



Medicines Act 1968

1968 CHAPTER 67

PART VIII

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

108 Enforcement in England and Wales.

(1) [^{F1}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 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), [^{F2}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;

^{F3}(b)

^{F3}(c)

the appropriate Minister shall, in respect of each area for which there is a [^{F4}drugs authority] make arrangements or give directions whereby [^{F5}the General Pharmaceutical Council], or the [^{F4}drugs authority] for that area, or both [^{F6}the Council] and that authority, to such extent as, in the case of [^{F7}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 [^{F8}paragraph (a)] of this subsection, in their application as mentioned in [^{F9}that paragraph]^{F10}

^{F11}(3)

^{F11}(4)

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^{F11}(5)

(6) [^{F12}the General Pharmaceutical Council] shall be under a duty, concurrently with the appropriate Minister,—

^{F13}(a)

(b) to enforce the provisions of any regulations made under section 60 ^{F14}... 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 [^{F15}section 78] of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.

^{F16}[^{F17}(6A)

(6B) [^{F18}the General Pharmaceutical Council] shall be under a duty to enforce [^{F19}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 [^{F20}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 [^{F21}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 [^{F22}those provisions or those rules] in their application to England and Wales.]

^{F23}(7)

^{F24}(8)

(9) Notwithstanding anything in subsections [^{F25}(2) to [^{F26}(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 [^{F27}(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 [^{F28}the General Pharmaceutical Council][^{F29}has in relation to any matter failed to perform a duty imposed on it by][^{F30}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”—

^{F31}(a)

(b) ^{F32}... means the [^{F33}Secretary of State].

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- [^{F34}(12) In this section “ drugs authority ” means—
- [^{F35}(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

- F1** 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)
- F2** 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)
- F3** 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)
- F4** 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)**
- F5** 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)
- F6** 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)
- F7** 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)
- F8** 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)
- F9** 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)
- F10** 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)
- F11** 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)
- F12** 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)
- F13** 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)
- F14** 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)
- F15** 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.
- F16** 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
- F17** 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)
- F18** 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)
- F19** 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
- F20** 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

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- F21** 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
- F22** 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
- F23** 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)
- F24** 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)
- F25** 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)
- F26** 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)
- F27** 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)
- F28** 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)
- F29** 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)
- F30** 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
- F31** 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)
- F32** 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)
- F33** Words substituted by virtue of S.I. 1968/1699, **arts. 2**, 5(4)(a)
- F34** 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)**
- F35** 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)

- C1** Power to modify s. 108(8)(W.) conferred by Local Government Act 1972 (c. 70), **s. 200(3)**
- C2** Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: S.I. 1969/388, **art. 2(1)**
- C3** 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)**
- C4** Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg. 12**.
- C5** 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)
- C6** 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**
- C7** S. 108: Functions transferred (W.) (1.7.1999) by virtue of S.I. 1999/672, art. 2, **Sch. 1**
- C8** 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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- C9** 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)
- C10** 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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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](#)