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# Medicines Act 1968

## 1968 CHAPTER 67

### PART II

#### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *General provisions and exemptions*

**<sup>F16</sup> The licensing authority.**

.....

**Textual Amendments**

**F1** Ss. 2A-9 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**<sup>F17</sup> General provisions as to dealing with medicinal products.**

.....

**Textual Amendments**

**F1** Ss. 2A-9 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**<sup>F18</sup> Provisions as to manufacture and wholesale dealing.**

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**Textual Amendments**

**F1** Ss. 2A-9 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**F1 9 Exemptions for doctors and dentists**

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**Textual Amendments**

**F1** Ss. 2A-9 repealed (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 35](#) (with [Sch. 32](#))

**10 Exemptions for pharmacists.**

(1) <sup>F2</sup> ... the restrictions imposed by [<sup>F3</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>F4</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>F5</sup>an appropriate practitioner], or
- (b) assembling a medicinal product [<sup>F6</sup>provided that where the assembling takes place in a registered pharmacy—
  - (i) it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail pharmacy business, and
  - (ii) the medicinal product has not been the subject of an advertisement]; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, or of procuring the assembly of a medicinal product.

<sup>F7</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>F8</sup> ...

<sup>F8</sup>( b ) .....

(4) Without prejudice to the preceding subsections, the restrictions imposed by [<sup>F9</sup>regulations 17(1) (manufacturing of medicinal products) and 46 (requirement for

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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 [<sup>F10</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 that registered pharmacy or at any other registered pharmacy forming part of the same retail pharmacy business];

and those restrictions do not apply to anything which is done in a hospital or a health centre by or under the supervision of a pharmacist and consists of preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1) (a) of this section.

[<sup>F11</sup>(5) Without prejudice to the preceding subsections, the restrictions imposed by [<sup>F12</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 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 [<sup>F13</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 that registered pharmacy.

<sup>F14</sup>( 6A ) . . . . .

<sup>F15</sup>( 7 ) . . . . .

[ The <sup>F17</sup> ... Ministers may make regulations prescribing conditions which must be <sup>F16</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.]

(8) For the purposes of this section “advertisement” shall have the meaning assigned to it by [<sup>F18</sup>regulation 7 (advertisements relating to medicinal products) of the 2012 Regulations] . ]

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[<sup>F19</sup>(9) In subsection (1) of this section, “care home service” has the meaning given by [<sup>F20</sup> paragraph 2 of schedule 12 to the [Public Services Reform \(Scotland\) Act 2010 \(asp 8\)](#)]. ]

#### Textual Amendments

- F2** Words in s. 10(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 10\(a\)](#) (with regs. 2(4), 3)
- F3** Words in s. 10(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(b\)](#) (with Sch. 32)
- F4** Words in s. 10(1) inserted (S.) (1.4.2002) by [2001 asp 8](#), s. 79, [Sch. 3 para. 5\(a\)](#); S.S.I. 2002/162, [art. 2\(h\)](#) (subject to [arts. 3-13](#))
- F5** Words in s. 10(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(a\)](#) (with Sch. 32)
- F6** Words added by [S.I. 1971/1445](#), [art. 3\(a\)](#)
- F7** S. 10(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 10\(b\)](#) (with regs. 2(4), 3)
- F8** S. 10(3)(b) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 10\(c\)](#) (with regs. 2(4), 3)
- F9** Words in s. 10(4) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(b\)](#) (with Sch. 32)
- F10** Words added by [S.I. 1971/1445](#), [art. 3\(b\)](#)
- F11** S. 10(5)–(8) added by [S.I. 1971/1445](#), [art. 3\(c\)](#)
- F12** Words in s. 10(5) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(c\)](#) (with Sch. 32)
- F13** Words in s. 10(6) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(d\)](#) (with Sch. 32)
- F14** S. 10(6A) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 10\(d\)](#) (with regs. 2(4), 3)
- F15** S. 10(7) 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)
- F16** S. 10(7A)–(7C) inserted (19.7.2006 for specified purposes) by [Health Act 2006 \(c. 28\)](#), [ss. 26\(1\)](#), 83(1)(e)
- F17** Word in s. 10(7A) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 10\(e\)](#) (with regs. 2(4), 3)
- F18** Words in s. 10(8) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 3\(f\)](#) (with Sch. 32)
- F19** S. 10(9) added (S.) (1.4.2002) by [2001 asp 8](#), ss. 79, [Sch. 3 para. 5\(b\)](#); S.S.I. 2002/162, [art. 2\(h\)](#) (subject to [arts. 3-13](#))
- F20** Words in s. 10(9) substituted (28.10.2011) by [The Public Services Reform \(Scotland\) Act 2010 \(Consequential Modifications of Enactments\) Order 2011 \(S.I. 2011/2581\)](#), [art. 1\(2\)\(b\)](#), [Sch. 2 para. 1](#)

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

- C1** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), [art. 3\(1\)](#)
- C2** S. 10 amended (E.W.S.) (*prosp.*) by [1954 c. 61](#), [s. 131\(1\)\(b\)](#) (as inserted (*prosp.*) by [1997 c. 19](#), ss. 1, 2(1), [Sch. para. 2](#))

<sup>F21</sup>11 **Exemption for nurses and midwives.**

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**Textual Amendments**

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

**F21 12 Exemptions in respect of herbal remedies.**

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**Textual Amendments**

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

**F21 13 Exemptions for imports.**

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**Textual Amendments**

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

**F21 14 Exemption for re-exports.**

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**Textual Amendments**

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

**15 Provision for extending or modifying exemptions.**

**F22**(1) .....

**F22**(2) .....

(3) The <sup>F23</sup> ... Ministers may by order provide that any of the provisions of [<sup>F24</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.

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**Textual Amendments**

- F22** 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](#))
- F23** Word in s. 15(3) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), [reg. 1](#), [Sch. 8 para. 11\(b\)](#) (with [regs. 2\(4\), 3](#))
- F24** Words in s. 15(3) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), [reg. 1\(2\)](#), [Sch. 34 para. 4\(b\)](#) [Sch. 35](#) (with [Sch. 32](#))

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

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

<sup>F25</sup> **16 Transitional exemptions.**

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**Textual Amendments**

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

<sup>F25</sup> **17 Termination of transitional exemptions.**

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**Textual Amendments**

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

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