Medicines Act 1968

1968 CHAPTER 67

PART VIII

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

Modifications etc. (not altering text)

C1 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 [F1the 2012 Regulations] to certain articles and substances.

(1) The MinistersF2... 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 **[**F3the 2012 Regulations**][**F4, 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.

(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

F1 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)

F2 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)

F3 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)

F4 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)

C2 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 [F5the 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—

(a) is used as an ingredient in the manufacture of medicinal products, or

(b) if used without proper safeguards, is capable of causing danger to the health of the community[F6]...,

and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of **[**[F7]the 2012 Regulations**]|**[F8], 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—

(a) 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

(b) 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

F5 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)

F6 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)

F7 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)

F8 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**

Modifications etc. (not altering text)

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)**

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.

Modifications etc. (not altering text)

C4 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)**

C5 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 [F9]... of a Minister under section 75 of this Act, and the validity of any **[**[F10]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—

(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 **[**[F11]issue a certificate**]** is quashed under this section, any **[**[F12]certificate issued**]** in pursuance of that decision shall be void, and any proceedings on the application for the **[**[F13]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 [F14]... in Northern Ireland.

Textual Amendments

F9 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)

F10 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)

F11 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)

F12 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)

F13 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)

F14 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)

C6 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)**

C7 S. 107 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.
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**

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**

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**

108 Enforcement in England and Wales.

(1) **[**[F15]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), **[**[F16]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;

F17(b) . . . . . .

F17(c) . . . . . .

the appropriate Minister shall, in respect of each area for which there is a **[**F18drugs authority**]** make arrangements or give directions whereby **[**F19the General Pharmaceutical Council**]**, or the **[**F18drugs authority**]** for that area, or both **[**F20the Council**]** and that authority, to such extent as, in the case of **[**F21that 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 **[**F22paragraph (a)**]** of this subsection, in their application as mentioned in **[**F23that paragraph**]**F24....

F25(3) . . . . . .

F25(4) . . . . . .

F25(5) . . . . . .

(6) **[**F26the General Pharmaceutical Council**]** shall be under a duty, concurrently with the appropriate Minister,—

F27(a) . . . . . .

(b) to enforce the provisions of any regulations made under section 60 F28... 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 **[**F29section 78**]** of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.

F30**[**F31(6A) . . . . . .

(6B) **[**F32the General Pharmaceutical Council**]** shall be under a duty to enforce **[**F33the 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 **[**F34those 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 **[**F35those 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 **[**F36those provisions or those rules**]** in their application to England and Wales.**]**

F37(7) . . . . . .

F38(8) . . . . . .

(9) Notwithstanding anything in subsections **[**F39(2) to **[**F40 (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 **[**F41(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 **[**F42the General Pharmaceutical Council**][**F43has in relation to any matter failed to perform a duty imposed on it by**][**F44subsection (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"—

F45(a) . . . . . .

(b) F46... means the **[**F47Secretary of State**]**.

[F48(12) In this section " drugs authority " means—

[F49(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

F15 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)

F16 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)

F17 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)

F18 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)**

F19 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)

F20 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)

F21 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)

F22 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)

F23 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)

F24 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)

F25 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)

F26 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)

F27 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)

F28 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)

F29 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.

F30 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

F31 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)

F32 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)

F33 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

F34 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

F35 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

F36 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

F37 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)

F38 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)

F39 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)

F40 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)

F41 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)

F42 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)

F43 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)

F44 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

F45 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)

F46 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)

F47 Words substituted by virtue of S.I. 1968/1699, **arts. 2**, 5(4)(a)

F48 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)**

F49 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)

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**

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**
C11 Power to modify s. 108(8)(W.) conferred by Local Government Act 1972 (c. 70), **s. 200(3)**
C12 Functions of Secretary of State in matters only affecting Wales exercisable by Secretary of State for Wales: S.I. 1969/388, **art. 2(1)**
C13 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)**
C14 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg. 12**.
C15 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)
C16 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**
C17 S. 108: Functions transferred (W.) (1.7.1999) by virtue of S.I. 1999/672, art. 2, **Sch. 1**

109 Enforcement in Scotland.

(1) **[**F50 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 **[**F51(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 F52... were a reference to the Secretary of State;

(b) any reference to England and Wales were a reference to Scotland; and

[F53**[**

F54(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 M1 Food and Drugs (Scotland) Act 1956 and to the area of such an authority; and **]**

F55(d)**]** . . . . . .

[F56(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 **[**F57 " a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 " **]]**

F58(3) . . . . . .

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

Textual Amendments

F50 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)

F51 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)
F52 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)
F53 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**
F54 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)**
F55 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)
F56 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)**
F57 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)**
F58 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)
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**
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**
C18 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)**
C19 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**
C20 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg. 12**.
C21 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)**
C22 S. 109: Functions transferred (S.) (1.7.1999) by S.I. 1999/1750, art. 2, **Sch. 1** (with art. 7)
C23 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.

110 Enforcement in Northern Ireland.

(1) Subject to the provisions of **[**[F59]subsections (3C) and (4)**]** of this section, it shall be the duty of the **[**[F60]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 **[**F61paragraph (a)**]** of subsection (2) of section 108 of this Act in their application as mentioned in **[**F62that paragraph**]**, within the **[**F63district**]** of any **[**F64district council**]**, the Minister may make arrangements or give directions whereby the **[**F64district 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 **[**F61paragraph (a)**]** in their application as so mentioned F65....

F66(3) . . . . . .

F67**[**F68(3A) . . . . . .

(3B) The Pharmaceutical Society **[**F69of Northern Ireland**]** shall be under a duty to enforce **[**F70the 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 **[**F71those 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 **[**F72those 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 F73... provisions or those regulations in their application to Northern Ireland.**]**

F74(4) . . . . . .

(5) **[**F75Subsection (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 **[**F76(2) to (6D)**]** of that section were a reference to subsections (2) **[**F77to (3D)**]** of this section; F78...

F78(b) . . . . . .

F79(6) . . . . . .

[F80(8) In this section "district council" means a council established under the Local Government Act (Northern Ireland) 1972.**]**

Textual Amendments

F59 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)

F60 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)

F61 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)

F62 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)

F63 Word in s. 110(2) substituted (14.8.2012) by virtue ofThe Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 20(b)(iii)** (with Sch. 32)

F64 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)

F65 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)

F66 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)

F67 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

F68 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)

F69 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)

F70 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

F71 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

F72 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

F73 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

F74 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)

F75 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)

F76 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)

F77 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)

F78 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)

F79 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)

F80 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)

Modifications etc. (not altering text)

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**

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**

C24 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)**

C25 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**

C26 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.

C27 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)**

C28 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, [F81]...

[[F82](aa) [F83]... 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—

[F84](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.

[F85](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,

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, [F86]... 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[F87]... or other person in charge of the ship, [F86]... 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.

[[F88](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

F81 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)

F82 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)

F83 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)

F84 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)

F85 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)

F86 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)

F87 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)

F88 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)

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**

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**

C29 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)**

C30 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**

C31 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.

C32 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)**

C33 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 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.

F89(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.

Textual Amendments

F89 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)

Modifications etc. (not altering text)

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**

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**

C33 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)

C34 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)**

C35 S. 112 modified by S.I. 1985/273, reg. 2, **Sch. 1 Pt. I**

C36 S. 112 restricted by S.I. 1985/273, **reg. 3(3)**

C37 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**

C38 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.

C39 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)**

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 [F90] ....

(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

F90 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)

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**

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**

C33 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)
C40 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)**
C41 S. 113 modified by S.I. 1985/273, reg. 2, **Sch. 1 Pt. I**
C42 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**
C43 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.
C44 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, [F91]... 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, [F91]... vehicle, stall or place, the master[F92]... 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 **[**[F93]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 **[**[F94] married or a civil partner) the spouse or civil partner **]** of that person.

Textual Amendments

F91 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)

F92 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)
F93 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
F94 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)
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**
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**
C33 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)
C45 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)**
C46 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**
C47 Ss. 108-114 applied (with modifications) (1.7.1992) by S.I. 1992/1520, **reg.12**.
C48 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)**

F95 115 Analysis of samples in other cases.

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Textual Amendments
F95 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)

[F96 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
F96 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**

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

C33 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)
C49 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)**
C50 S. 115A applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**

[F95]116 Liability to forfeiture under Customs and Excise Act 1952.

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Textual Amendments
F95 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)

[F97]117 Special enforcement and sampling provisions relating to animal feeding stuffs.

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Textual Amendments
F97 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)
C51 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.

[[F98](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**[**[F99]or a Scottish public authority for the purposes of the Freedom of Information (Scotland) Act 2002**]**, and

(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

F98 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**

F99 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)

C52 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)**

C53 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**

C54 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**

C55 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)

C56 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)

C57 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)**

C58 S. 119 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3)**, 3

C59 S. 119 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**

C60 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**

C61 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**

C62 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)

C63 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**

[F100]120 Compensation for loss of employment or loss or diminution of emoluments.

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Textual Amendments

F100 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)

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)**

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.

(4) This section applies to the following provisions, that is to say, sections **[**[F101]63, 64, 87 and 88**]**, and the provisions of any regulations made under any of those sections.

Textual Amendments

F101 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)

C65 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)**

C66 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**

C67 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**

C68 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)

C69 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—

(a) 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;

(b) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and

(c) 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, **[**F102sections 63(b), 64, 87 and 88**]**F103... 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.

(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

F102 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)

F103 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)

C67 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**

C68 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)

C69 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**

C70 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 [F104]... 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.

(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

F104 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)

C67 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**

C68 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)

C69 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**

C71 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)**

C72 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) **[**[F105]in respect of any premises at or from which**]** the business is carried on, is the pharmacist referred to in **[**[F106]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.

(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

F105 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

F106 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)

C67 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**

C68 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)

C69 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**

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 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**

C75 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 **[**F107section 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 **[**F108section 331 of the M2Criminal 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 **[**F108subsection 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 **[**F109section 34 of the M3Magistrates' Courts Act (Northern Ireland) 1964**][**F109Article 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 **[**F110punishable 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 **[**F111the General Pharmaceutical Council**]** nor any other body referred to in subsection (2) F112... of section 108 of this Act shall institute proceedings for an offence

under this Act in respect of a contravention of a provision which, by virtue of **[**F113that subsection**]**, **[**F114the 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) **[**F115A 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 **[**F116Minister 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 **[**F116Minister 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

F107 Words substituted by Magistrates' Courts Act 1980 (c. 43, SIF 82), s. 154, **Sch. 7 para. 76**

F108 Words substituted by virtue of Criminal Procedure (Scotland) Act 1975 (c. 21), **s. 460(1)**(*b*)

F109 Words substituted(N.I.) by S.I. 1981/1675 (N.I. 26), **Sch. 6 Pt. I para. 15**

F110 Words substituted by S.I. 1980/704, **Sch. 1 Pt. II para. 50**

F111 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)

F112 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)

F113 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)

F114 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)

F115 Words substituted by S.R. &O. (N.I.) 1973 No. 211, **Sch.**

F116 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)

C67 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**

C68 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)

C69 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**

C76 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)**

C77 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—

F117(a) . . . . . .

F118(b) . . . . . .

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

where it is proved that the F119... medicinal product in question was found on a vehicle from which F120... medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that F119... 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 F121... in his possession for the purpose of sale or supply, where it is proved that the medicinal product F121... 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 F122..., 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), F123... subsection (2) of section 87 and subsection (3) of section 88F124... as applied by subsection (1) of section 90, and to subsection (2) of section 90 except in so far as it relates to leaflets.

F125(4) . . . . . .

Textual Amendments

F117 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)

F118 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)

F119 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)

F120 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)

F121 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)

F122 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)

F123 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)

F124 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)

F125 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)

C68 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)

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. 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**

C80 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)

C68 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)

C81 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)**

C82 S. 127 applied by S.I. 1986/1180, **art. 2(2)** and S.I. 1984/673, **art. 2(2)**

C83 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**

C84 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**

C85 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**

128 Financial provisions.

(1) Any expenses incurred in consequence of this Act by **[**F126either 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) F127

(4) Where **[**F128the 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) **[**F129either 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 **[**F128the 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 **[**F130the 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

F126 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)

F127 S. 128(3) repealed by Medicines Act 1971 (c. 69), **s. 1(4)**

F128 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)

F129 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)

F130 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)

Modifications etc. (not altering text)

C86 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)**

C87 S. 128 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C88 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 **[**F131section 72A of this Act or**]** paragraph 1F132... or paragraph 6 of Schedule 4 to this Act F133...) 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 **[**F13458, 62, 79 **[**F135, 84A(5)**]** and 106**]** and paragraph 27 of Schedule 3, or

F136(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 provisionF137... 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**[**F138 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**[**F139 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.

F140(6A) . . . . . .

(7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III, F141... of this Act, or under section 104 or section 105 of this Act, and they consult **[**F142an 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.

Textual Amendments

F131 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

F132 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)

F133 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)

F134 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)

F135 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**

F136 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)

F137 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)

F138 Words in s. 129(5) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 32(a)**, 83(1)(e)

F139 Words in s. 129(5) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 32(b)**, 83(1)(e)

F140 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)

F141 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)

F142 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)

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. 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**

C91 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**

C92 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)**

C93 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**

C94 S. 129(1)(2)(3)(5) applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

C95 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.

[F143(1) In this Act, "medicinal product" has the meaning given by regulation 2 of the 2012 Regulations.**]**

F144(2) . . . . . .

F144(3) . . . . . .

F145(3A) . . . . . .

F145(3B) . . . . . .

F145(3C) . . . . . .

F144(4) . . . . . .

F144(5) . . . . . .

F144[F146(5A)] . . . . . .

F144[F147(5B)] . . . . . .

F144(6) . . . . . .

(7) F148

F144(8) . . . . . .

(9) In this Act " administer " means administer to a human being F149..., 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 (F150...) a substance or article is a reference to administering (F150...) 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.

F151(10) . . . . . .

Textual Amendments

F143 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)

F144 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)

F145 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)

F146 S. 130(5A) inserted (1.1.1995) by S.I. 1994/ 3119, reg. 2(b)

F147 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))

F148 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**

F149 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)

F150 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)

F151 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)

C96 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

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 if 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 **[**F152 the National Health Service Act 2006, the National Health Service (Wales) Act 2006, **]** the National Health Service (Scotland) M4**[**F153Act 1978**][**F154, 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

F152 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)

F153 Words substituted by National Health Service (Scotland) Act 1978 (c. 29), **Sch. 16 para. 30**

F154 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)

C97 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)**

C98 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**

C99 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.

[F155(1) In this Act—

(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.]

F156(2) . . . . . .

F156(3) . . . . . .

(4) Any reference in this Act to the holder of a F157... certificate shall be construed as a reference to the holder of a F157... certificate which is for the time being in force.

F158(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

F155 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)

F156 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)

F157 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)

F158 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)

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. 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**

C102 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**

C103 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 M5Interpretation Act 1889 (which relates to offences under two or more laws), the provisions of this Act shall not be construed as—

(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)

C104 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)**

C105 S. 133 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C106 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) . . . . . [F159]

(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) **[**[F160]Sections 16(1) and 17(2)(a) of the [M6]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

F159 S. 134(2) repealed by Northern Ireland Constitution Act 1973 (c. 36), **Sch. 6 Pt. I**

F160 Words substituted by virtue of Interpretation Act 1978 (c. 30), **s. 25(2)**

Modifications etc. (not altering text)

C107 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)**

C108 S. 134 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.
C109 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 :
F161 ...

(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
F161 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)
C110 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)**
C111 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.

[F162(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

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).

Textual Amendments

F162 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.

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 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

C114 S. 136(3) extended (E.W.S.) by Animal Health Act 1981 (c. 22, SIF 4:4), **s. 95(4)**

Changes to legislation:
Medicines Act 1968, Part VIII is up to date with all changes known to be in force on or before 15 April 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:
Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 69(1A)(1B) added (prosp.) by 1997 c. 19 s. 1Sch. para. 5(b)
- s. 84B inserted by S.I. 2016/372 art. 12