(10)**  
S. 129 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**
- C151** S. 129 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C152** S. 129 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)**
- C153** S. 129 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**
- C154** S. 129(1)(2)(3)(5) applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), reg. 2(1)(2), **Sch.**
- C155** S. 129(2)(3)(c)(5)(6) extended by [Medicines Act 1971 \(c. 69\)](#), **s. 1(3)(b)**

## 130 Meaning of “medicinal product” and related expressions.

[<sup>F462</sup>(1) In this Act, “medicinal product” has the meaning given by regulation 2 of the 2012 Regulations.]

<sup>F463</sup>(2) .....

<sup>F463</sup>(3) .....

<sup>F464</sup>(3A) .....

<sup>F464</sup>(3B) .....

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- F464(3C) .....
- F463(4) .....
- F463(5) .....
- F463[F465](5A) .....
- F463[F466](5B) .....
- F463(6) .....
- (7) ..... F467
- F463(8) .....
- (9) In this Act “ administer ” means administer to a human being <sup>F468</sup>..., whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not; and any reference in this Act to administering (<sup>F469</sup>...) a substance or article is a reference to administering (<sup>F469</sup>...) it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle.
- F470(10) .....

#### Textual Amendments

- F462** S. 130(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 31\(a\)](#) (with [Sch. 32](#))
- F463** S. 130(2)-(8) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 31\(b\)](#), [Sch. 35](#) (with [Sch. 32](#))
- F464** S. 130(3A)-(3C) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 66\(b\)](#) (with regs. 2(4), 3)
- F465** S. 130(5A) inserted (1.1.1995) by S.I. 1994/ 3119, reg. 2(b)
- F466** S. 130(5B) inserted (8.11.2005) by [The Blood Safety and Quality Regulations 2005 \(S.I. 2005/50\)](#), regs. 1(2), 25(1)(d) (with reg. 2(2)-(4))
- F467** S. 130(7) repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, [Sch. 1 para. 3\(9\)](#), [Sch. 2](#)
- F468** Words in s. 130(9) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 66\(f\)\(i\)](#) (with regs. 2(4), 3)
- F469** Words in s. 130(9) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, [Sch. 8 para. 66\(f\)\(ii\)](#) (with regs. 2(4), 3)
- F470** S. 130(10) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 31\(b\)](#), [Sch. 35](#) (with [Sch. 32](#))

#### Modifications etc. (not altering text)

- C156** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

### 131 Meaning of “wholesale dealing”, “retail sale” and related expressions.

- (1) In this Act any reference to selling anything by way of wholesale dealing is a reference to selling it to a person as being a person who buys it for one or more of the purposes

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specified in subsection (2) of this section, except that it does not include any such sale by the person who manufactured it.

- (2) The purposes referred to in the preceding subsection, in relation to a person to whom anything is sold, are the purposes of—
  - (a) selling or supplying it, or
  - (b) 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.
- (3) In this Act any reference to selling by retail, or to retail sale, is a reference to selling a substance or article to a person as being a person who buys it otherwise than for a purpose specified in subsection (2) of this section.
- (4) In this Act any reference to supplying anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of—
  - (a) selling or supplying it, or
  - (b) 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.
- (5) For the purposes of this section the provision of services by or on behalf of the Minister of Health, the Secretary of State or the Ministry of Health and Social Services for Northern Ireland under [<sup>F471</sup> the National Health Service Act 2006, the National Health Service (Wales) Act 2006, ] the National Health Service (Scotland) <sup>M4</sup>[<sup>F472</sup> Act 1978][<sup>F473</sup>, the Health and Personal Social Services (Northern Ireland) Order 1972 or the Health and Social Care (Reform) Act (Northern Ireland) 2009] shall be treated as the carrying on of a business by that Minister, the Secretary of State or that Ministry, as the case may be.

#### Textual Amendments

- F471** Words in s. 131(5) substituted (1.3.2007) by [National Health Service \(Consequential Provisions\) Act 2006 \(c. 43\), s. 8\(2\), Sch. 1 para. 44](#) (with Sch. 3 Pt. 1)
- F472** Words substituted by [National Health Service \(Scotland\) Act 1978 \(c. 29\), Sch. 16 para. 30](#)
- F473** Words in s. 131(5) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\), reg. 1\(2\), Sch. 34 para. 32](#) (with Sch. 32)

#### Modifications etc. (not altering text)

- C157** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C158** S. 131 applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\), regs. 1, 47, Schs. 9](#)
- C159** S. 131 amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9 \(29.8.2006\)](#) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\), regs. 1\(1\), 32](#)

#### Marginal Citations

- M4** [1978 c. 29.](#)

## 132 General interpretation provisions.

[<sup>F474</sup>(1) In this Act—

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- (a) unless the context otherwise requires, any expression defined by any provision of the 2012 Regulations, and not defined in this Act, has the same meaning as it has for the purposes of those Regulations; and
- (b) “the 2012 Regulations” means the Human Medicines Regulations 2012. ]

<sup>F475</sup>(2) .....

<sup>F475</sup>(3) .....

- (4) Any reference in this Act to the holder of a <sup>F476</sup>... certificate shall be construed as a reference to the holder of a <sup>F476</sup>... certificate which is for the time being in force.

<sup>F477</sup>(5) .....

- (6) Except in so far as the context otherwise requires, any reference in this Act to an enactment shall be construed as a reference to that enactment as amended or extended by or under any other enactment, including this Act.

#### Textual Amendments

- F474** S. 132(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 33(a)** (with Sch. 32)
- F475** S. 132(2)(3) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 33(b)**, **Sch. 35** (with Sch. 32)
- F476** Words in s. 132(4) omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 33(c)** (with Sch. 32)
- F477** S. 132(5) repealed (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 33(d)**, **Sch. 35** (with Sch. 32)

#### Modifications etc. (not altering text)

- C160** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), **art. 3(1)**
- C161** S. 132 extended (3.4.1992) by [S.I. 1992/605](#), **regs. 2(4)**, 3  
S. 132 applied (1.1.1995) by [S.I. 1994/3142](#), **reg. 18(2)**  
S. 132 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, **Sch. 5**
- C162** S. 132(1) applied (with modifications) (1.5.2004) by [Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(S.I. 2004/1031\)](#), regs. 1, 47, **Schs. 9**
- C163** S. 132(1) amendment to earlier affecting provision [SI 2004/1031 reg. 47 Sch. 9 \(29.8.2006\)](#) by [Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006 \(S.I. 2006/1928\)](#), regs. 1(1), **32**

### 133 General provisions as to operation of Act.

- (1) The provisions of this Act, and of any regulations or orders made under it, shall operate cumulatively; and any exemption or exception from any of those provisions shall not be construed as conferring any exemption or exception in relation to any other of those provisions.
- (2) Except in so far as this Act otherwise expressly provides, and subject to the provisions of section 33 of the <sup>M5</sup>Interpretation Act 1889 (which relates to offences under two or more laws), the provisions of this Act shall not be construed as—



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- (a) conferring a right of action in any civil proceedings (other than proceedings for the recovery of a fine) in respect of any contravention of this Act or of any regulations or order made under this Act, or
  - (b) affecting any restriction imposed by or under any other enactment, whether contained in a public general Act or in a local or private Act, or
  - (c) derogating from any right of action or other remedy (whether civil or criminal) in proceedings instituted otherwise than under this Act.
- (3) No exemption conferred by or under any provision of this Act shall be construed as derogating from any exemption or immunity of the Crown.

**Modifications etc. (not altering text)**

- C164** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)
- C165** S. 133 applied (with modifications) (3.4.1992) by [S.I. 1992/605, reg. 2\(1\)\(2\)](#), Sch.
- C166** S.133(2) applied (1.1.1995) by [S.I. 1994/3142, reg. 18\(2\)](#)  
S. 132(2) applied (31.3.1997) by [S.I. 1997/322, reg. 34, Sch.5](#)

**Marginal Citations**

- M5** 1889 c. 63.

**134 Special provisions as to Northern Ireland.**

- (1) Nothing in this Act shall authorise any department of the Government of Northern Ireland to incur any expenses attributable to the provisions of this Act, which are not expenses falling to be defrayed in accordance with section 128(1) of this Act, until provision has been made by the Parliament of Northern Ireland for those expenses to be defrayed out of moneys provided by that Parliament.
- (2) ..... <sup>F478</sup>
- (3) The provisions of Schedule 4 to this Act shall have effect with respect to the application of this Act in relation to Northern Ireland.
- (4) In this Act “enactment” includes an enactment of the Parliament of Northern Ireland; and (without prejudice to section 132(6) of this Act) any reference in this Act to such an enactment shall include a reference to any enactment re-enacting it with or without modifications.
- (5) [<sup>F479</sup>Sections 16(1) and 17(2)(a) of the <sup>M6</sup>Interpretation Act 1978] shall have the like operation in relation to any repeal by this Act of an enactment of the Parliament of Northern Ireland as it has in relation to the repeal of an enactment of the Parliament of the United Kingdom.

**Textual Amendments**

- F478** S. 134(2) repealed by [Northern Ireland Constitution Act 1973 \(c. 36\), Sch. 6 Pt. I](#)
- F479** Words substituted by virtue of [Interpretation Act 1978 \(c. 30\), s. 25\(2\)](#)

**Modifications etc. (not altering text)**

- C167** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403, art. 3\(1\)](#)

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**C168** S. 134 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**, Sch.

**C169** S. 134(3)(4)(5) applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**

S. 134(3)(4)(5) applied (31.3.1997) by S.I. 1997/322, **reg. 34, Sch. 5**

#### Marginal Citations

**M6** 1978 c. 30.

### 135 Minor and consequential amendments and repeals.

- (1) The enactments of the Parliament of the United Kingdom which are specified in Schedule 5 to this Act shall have effect subject to the amendments set out in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.
- (2) The enactments of that Parliament which are specified in Schedule 6 to this Act are hereby repealed to the extent specified in the third column of that Schedule :  
<sup>F480</sup> ...
- (3) The enactments of the Parliament of Northern Ireland which are specified in Schedule 7 to this Act shall have effect subject to the amendments specified in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.
- (4) The enactments of the Parliament of Northern Ireland specified in Schedule 8 to this Act are hereby repealed to the extent specified in the third column of that Schedule.

#### Textual Amendments

**F480** S. 135(2) proviso repealed (22.7.2004) by Statute Law (Repeals) Act 2004 (c. 14), **Sch. 1 Pt. 17** Group 7

#### Modifications etc. (not altering text)

**C170** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

**C171** The text of s. 135 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

### 136 Short title, extent and commencement.

- (1) This Act may be cited as the Medicines Act 1968.
- <sup>F481</sup>(2) Except as provided by section 78(5B), this Act extends to Northern Ireland.]
- (3) The following provisions of this Act, that is to say, sections 63 to 65, 77, 85(5), 86(3), 90(2), 93, 97 and 135, shall not come into operation on the passing of this Act but shall come into operation on such day as the Ministers may by order appoint, and different days may be so appointed for, or for different purposes of, any one or more of those provisions (including, in the case of section 135 of this Act, the amendment or repeal of different enactments to which that section is applicable).
- (4) Any order made under this section may make such transitional provision as appears to the Ministers to be necessary or expedient in connection with the provisions of this Act which are thereby brought (wholly or in part) into force, including such adaptations

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of those provisions or any provision of this Act then in force as appear to them to be necessary or expedient in consequence of the partial operation of this Act (whether before, on or after the day appointed by the order).

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**Textual Amendments**

**F481** S. 136(2) substituted (27.9.2010) by [The Pharmacy Order 2010 \(S.I. 2010/231\)](#), art. 1(5), [Sch. 4 para. 1\(19\)](#); [S.I. 2010/1621](#), art. 2(1), Sch.

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**Modifications etc. (not altering text)**

**C172** Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by [S.I. 1985/403](#), [art. 3\(1\)](#)

**C173** Power of appointment conferred by s. 136(3) fully exercised except in relation to s. 135(as to which it has been exercised in part only):S.I.s 1972/188, 1225; 1973/1851, 1529; 1989/192

**C174** S. 136(3) extended (E.W.S.) by [Animal Health Act 1981 \(c. 22, SIF 4:4\)](#), [s. 95\(4\)](#)

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## SCHEDULES

### F482 SCHEDULE 1

Section 5.

#### Textual Amendments

**F482** [Sch. 1](#) repealed (31.5.2005 for specified purposes, 30.10.2005 in so far as not already in force) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1)(2)**7(1)**

### F483 SCHEDULE 1A

Section 5

#### Textual Amendments

**F483** [Sch. 1A](#) repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

### F484 SCHEDULE 2

Section 29.

#### Textual Amendments

**F484** [Sch. 2](#) repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

## SCHEDULE 3

### SAMPLING

#### Modifications etc. (not altering text)

**C175** [Sch. 3](#) modified (3.4.1992) by [S.I. 1992/605](#), [regs. 2\(3\)](#), 3  
[Sch. 3](#) applied (3.10.1994) by [S.I. 1994/2328](#), [reg. 11\(c\)](#)  
[Sch. 3](#) applied (with modifications) (1.1.1995) by [S.I. 1994/3144](#), [reg. 10](#), [Sch. 4](#)  
[Sch. 3](#) applied (31.3.1997) by [S.I. 1997/322](#), [reg. 34](#), [Sch. 5](#)

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- Sch. 3 applied (1.2.2000) by S.I. 2000/7, **reg. 5**
- C176** Sch. 3 applied (with modifications) (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), regs. 1, 47, **Schs. 9**
- C177** Sch. 3 applied (with modifications) (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), regs. 1(a), 11, **Schs. 4** (with Sch. 6)
- C178** Sch. 3 amendment to earlier affecting provision SI 2004/1031 reg. 47 Sch. 9 (29.8.2006) by Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **32**

### Introductory

- 1 (1) The provisions of this Schedule shall have effect where a person authorised in that behalf by an enforcement authority (in this Schedule referred to as a “sampling officer”) obtains a sample of any substance or article—
- (a) for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention of any provisions of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act, that authority (in this Schedule referred to as “the relevant enforcement authority”) is required or empowered to enforce, or
- (b) otherwise for any purpose connected with the performance by that authority of their functions under this Act or under any such regulations or order, and the sampling officer obtains the sample by purchase or in the exercise of any power conferred by section 112 of this Act.
- (2) In this Schedule “public analyst”, [<sup>F485</sup>except in relation to Northern Ireland, has the meaning assigned to it by section 27 of the Food Safety Act 1990], and in relation to Northern Ireland has the meaning assigned to it by [<sup>F486</sup>Article 27(1) of the Food Safety (Northern Ireland) Order 1991].

### Textual Amendments

- F485** Words in Sch. 3 para. 1(2) substituted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 12**
- F486** Words in Sch. 3 para. 1(2) substituted (N.I.) (21.5.1991) by S.I. 1991/762, art. 51(1), **Sch. 2 para.10**; S.R. 1991/175, **art. 2(1)**.

### Division of sample

- 2 The sampling officer shall forthwith divide the sample into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.
- 3 If the sample was purchased by the sampling officer, otherwise than from an automatic machine, he shall supply one part of the sample to the seller.
- 4 If the sampling officer obtained the sample from an automatic machine, then—
- (a) if a person’s name, and an address in the United Kingdom, are stated on the machine as being the name and address of the owner of the machine, the sampling officer shall supply one part of the sample to that person;
- (b) in any other case, the sampling officer shall supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

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F487<sup>5</sup> .....

**Textual Amendments**  
 F487 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), Sch 35 (with Sch. 32)

F487<sup>6</sup> .....

**Textual Amendments**  
 F487 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), Sch 35 (with Sch. 32)

F487<sup>7</sup> .....

**Textual Amendments**  
 F487 Sch. 3 paras. 5-7 repealed (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(a), Sch 35 (with Sch. 32)

8 In any case not falling within any of paragraphs [F488<sup>3</sup> or 4] of this Schedule the sampling officer shall supply one part of the sample to the person appearing to him to be the owner of the substance or article from which the sample was taken.

**Textual Amendments**  
 F488 Words in Sch. 3 para. 8 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(b) (with Sch. 32)

9 In every case falling within any of paragraphs [F489<sup>3</sup>, 4, or 8] of this Schedule the sampling officer shall inform the person to whom the part of the sample in question is supplied that the sample has been obtained for the purpose of analysis or other appropriate examination.

**Textual Amendments**  
 F489 Words in Sch. 3 para. 9 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 34(e) (with Sch. 32)

10 Of the remaining parts of the sample into which the sample is divided in accordance with paragraph 2 of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall—  
 (a) retain one part for future comparison, and  
 (b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.

11 Where a sample consists of substances or articles enclosed in unopened containers, and it appears to the sampling officer that to open the containers and divide the contents into parts—

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- (a) is not reasonably practicable, or
  - (b) might affect the composition or impede the proper analysis or other examination of the contents,
- the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them.
- 12 Section 127 of this Act shall have effect in relation to supplying any part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.
- 13 If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample ought to be supplied in pursuance of the preceding paragraphs, he may retain that part of the sample instead of supplying it.

*Notice to person named on container*

- 14 (1) Where it appears to the sampling officer that a substance or article of which he has obtained a sample was manufactured or assembled by a person whose name and address in the United Kingdom are stated on its container, and who is not a person to whom a part of the sample is required to be supplied under the preceding provisions of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall serve notice on that person—
- (a) stating that the sample has been obtained by the sampling officer, and
  - (b) specifying the person from whom the sampling officer purchased it, or, if he obtained it otherwise than by purchase, the place from which he obtained it.
- (2) The notice required to be served under the preceding sub-paragraph shall be served before the end of the period of three days beginning with the day on which the sample was obtained.

*Analysis or other examination of sample*

- 15 If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall—
- (a) submit it for analysis to the public analyst for the area in which the sample was obtained, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area, or
  - (b) submit it for other appropriate examination to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.
- 16 Where the relevant enforcement authority is a Minister or the Pharmaceutical Society, and the sampling officer decides to have the sample analysed, he may (instead of submitting it to a public analyst) submit it for analysis to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.
- 17 Any such arrangements as are mentioned in paragraph 15(b) or paragraph 16 of this Schedule,—
- F490 (a) .....

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- (b) if <sup>F491</sup>... they are made by an enforcement authority in England and Wales other than [<sup>F492</sup>the Secretary of State], shall be arrangements approved by [<sup>F492</sup>the Secretary of State];
- (c) if they are made by an enforcement authority in Scotland other than the Secretary of State, shall be arrangements approved by the Secretary of State;

and any such arrangements as are mentioned in paragraph 15(b) of this Schedule, if made by [<sup>F493</sup>the Pharmaceutical Society of Northern Ireland] in Northern Ireland, shall be arrangements approved by [<sup>F494</sup>the Minister for Health, Social Services and Public Safety].

#### Textual Amendments

- F490** Sch. 3 para. 17(a) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 68(a)** (with regs. 2(4), 3)
- F491** Words in Sch. 3 para. 17(b) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 68(b)** (with regs. 2(4), 3)
- F492** Words substituted by virtue of [S.I. 1968/1699](#), **arts. 2, 5(4)(a)**
- F493** Words in [Sch. 3 para. 17](#) substituted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 34(d)(i)** (with Sch. 32)
- F494** Words in Sch. 3 para. 17 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 34(d)(ii)** (with Sch. 32)

#### Modifications etc. (not altering text)

- C179** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: [S.I. 1969/388](#), **art. 2(1)**

- 18 (1) Subject to the following sub-paragraph, the person to whom the sample is submitted under paragraph 15 or paragraph 16 of this Schedule shall analyse or examine the sample (as the case may be), or cause the sample to be analysed or examined by some other person under his direction, as soon as practicable.
  - (2) If the person to whom the sample is so submitted is a public analyst, and that analyst determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.
- 19 (1) A public analyst who has analysed a sample submitted to him under the preceding provisions of this Schedule, or who has caused such a sample to be analysed by some other person under his direction, shall issue and send to the sampling officer a certificate specifying the result of the analysis.
  - (2) A person having the management or control of a laboratory in which a sample submitted to him under the preceding provisions of this Schedule has been analysed or examined, or a person appointed by him for the purpose, shall issue and send to the sampling officer a certificate specifying the result of the analysis or examination.
  - (3) Any certificate issued under this paragraph shall be in a form prescribed by the Ministers and shall be signed by the person who issues the certificate.
- 20 (1) Any person to whom, in accordance with paragraphs 2 to 8 of this Schedule, a part of the sample is required to be supplied shall, on payment of the prescribed fee to



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the relevant enforcement authority, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19 of this Schedule.

- (2) Any regulations prescribing a fee for the purposes of this paragraph shall be made by the Ministers.

#### *Provisions as to evidence*

- 21 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 of this Schedule shall be sufficient evidence of the facts stated in the document, unless the other party requires that the person who issued the certificate shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 22 In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings, which has been supplied to him by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated in the document.
- 23 (1) If in any such proceedings before a magistrates' court a defendant intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, a notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least three clear days before the day on which the summons is returnable.
- (2) If the preceding sub-paragraph is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper.
- (3) In Scotland, if in any such proceedings in the sheriff court the accused intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.
- (4) If sub-paragraph (3) of this paragraph is not complied with, the sheriff may, if he thinks fit, adjourn the diet on such terms as he deems proper.

#### *Analysis under direction of court*

- 24 (1) In any proceedings for an offence under this Act, where the proceedings relate to a substance or article of which a sample has been obtained as mentioned in paragraph 1 of this Schedule, the part of the sample retained in pursuance of paragraph 10(a) of this Schedule shall be produced as evidence; and the court—
- (a) at the request of either party to the proceedings shall, and
- (b) in the absence of any such request may if it thinks fit,
- cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, the Government Chemist for Northern Ireland) or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.
- (2) If, in a case where an appeal is brought, no action has been taken under the preceding sub-paragraph, the provisions of that sub-paragraph shall have effect in relation to the court by which the appeal is heard.

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- (3) A person to whom a part of a sample is sent under this paragraph for analysis or other examination shall analyse or examine it, or cause it to be analysed or examined on his behalf, and shall transmit to the court a certificate specifying the result of the analysis or examination.
- (4) Any such certificate shall be signed by that person, or signed on his behalf by the person who made the analysis or examination or a person under whose direction it was made.
- (5) Any such certificate shall be evidence (and, in Scotland, shall be sufficient evidence) of the facts stated in the certificate unless any party to the proceedings requires that the person by whom it was signed shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.
- 25 The costs of any analysis or examination under paragraph 24 of this Schedule shall be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

*Proof by written statement*

- 26 In relation to England and Wales section 9 of the <sup>M7</sup>Criminal Justice Act 1967, and in relation to Northern Ireland any corresponding enactment which may be passed by the Parliament of Northern Ireland, shall not have effect with respect to any document produced as mentioned in paragraph 21 or paragraph 22 of this Schedule or with respect to any certificate transmitted to a court under paragraph 24 of this Schedule.

**Marginal Citations**

M7 1967 c. 80.

*Power to modify sampling provisions*

- 27 The Ministers may by order provide that, in relation to substances or articles of any such description as may be specified in the order, the preceding provisions of this Schedule shall have effect subject to such exceptions and modifications as may be specified in the order.

*Payment for sample taken under compulsory powers*

- 28 (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 112 of this Act he shall, if payment is demanded, pay the value of the sample to the person to whom a part of the sample is required under paragraph 5, paragraph 7 or paragraph 8 of this Schedule (as the case may be) to be supplied.
- (2) In default of agreement between the sampling officer and the person mentioned in the preceding sub-paragraph, the value of the sample shall be determined by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question or, if they are unable to agree on the appointment of an arbitrator, shall be determined by the county court<sup>F495</sup> for the district (or, in Northern Ireland, the division) in which the sample was taken].

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[<sup>F496</sup>(2A) For the purposes of this paragraph, England and Wales is to be treated as the district of the county court in England and Wales.]

(3) In the application of this paragraph to Scotland, for references to an arbitrator there shall be substituted references to an arbiter and for the reference to the county court there shall be substituted a reference to the sheriff.

#### Textual Amendments

**F495** Words in Sch. 3 para. 28(2) repealed (N.I.) (31.10.2016) by [Justice Act \(Northern Ireland\) 2015 \(c. 9\)](#), s. 106(2), [Sch. 1 para. 60](#), [Sch. 9 Pt. 1](#) (with [Sch. 8 para. 1](#)); [S.R. 2016/387](#), art. 2(k)(m) (with art. 3)

**F496** Sch. 3 para. 28(2A) inserted (22.4.2014) by [Crime and Courts Act 2013 \(c. 22\)](#), s. 61(3), [Sch. 9 para. 111](#); [S.I. 2014/954](#), art. 2(c) (with art. 3) (with transitional provisions and savings in [S.I. 2014/956](#), arts. 3-11)

#### *Application of s. 64 to samples*

29 Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 112 of this Act, the provisions of subsections (1) to (4) of section 64 of this Act shall have effect as if the taking of the product as a sample were a sale of it to the sampling officer by the person from whom it is taken; and, if the product was prepared in pursuance of a prescription given by a practitioner, those provisions shall so have effect as if, in subsection (1) of that section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”

## SCHEDULE 4

Section 134.

### PROVISIONS RELATING TO NORTHERN IRELAND

#### Modifications etc. (not altering text)

**C180** Sch. 4 applied (31.3.1997) by [S.I. 1997/322](#), reg. 34, [Sch.5](#)

**C181** Paras. 6, 8, 11 extended by [Medicines Act 1971 \(c. 69\)](#), s. 1(3)(c)

1 (1) [<sup>F497</sup>the Minister for Health, Social Services and Public Safety] may by order make provision for the application of this Act in relation to druggists subject to such exceptions and modifications as may be specified in the order.

(2) In this paragraph “druggist” means a person registered in the register of druggists for Northern Ireland made out and maintained under [<sup>F498</sup>Articles 6 and 9 of the <sup>M8</sup>Pharmacy (Northern Ireland) Order 1976].

#### Textual Amendments

**F497** Words in [Sch. 4](#) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 35\(a\)](#) (with [Sch. 32](#))

**F498** Words substituted by [S.I. 1976/1213 \(N.I. 22\)](#), [Sch. 5 para. 8](#)

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**Marginal Citations**

**M8** S.I. 1976/1213 (N.I. 22)

F499<sup>2</sup> .....

**Textual Amendments**

**F499** Sch. 4 paras. 2-5 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(a)** (with regs. 2(4), 3)

F499<sup>3</sup> .....

**Textual Amendments**

**F499** Sch. 4 paras. 2-5 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(a)** (with regs. 2(4), 3)

F499<sup>4</sup> .....

**Textual Amendments**

**F499** Sch. 4 paras. 2-5 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(a)** (with regs. 2(4), 3)

F499<sup>5</sup> .....

**Textual Amendments**

**F499** Sch. 4 paras. 2-5 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(a)** (with regs. 2(4), 3)

6 [F500The appropriate Northern Ireland Minister] may in relation to Northern Ireland exercise any power of making an order or regulations which is conferred on the [F501Ministers] by any provision of this Act F502 ... F503F502 ... F504F502 ... where in his F505 ... opinion there are special circumstances which render it expedient to do so.

**Textual Amendments**

**F500** Words in Sch. 4 para. 6 substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(b)(i)** (with regs. 2(4), 3)

**F501** Word in Sch. 4 para. 6 substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(b)(ii)** (with regs. 2(4), 3)

**F502** Words in Sch. 4 para. 6 omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 35(b)** (with Sch. 32)

**F503** Words in Sch. 4 para. 6 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(b)(iii)** (with regs. 2(4), 3)

**F504** Words repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, Sch. 1 para. 3(11), **Sch. 2**

**F505** Words in Sch. 4 para. 6 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(b)(iv)** (with regs. 2(4), 3)

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F5067 .....

**Textual Amendments**

**F506** Sch. 4 para. 7 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(c)** (with regs. 2(4), 3)

8 Every order or regulation under this Act made by [<sup>F497</sup>the Minister for Health, Social Services and Public Safety]<sup>F507</sup> ... by virtue of the power conferred by paragraph 1<sup>F508</sup> ... or paragraph 6 of this Schedule<sup>F509</sup> ... shall be subject to negative resolution within the meaning of section 41(6) of the <sup>M9</sup>Interpretation Act (Northern Ireland) 1954 as if it were a statutory instrument within the meaning of that Act.

**Textual Amendments**

**F497** Words in Sch. 4 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 35(a)** (with Sch. 32)

**F507** Words in Sch. 4 para. 8 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(d)(i)** (with regs. 2(4), 3)

**F508** Words in Sch. 4 para. 8 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(d)(ii)** (with regs. 2(4), 3)

**F509** Words in Sch. 4 para. 8 omitted (14.8.2012) by virtue of [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 35(e)** (with Sch. 32)

**Marginal Citations**

**M9** 1954 c. 33 (N.I.)

9 In this Schedule “[<sup>F510</sup>the appropriate Northern Ireland Minister]”—  
(a) <sup>F511</sup> ... means [<sup>F497</sup>the Minister for Health, Social Services and Public Safety];  
<sup>F512</sup>(b) .....  
<sup>F512</sup>(c) .....  
<sup>F513</sup> ...

**Textual Amendments**

**F497** Words in Sch. 4 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 35(a)** (with Sch. 32)

**F510** Words in Sch. 4 para. 9 substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(e)(i)** (with regs. 2(4), 3)

**F511** Words in Sch. 4 para. 9(a) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(e)(ii)** (with regs. 2(4), 3)

**F512** Sch. 4 para. 9(b)(c) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(e)(iii)** (with regs. 2(4), 3)

**F513** Words in Sch. 4 para. 9 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(e)(iv)** (with regs. 2(4), 3)

10 In this Act any reference to [<sup>F514</sup>the Department of Health, Social Services and Public Safety]<sup>F515</sup> ..., and any reference which is to be construed as including a

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reference to [<sup>F516</sup>that Minister], shall include a reference to the Ministry of Health and Social Services for Northern Ireland <sup>F517</sup>....

**Textual Amendments**

- F514** Words in Sch. 4 para. 10 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 35(d)** (with Sch. 32)
- F515** Words in Sch. 4 para. 10 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(f)(i)** (with regs. 2(4), 3)
- F516** Words in Sch. 4 para. 10 substituted (1.10.2006) by [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(f)(ii)** (with regs. 2(4), 3)
- F517** Words in Sch. 4 para. 10 omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 69(f)(iii)** (with regs. 2(4), 3)

11 [<sup>F518</sup>The Statutory Rules (Northern Ireland) Order 1979, except article 5(2)(a) of that Order] (which requires the responsible officer of each rule-making authority making any statutory rules to send copies of them, and certain information, to the Ministry of Finance for Northern Ireland for registration [<sup>F518</sup>under that Order]), shall not apply to any orders or regulations made under this Act by statutory instrument.

**Textual Amendments**

- F518** Words substituted by [S.I. 1979/1573](#), **Sch. 4 para. 10**

SCHEDULE 5

Section 135(1)

AMENDMENTS OF ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM.

*The Venereal Disease Act 1917 (c. 21).*

<sup>F519</sup><sub>1</sub> .....

**Textual Amendments**

- F519** Sch. 5 para. 1 repealed (22.7.2004) by [Statute Law \(Repeals\) Act 2004 \(c. 14\)](#), **Sch. 1 Pt. 17** Group 7

**Modifications etc. (not altering text)**

- C182** The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

2, 9. .... <sup>F520</sup>

**Textual Amendments**

- F520** Sch. 5 paras. 2–9 repealed by [Poisons Act 1972 \(c. 66\)](#), **Sch. 2**

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*The Cancer Act 1939 (c. 13.)*

- 10 In section 4, in subsection (4)(a)(v), for the words “authorised sellers of poisons” there shall be substituted the words “persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968”.

**Modifications etc. (not altering text)**

**C183** The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

- 11 ..... **F521**

**Textual Amendments**

**F521** Sch. 5 para. 11 repealed by [National Health Service Act 1977 \(c. 49\)](#), **Sch. 16**

- 12 ..... **F522**

**Textual Amendments**

**F522** Sch. 5 para. 12 repealed by [National Health Service \(Scotland\) Act 1978 \(c. 29\)](#), **Sch. 17**

- <sup>F523</sup>13 .....

**Textual Amendments**

**F523** Sch. 5 para. 13 repealed (5.11.1993) by [1993 c. 50, s. 1\(1\)](#), **Sch. 1Pt. XII**

- 14, 15. .... **F524**

**Textual Amendments**

**F524** Sch. 5 paras. 14, 15 repealed by [Misuse of Drugs Act 1971 \(c. 38\)](#), **Sch. 6**

*The Trade Descriptions Act 1968 (c. 29).*

- 16 In section 2, in subsection 5, after the word “section” there shall be inserted “(a)”, and at the end of the subsection there shall be inserted the following paragraph:—

“(b) where by virtue of any provision made under Part V of the Medicines Act 1968 (or made under any provisions of the said Part V as applied by an order made under section 104 or section 105 of that Act) anything which, in accordance with this Act, constitutes the application of a trade description to goods is subject to any requirements or restrictions imposed by that provision, any particular description specified in that provision, when applied to goods in circumstances to which those requirements or restrictions are applicable, shall be deemed not to be a trade description.”

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**Modifications etc. (not altering text)**

**C184** The text of Sch. 5 paras. 1, 10, 13, 16, 7, Schs. 6, 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991.

**[<sup>F525</sup>17** In section 22, in subsection (2), after the words “the Food and Drugs Act (Northern Ireland) 1958”<sup>M10</sup> there shall be inserted the words “or the Medicines Act 1968” ; in paragraph (b) the word “and”, where it occurs at the end of that paragraph, shall be omitted ; and at the end of paragraph (c) there shall be inserted the words

(d) in relation to the said Act of 1968, so much of Schedule 3 to that Act as is applicable to the circumstances in which the sample was procured,”

at the end of the subsection there shall be inserted the words “or paragraph 27 of Schedule 3 to the said Act of 1968”.]

**Textual Amendments**

**F525** Sch. 5 para. 17 repealed (E.W.S.) by [Food Safety Act 1990 \(c. 16, SIF 53:1, 2\), ss. 54, 59\(4\), Sch. 5](#)

**Marginal Citations**

**M10** [1958 c. 27 \(N.I.\)](#)

SCHEDULE 6

Section 135(2)

ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM REPEALED.

**Modifications etc. (not altering text)**

**C185** The text of Sch. 6 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991

Section 135(2). SCHEDULE 6 ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM REPEALED

Chapter	Short Title	Extent of Repeal
7 & 8 Geo. 5, c. 21. 23 & 24 Geo. 5, c. 25.	The Venereal Disease Act 1917. The Pharmacy and Poisons Act 1933.	Section 5(2), except the proviso. Sections 8 to 14. In section 17, in subsection (2), the words “persons who are to be entitled to sell poisons in Part II”, and, in subsection (6), the words from “and in this Act” to the end of the subsection. In section 18(2)(a)(ii) the word “registered”. Section 19. In section 23, in subsection (1), paragraph (a), paragraph (b) (i) and paragraph (i); and in subsection (3), in the reference to paragraphs (a), (b)(i), (c), (d), (e) and (f), the references to paragraphs (a) and (f). In section 25, in subsection (1) the words “Part I of this Act and of section nineteen and”, in subsection (4) these words and the word “registered”, and subsection (5). In section 29, the definitions of “authorised seller of poisons” and “poison” and paragraph (a) of the definition of “registered”. In section 4, subsection (1)(b), subsection (3) and subsection (4)(a)(vii). The whole Act. Sections 3 and 4. In section 12, the definition of “authorised seller of poisons”.
2 & 3 Geo. 6, c. 13.	The Cancer Act 1959.	In section 4, subsection (1)(b), subsection (3) and subsection (4)(a)(vii).
4 & 5 Geo. 6, c. 42. 11 & 12 Geo. 6, c. 37.	The Pharmacy and Medicines Act 1941. The Radioactive Substances Act 1948.	The whole Act. Sections 3 and 4. In section 12, the definition of “authorised seller of poisons”.



SCHEDULE 7

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Chapter	Short Title	Extent of Repeal
14 Geo. 6. c. 36.	The Diseases of Animals Act 1950.	Part II and Schedule 3.
2 & 3 Eliz. 2. c. 61.	The Pharmacy Act 1954.	Section 19.
4 Eliz. 2. c. 16.	The Food and Drugs Act 1955.	In section 1, subsection (2) and subsection (3)(a). In section 2(3), the words from "except" to "drugs". Section 3(2). In section 6(6), the words from "except" to "drugs". In section 9(1)(c), the words from "but" to the end of the subsection. In section 109(3)(a), the words from "so" to the end of the paragraph. In section 114(4), the words from "the authority concerned" to "in any other case". The words "or drug" and "drug" wherever they occur, except in section 135. In Schedule 8, in column 2, in the first paragraph, the words from "other" to "drug". In Part I of Schedule 9, in column 2, paragraph (a)(iii) of the definition relating to sections 321 to 323 of the Public Health Act 1936.
4 & 5 Eliz. 2. c. 22.	The Therapeutic Substances Act 1956.	The whole Act.
4 & 5 Eliz. 2. c. 30.	The Food and Drugs (Scotland) Act 1956.	In section 1, subsection (2) and subsection (3)(a). In section 2(3) the words from Section 3(2). In section 6(6) the words from "except" to "drugs". In section 28(2) the words from "but" to the end of the subsection. The words "or drug" and "drug" wherever they occur, except in section 58.
4 & 5 Eliz. 2. c. 76.	The Medical Act 1956.	Section 47. Section 47(9) and (10).
1963 c. 9.	The Purchase Tax Act 1963.	In Part II of Schedule 1, in paragraph 5(2), the definition of "authorised seller of poisons".

Sch. 6

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Chapter	Short Title	Extent of Repeal
1964 c. 64.	The Drugs (Prevention of Misuse) Act 1964.	In section 1, in subsection (7), the reference to, and the paragraph, substituted for, paragraph (k) of subsection (2).
1965 c. 15.	The Dangerous Drugs Act 1965.	In section 9 the definition of "authorised seller of poisons". In section 11, in subsection (4) the words "in subsection (1) thereof".

F526F526 SCHEDULE 7

**Textual Amendments**

F526 Sch. 7 repealed by S.I. 1976/1213 (N.I. 22), Sch. 6 and 1976/1214 (N.I. 23), Sch. 3

F526

SCHEDULE 8

Section 135(4)

ENACTMENTS OF PARLIAMENT OF NORTHERN IRELAND REPEALED.

**Modifications etc. (not altering text)**

C186 The text of Sch. 8 is in the form in which it was originally enacted: it was not reproduced in Statutes in Force and does not reflect any amendments or repeals which may have been made prior to 1.2.1991

**Changes to legislation:** Medicines Act 1968 is up to date with all changes known to be in force on or before 08 May 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. (See end of Document for details) View outstanding changes

SCHEDULE 8  
 ENACTMENTS OF PARLIAMENT OF NORTHERN IRELAND REPEALED

Section 133(4)

Session or Year and Chapter	Short Title	Extent of Repeal
15 & 16 (Geo. 5, c. 4) (N.I.), 1945 c. 9 (N.I.)	The Pharmacy and Poisons Act (Northern Ireland) 1925, The Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945	Section 17, Section 18, Schedule 3, Part I. In section 14, in subsection (1) the words "if he is a registered person" and the words from "and, if he is a representative" onwards, and in subsection (2) the proviso. Sections 13 to 18. In section 19, in subsection (1) the words "or to be an authorised seller of poisons" and the words from "or, if the owner is a body corporate" to "employee of the body corporate"; in subsection (2) in paragraph (a) the words from "or, if the owner" onwards and in paragraph (d) the words from "or, if the owner is a body corporate" to "employee of the body corporate"; and subsection (3). In section 27(1)(a)(iii) the words from "in accordance" onwards. Section 28. In section 32, in subsection (1) paragraphs (a), (b) and (c), and in subsection (2) the references to paragraphs (a) and (c) of subsection (1). In section 33(3) the words "section four, section five or". In section 36(2) and (3) the words "I and". Section 37. In section 38(1) the definitions of "authorised seller of poisons", "poison", "premises having an annual licence" and "retailing". In Schedule 2 in the proviso to paragraph (1) the word "or" at the end of paragraph (a) and paragraphs (b) and (c). 3 N°4

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Session or Year and Chapter	Short Title	Extent of Repeal
1955 c. 31 (N.I.)	The Pharmacy and Poisons Act (Northern Ireland) 1955.	Section 2, Section 14.
1958 c. 13 (N.I.)	The Diseases of Animals Act (Northern Ireland) 1958.	Part II, In Schedule 4, Part I.
1958 c. 27 (N.I.)	The Food and Drugs Act (Northern Ireland) 1958.	In section 1 subsection (2), subsection (3)(b) and in subsection (6) the words "or drug". In section 2 in subsection (1) the words "or drug" in both places where they occur, and in subsection (3) the words " , except so far as it relates to drugs". Section 3(2). In section 6 in subsection (1) the words "or drug" in each of the three places where they occur, in subsection (2) those words in each of the two places where they occur, in subsection (5) those words and in subsection (6) the words " , except so far as it relates to drugs". In section 33 in subsection (2) the words "or drug" and subsections (3). In section 34 in subsection (1) the word " , drug" and in subsection (2) the words "or drug". In section 35 in subsections (1) and (4) the word " , drug". In section 38 the word " , drug" in both places where it occurs. In section 44 in subsection (2)(a) the word " , drug" in both places where it occurs and in subsection (3) that word in both places where it occurs. In section 47, in subsection (1) the words " so far as those sections or regulations relate to food" , and in subsection (3)(a) the words " so far as it relates to food".
1966 c. 23 (N.I.)	The Diseases of Animals (Amendment) Act (Northern Ireland) 1966.	Section 3(2).

Sch. 8

Session or Year and Chapter	Short Title	Extent of Repeal
1967 c. 12 (N.I.)	The Pharmacy Act (Northern Ireland) 1967.	Section 2, In Schedule 1 the entries amending sections 17 and 27 of the Pharmacy and Poisons Act (Northern Ireland) 1925 and the entries amending the proviso to section 16(2) and sections 15, 16, 17 and 18 of, and paragraph 1 of Schedule 2 to, the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945.
1967 c. 29 (N.I.)	The Increase of Fines Act (Northern Ireland) 1967.	In the Schedule the entries relating to sections 15(4) and 16(1A) of the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945 and Section 32 of the Diseases of Animals Act (Northern Ireland) 1958.

**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- s. 10233133 amended (prosp.) by [1997 c. 19 s. 1Sch. para. 2](#)(adding [1954 c 61 s. 13A-13M](#))
- s. 52 amended (prosp.) by [1997 c. 19 s. 1Sch. para. 2](#)(adding [1954 c 61 s. 13A-13M](#))
- s. 69(1) amended (prosp.) by [1997 c. 19 s. 1Sch. para. 5\(a\)](#)
- s. 75(4)-(6) omitted by [S.I. 2016/372 art. 8](#)

**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](#)