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 Act to certain articles and substances.

(1) The Ministers[F1]... 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 this Act[F2], 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(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)

F2 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 Act 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[F3]...,

and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act[F4, 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

F3 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)

F4 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 of the licensing authority under Part II of this Act or of a Minister under section 75 of this Act, and the validity of any licence or certificate granted or 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 grant a licence or certificate is quashed under this section, any licence or certificate granted in pursuance of that decision shall be void, and any proceedings on the application for the grant of the licence or 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 of Justice in Northern Ireland.

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) **[**F5 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), sections 64 and 65, subsections (3) to (5) of section 85, and sections 87(2), 88(3) and 89(2) 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;

(b) the provisions of subsections (2) and (3) of section 86 of this Act, in their application to the supply, or possession for the purpose of supply, of leaflets with medicinal products sold or to be sold by retail, or supplied or to be supplied in circumstances corresponding to retail sale; and

(c) the provisions of sections 93 and 94 of this Act and any regulations made under section 95 of this Act,

the appropriate Minister shall, in respect of each area for which there is a **[**F6drugs authority**]** make arrangements or give directions whereby the Pharmaceutical Society, or the **[**F6drugs authority**]** for that area, or both the Society and that authority, to such extent as, in the case of that Society 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 paragraphs (a) and (b) of this subsection, in their application as mentioned in those paragraphs, and the provisions and regulations specified in paragraph (c) of this subsection.

(3) Any arrangements made with, or directions given to, the Pharmaceutical Society under subsection (2) of this section, in so far as they relate to the provisions and regulations specified in paragraph (c) of that subsection, shall be limited to the enforcement of those provisions and regulations in respect of—

(a) any advertisement issued or representation made on or in any premises, ship, aircraft, vehicle, stall or place where medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale, and

(b) any advertisement displayed on, or in close proximity to, an automatic machine in which medicinal products are offered or exposed for sale.

(4) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that any such body to which this subsection applies as may be specified in the regulations shall, to such extent as in the case of that body may be so specified, and either—

(a) in respect of England and Wales generally, or

(b) in respect of such area in England or Wales as may be so specified,

have power concurrently with the appropriate Minister, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.

(5) Subsection (4) of this section applies to the following bodies, that is to say, the Pharmaceutical Society, any, **[**F6drugs authority**]** the council of any county district which is not a, **[**F6drugs authority**]** and the overseers of the Inner Temple and the Middle Temple.

(6) The Pharmaceutical Society shall be under a duty, concurrently with the appropriate Minister,—

(a) to enforce the provisions of sections F7..., 52 and 58 of this Act F7... in their application to England and Wales;

(b) to enforce the provisions of any regulations made under section 60 or section 61 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 sections 77 and 78 of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.

[F8(6A) The Pharmaceutical Society shall be under a duty, concurrently with the appropriate Minister, to enforce the provisions of subsections (4) and (5) of section 72A of this Act in their application to England and Wales.

(6B) The Pharmaceutical Society shall be under a duty to enforce the other provisions of section 72A of this Act, and any regulations made under them, in their application to England and Wales.

(6C) The appropriate Minister shall be under no duty to enforce those other provisions, or any regulations made under them, 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 those other provisions, or any regulations made under them, in their application to England and Wales, and

(b) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to England and Wales.**]**

(7) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that, in respect of each area in England or Wales for which there is a food and drugs authority, the Pharmaceutical Society, or the food and drugs authority for that area, or both the Society and that authority, to such extent as,

in the case of that Society or authority, the regulations may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions of sections 53 and 54 of this Act.

F9(8) . . . . . .

(9) Notwithstanding anything in subsections **[**F10(2) to (7)**]** 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**[**F11 (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 the Pharmaceutical Society or any other body on whom a duty to enforce any provisions is imposed by or under subsections **[**F12 (4) to (6A), (7) and (8) **]** of this section have in relation to any matter failed to perform that duty, and that the public interest requires that the provisions in question should be enforced in relation to it, he may determine that he will himself enforce those provisions in relation to that matter.

(11) In this section "the appropriate Minister"—

F13(a) . . . . . .

(b) F14... means the **[**F15Secretary of State**]**.

[F16(12) In this section " drugs authority " means—

(a) as respects each London borough, metropolitan district **[**F17, county borough**]** or non-metropolitan county, the council of that borough, district **[**F17, county borough**]** or county; and

(b) as respects the City of London (including the Temples), the Common Council of that City.**]**

Textual Amendments

F5 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)

F6 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)**

F7 Words in s. 108(6)(a) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 56(a)** (with regs. 2(4), 3)

F8 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)

F9 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)

F10 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)

F11 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)

F12 Words in s. 108(10) substituted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(1)(d)**, 83(7); S.I. 2008/2714, art. 2(a)

F13 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)
F14 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)
F15 Words substituted by virtue of S.I. 1968/1699, **arts. 2**, 5(4)(a)
F16 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)**
F17 S. 108(12)(a) words inserted (1.4.1996) by 1994 c. 19, s. 66(6), **Sch. 16 para. 33(b)**; S.I. 1996/396, art. 4, **Sch. 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**
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) **[**F18 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 (2) and (3) and (6) to (10) of section 108 of this Act shall have effect in relation to Scotland as if—

(a) any reference to the appropriate Minister or to the Minister of Health and the Minister of Agriculture, Fisheries and Food acting jointly were a reference to the Secretary of State;

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

[F19**[**

F20(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 **]**

[F21(d)**]** . . . . . .

[F22(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 **[**F23 " a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 " **]]**

(3) Regulations made by the Secretary of State may provide that, to such extent as may be specified in the regulations—

(a) the Pharmaceutical Society, in respect of Scotland generally, or in respect of such area in Scotland as may be so specified,

(b) a local authority within the meaning of section 26(4) of the M2Food and Drugs (Scotland) Act 1956, in respect of their area,

shall have power concurrently with the Secretary of State, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.

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

Textual Amendments

F18 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)

F19 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**

F20 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)**

F21 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)

F22 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)**

F23 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)**

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.
M2 1956 c. 30.

110 Enforcement in Northern Ireland.

(1) Subject to the provisions of **[**F24 subsections (3C) and (4) **]** of this section, it shall be the duty of the Minister of Health and Social Services for Northern Ireland (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 paragraphs (a) and (b) of subsection (2) of section 108 of this Act in their application as mentioned in those paragraphs, and the provisions and regulations specified in paragraph (c) of that subsection, within the **[**F25district**]** of any **[**F25district council**]**, the Minister may make arrangements or give directions whereby the **[**F25district 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 paragraphs (a) and (b) in their application as so mentioned and the provisions and regulations specified in the said paragraph (c).

(3) For the purpose of performing that duty in relation to the provisions of sections 53 and 54 of this Act and any regulations made under section 66 of this Act within the **[**F25district**]** of any **[**F25district council**]**, the Minister may make arrangements or give directions whereby the **[**F25district 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 those provisions and regulations.

[F26(3A) The Pharmaceutical Society shall be under a duty, concurrently with the Minister, to enforce the provisions of subsections (4) and (5) of section 72A of this Act in their application to Northern Ireland.

(3B) The Pharmaceutical Society shall be under a duty to enforce the other provisions of section 72A of this Act, and any regulations made under them, in their application to Northern Ireland.

(3C) The Minister shall be under no duty to enforce those other provisions, or any regulations made under them, 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 those other provisions, or any regulations made under them, in their application to Northern Ireland, and

(b) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to Northern Ireland.**]**

F27(4) . . . . . .

(5) Subsections (9) and (10) 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 **[**F28(2) to (7)**]** of that section were a reference to subsections (2) **[**F29 to (3D) **]** of this section; and

(b) in the said subsection (10) any reference to the appropriate Minister were a reference to the Minister within the meaning of this section, and for the words "the Pharmaceutical Society or any other body" there were substituted the words "any **[**F25district council**]**" and the reference to subsections **[**F30 (4) to (6A), (7) and (8) **]** of that section were a reference to subsection (3) of this section.

(6) F31

[F32(8) In this section " district council " means a council established under the M3 Local Government Act (Northern Ireland) 1972. **]**

Textual Amendments

F24 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)

F25 Words substituted by S.R. &O. (N.I.) 1973 No. 211 , **Sch.**

F26 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)

F27 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)

F28 Words in s. 110(5)(a) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 58(c)(i)** (with regs. 2(4), 3)

F29 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)

F30 Words in s. 110(5)(b) substituted (1.10.2009) by Health Act 2006 (c. 28), **ss. 31(3)(d)**, 83(7); S.I. 2008/2714, art. 2(a)

F31 S. 110(6)(7) repealed by S.R. & O. (N.I.) 1973 No. 211 , **Sch.**

F32 S. 110(8) substituted by S.R. & O. (N.I.) 1973 No. 211, **Sch.**

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)

Marginal Citations
M3 1972 c. 9 (N.I.)

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, [F33]...

[[F34](aa) for the purpose specified in the third sub-paragraph of Article 111(1) of the 2001 Directive, 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—

(a) to enter any ship, aircraft or hover vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in 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;

(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.

(3) Without prejudice to subsection (1) of this section, any person duly authorised in writing by the licensing authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part II of this Act for the purpose of verifying any statement contained in the application for the licence or certificate.

(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, aircraft, 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, commander or other person in charge of the ship, aircraft, 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.

(9) In the application of this section to Scotland, references to a justice of the peace include references to the sheriff and a magistrate.

Textual Amendments

F33 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)

F34 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)

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.

(7) Without prejudice to the preceding provisions of this section, any person duly authorised in writing by the licensing authority shall have the rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for a licence or certificate under Part II of this Act, and may exercise those rights for the purpose of verifying any statement contained in the application for the licence or certificate; and, where by virtue of this subsection a person exercises any such right as is specified in subsection (4) of this section, he shall be subject to the duty imposed by subsection (6) of this section.

(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.

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 (including that subsection as applied by subsection (7) of that section).

(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.

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, aircraft, 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, aircraft, vehicle, stall or place, the master, commander 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 **[**F35level 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 **[**F36 married or a civil partner) the spouse or civil partner **]** of that person.

Textual Amendments

F35 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

F36 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)**

115 Analysis of samples in other cases.

(1) A person who, not being a person authorised in that behalf by an enforcement authority, has purchased a medicinal product may submit a sample of it for analysis to the public analyst for the area in which the product was purchased, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area.

(2) Paragraphs 2 to 13 of Schedule 3 to this Act shall have effect in relation to a person proposing to submit a sample in pursuance of the preceding subsection, as if in those paragraphs any reference to the sampling officer were a reference to that person.

(3) Subject to the following provisions of this section, a public analyst to whom a sample is submitted under subsection (1) of this section shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(4) If the public analyst to whom a sample is submitted under subsection (1) of this section determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and (subject to the next following subsection) that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(5) A public analyst to whom a sample is submitted or sent under this section may demand payment in advance of the prescribed fee, and, if he demands such payment, he shall not be required to analyse the sample or cause it to be analysed until the fee has been paid.

(6) A public analyst who has analysed a sample or caused a sample to be analysed under this section shall issue a certificate specifying the result of the analysis to the person by whom the sample was originally submitted.

(7) Any certificate issued under subsection (6) of this section shall be in a form prescribed by the Ministers and shall be signed by the public analyst who issues the certificate.

(8) Paragraphs 21 to 23 of Schedule 3 to this Act shall have effect in relation to a certificate issued under subsection (6) of this section as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) Any regulations prescribing a fee for the purposes of this section shall be made by the Ministers.

(10) In this section "public analyst" has the meaning assigned to it by paragraph 1(2) of Schedule 3 to this Act.

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. 115 modified by S.I. 1985/273, **reg. 2 Sch. 1 Pt. I**
S. 115 applied (1.1.1995) by S.I. 1994/3142, **reg. 18(2)**
S. 115 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**
S. 115 applied (31.3.1997) by S.I. 1997/322, reg. 34, **Sch.5**

C51 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)**

[F37 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

F37 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)

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

116 Liability to forfeiture under Customs and Excise Act 1952.

(1) For the purposes of [F38 section 49 of the Customs and Excise Management Act 1979] (forfeiture of goods improperly imported) any imported goods shall be deemed to be imported contrary to a restriction for the time being in force with respect to them under this Act if—

(a) they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and

(b) they are imported in such circumstances as are specified in that order.

(2) For the purposes of **[**F38section 68 of the Customs and Excise Management Act 1979**]** (offences in relation to exportation of prohibited or restricted goods) any goods shall be deemed to be exported contrary to a restriction for the time being in force with respect to them under this Act if—

(a) they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and

(b) they are exported in such circumstances as are specified in that order.

(3) Any class of goods specified in an order under subsection (1) or subsection (2) of this section shall be so specified as to consist exclusively of goods appearing to the Ministers to be goods which are, or normally are, medicinal products F39....

Textual Amendments

F38 Words substituted by Customs and Excise Management Act 1979 (c. 2, SIF 40:1), s. 177(1), **Sch. 4 para. 12** Table Pt. I

F39 Words in s. 116(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 59** (with regs. 2(4), 3)

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)

C54 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)**

C55 S. 116 applied (with modifications) (1.1.1995) by S.I. 1994/3144, reg.10, **Sch. 4**

F40117 Special enforcement and sampling provisions relating to animal feeding stuffs.

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Textual Amendments

F40 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)

C56 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.

[F41(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**[**F42or 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

F41 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**

F42 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)

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. 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**

C59 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**

C60 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)

C61 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)

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

C63 S. 119 modified (3.4.1992) by S.I. 1992/605, **regs. 2(3)**, 3

C64 S. 119 modified (30.1.1992) by S.I. 1992/32, **reg. 12(1)(2)**

C65 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**

C66 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**

C67 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)

C68 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**

[F43]120 Compensation for loss of employment or loss or diminution of emoluments.

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Textual Amendments

F43 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)

C69 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 63 to 65, **[**F44 85 to 89**]**, and 93 to 96, and the provisions of any regulations made under any of those sections.

Textual Amendments

F44 Words in s. 121(4) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 61** (with regs. 2(4), 3)

Modifications etc. (not altering text)

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)**

C71 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**

C72 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**

C73 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)

C74 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, section 63(b), sections 64 and 65, sections 85 to 88 [F45]... 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

F45 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)

C72 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**

C73 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)

C74 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**

C75 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 section 115 of this Act, or under 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.

Modifications etc. (not altering text)

C72 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**

C73 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)

C74 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. 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) at any premises where the business is carried on, is the pharmacist referred to in **[**F46 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

F46 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)

C72 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**

C73 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)

C74 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**

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. 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**

C80 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 **[**F47 section 127(1) of the Magistrates' Courts Act 1980**]**, a magistrates' court in England or Wales may try an information for an offence under this Act if the information was laid at any time within twelve months from the commission of the offence.

(2) Notwithstanding anything in **[**F48 section 331 of the M4 Criminal Procedure (Scotland) Act 1975**]** (limitation of time for proceedings in statutory offences) summary proceedings in Scotland for an offence under this Act may be commenced at any time within twelve months from the time when the offence was committed, and **[**F48 subsection 3 of the said section 331**]** shall apply for the purposes of this subsection as it applies for the purposes of that section.

(3) Notwithstanding anything in **[**F49section 34 of the M5Magistrates' Courts Act (Northern Ireland) 1964**][**F49Article 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 **[**F50punishable 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 the Pharmaceutical Society nor any other body referred to in subsection (2) F51... 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 **[**F52that subsection**]**, that Society 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) **[**F53A 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 Minister of Health and Social Services for Northern Ireland 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 Minister of Health and Social Services for Northern Ireland 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

F47 Words substituted by Magistrates' Courts Act 1980 (c. 43, SIF 82), s. 154, **Sch. 7 para. 76**

F48 Words substituted by virtue of Criminal Procedure (Scotland) Act 1975 (c. 21), **s. 460(1)**(*b*)

F49 Words substituted(N.I.) by S.I. 1981/1675 (N.I. 26), **Sch. 6 Pt. I para. 15**

F50 Words substituted by S.I. 1980/704, **Sch. 1 Pt. II para. 50**

F51 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)

F52 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)

F53 Words substituted by S.R. &O. (N.I.) 1973 No. 211, **Sch.**

Modifications etc. (not altering text)

C72 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**

C73 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)

C74 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**

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. 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

M4 1975 c. 21.

M5 1964 c. 21 (N.I.)

126 Presumptions.

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

F54(a) . . . . . .

(b) offering a medicinal product for sale by retail in contravention of section 52 or section 53 of this Act, or

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

where it is proved that the F55... medicinal product in question was found on a vehicle from which F56... medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that F55... 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 F57... in his possession for the purpose of sale or supply, where it is proved that the medicinal product F57... 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 F58..., 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), subsections (3) and (5) of section 85, subsection (2) of section 87 and subsection (3) of section 88F59...

(4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of subsection (2) or subsection (3) of section 86 of this ActF60..., where it is proved that the leaflet 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 F61..., it shall be presumed, unless the contrary is proved, that he had the leaflet **[**F62in his possession for the purpose of supplying it with a medicinal product**]**

Textual Amendments

F54 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)

F55 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)

F56 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)

F57 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)

F58 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)

F59 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)

F60 Words in s. 126(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 64(d)(i)** (with regs. 2(4), 3)

F61 Words in s. 126(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 64(d)(ii)** (with regs. 2(4), 3)

F62 Words in s. 126(4) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 64(d)(iii)** (with regs. 2(4), 3)

Modifications etc. (not altering text)

C73 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)

C83 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)**

C84 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**

C85 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)

C73 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)

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

C88 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**

C89 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**

C90 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 any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, 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) F63

(4) Where the Pharmaceutical Society 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) a Minister makes a determination in respect of the enforcement of any provision in relation to a particular matter, he shall be entitled to recover from the Pharmaceutical Society 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 any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, other than Ministers in the Government of Northern Ireland, 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

F63 S. 128(3) repealed by Medicines Act 1971 (c. 69), **s. 1(4)**

Modifications etc. (not altering text)

C91 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)**

C92 S. 128 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C93 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 paragraph 1[F64]... or paragraph 6 of Schedule 4 to this Act or any regulations made solely by the Minister of Health and Social Services for Northern Ireland under section 120 of this Act) 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 13, 15(1)[F65]... 49, 54(2), 55(2), 56, 57(1), 58, 62, 79, 106, 116[F65]... and 130(5)(c) and paragraph 27 of Schedule 3, or

(b) an order made under section 105 of this Act otherwise than as mentioned in subsection (3) of that section, or

(c) any regulations made under any provision, other than section 79, of this Act,

shall be subject to annulment in pursuance of a resolution of either House of Parliament.

(4) Any power to make an order under any provision, other than sections 16(1), 17, 25(1), 37(3), 52 and 69(3), 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**[**[F66] 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**[**[F67] 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.

[F68](6A) . . . . . .

(7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III, Part V or Part VI of this Act, or under section 104 or section 105 of this Act, and they consult a committee established under section 4 of this Act, 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

F64 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)

F65 Words in s. 129(3)(a) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 65(b)** (with regs. 2(4), 3)

F66 Words in s. 129(5) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 32(a)**, 83(1)(e)

F67 Words in s. 129(5) inserted (19.7.2006 for specified purposes) by Health Act 2006 (c. 28), **ss. 32(b)**, 83(1)(e)

F68 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)

Modifications etc. (not altering text)

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

C95 S. 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**

C96 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**

C97 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)**

C98 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**

C99 S. 129(1)(2)(3)(5) applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

C100 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.

(1) Subject to the following provisions of this section, in this Act "medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say—

(a) use by being administered to one or more human beings [F69]... for a medicinal purpose;

(b) use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings [F69]... for a medicinal purpose.

(2) In this Act "a medicinal purpose" means any one or more of the following purposes, that is to say—

(a) treating or preventing disease;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

(c) contraception;
(d) inducing anaesthesia;
(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) In paragraph (b) of subsection (1) of this section the reference to use in circumstances to which that paragraph applies is a reference to any one or more of the following, that is to say—
(a) use in a pharmacy or in a hospital;
(b) use by a practitioner;
(c) use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies.

F70(3A) . . . . . .

F70(3B) . . . . . .

F70(3C) . . . . . .

(4) Notwithstanding anything in subsection (1) F71... of this section, in this Act "medicinal product" does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings F72..., where it is to be administered to them—
(a) in the course of the business of the person who has manufactured it (in this subsection referred to as "the manufacturer"), or on behalf of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person, and
(b) solely by way of a test for ascertaining what effects it has when so administered, and
(c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings F73...
and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in paragraphs (a) to (c) of this subsection.

(5) In this Act "medicinal product" shall also be taken not to include—
(a) substances used in dental surgery for filling dental cavities;
(b) bandages and other surgical dressings, except medicated dressings **[**F74within subsection (5A) below**]**;
[F75(ba) whole human blood and human blood components;**]**
(c) substances and articles of such other descriptions or classes as may be specified by an order made by the Ministers F76... for the purposes of this subsection.

[F77(5A) Medicated dressings are within this subsection (and accordingly are not excluded from the definition of "medicinal product" by subsection (5)(b) above) if—
(a) their medication has a curative function which is not limited to sterilising the dressing; and
(b) they are not dressings of a kind to which the requirements of Article 2 of Council Directive 93/42/ EEC F78 (placing medical devices on the market

and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.**]**

[F79(5B) For the purposes of this section, "human blood component" means any of the following constituents of human blood: red cells, white cells, platelets and plasma.**]**

(6) Where in accordance with the preceding provisions of this section a substance or article is a medicinal product immediately after it has been manufactured, imported or exported as mentioned in subsection (1) F80... of this section, or immediately after the first occasion on which it has been sold or supplied as mentioned in **[**F81that subsection**]**, then . . . F82 it shall not cease to be a medicinal product for the purposes of this Act by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in a way other than those specified in **[**F81that subsection**]** .

(7) F83

(8) For the purposes of this Act medicinal products are of the same description if (but only if)—

(a) they are manufactured to the same specification, and

(b) they are, or are to be, sold, supplied, imported or exported in the same pharmaceutical form,

and in this Act " description ", in relation to medicinal products, shall be construed accordingly.

(9) In this Act " administer " means administer to a human being F84..., 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 (F85...) a substance or article is a reference to administering (F85...) 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.

(10) For the purposes of this Act a document, advertisement or representation shall be taken to be likely to mislead as to the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters, that is to say—

(a) any purposes for which medicinal products of that description can with reasonable safety be used;

(b) any purposes for which such products cannot be so used; and

(c) any effects which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

Textual Amendments

F69 Words in s. 130(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(a)** (with regs. 2(4), 3)

F70 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)

F71 Words in s. 130(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(c)(i)** (with regs. 2(4), 3)

F72 Words in s. 130(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(c)(ii)** (with regs. 2(4), 3)

F73 Words in s. 130(4)(c) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(c)(iii)** (with regs. 2(4), 3)
F74 Words in s. 130(5)(b) substituted (1.1.1995) by S.I. 1994/3119 , **reg. 2(a)**
F75 S. 130(5)(ba) inserted (8.11.2005) by The Blood Safety and Quality Regulations 2005 (S.I. 2005/50) , regs. 1(2) , **25(1)(c)** (with reg. 2(2)-(4))
F76 Words in s. 130(5)(c) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(d)** (with regs. 2(4), 3)
F77 S. 130(5A) inserted (1.1.1995) by S.I. 1994/ 3119, reg. 2(b)
F78 O.J. No. L 169 12.7.93 p.1.
F79 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))
F80 Words in s. 130(6) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(e)(i)** (with regs. 2(4), 3)
F81 Words in s. 130(6) substituted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 66(e)(ii)** (with regs. 2(4), 3)
F82 Words repealed by Animal Health and Welfare Act 1984 (c. 40, SIF 2:8) , s. 16 , Sch. 1 para. 3(8)(c) , **Sch. 2**
F83 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**
F84 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)
F85 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)

Modifications etc. (not altering text)
C101 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 **[**F86 the National Health Service Act 2006, the National Health Service (Wales) Act 2006, **]** the National Health Service (Scotland) M6**[**F87Act 1978**]** or the M7**[**F88Health and Personal Social Services (Northern Ireland) Order 1972**]** 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

F86 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)

F87 Words substituted by National Health Service (Scotland) Act 1978 (c. 29), **Sch. 16 para. 30**

F88 Words substituted by National Health Service Reorganisation Act 1973 (c. 32), **Sch. 4 para. 128(2)**

Modifications etc. (not altering text)

C102 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)**

C103 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**

C104 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

M6 1978 c. 29.

M7 S.I. 1972 No. 1265.

132 General interpretation provisions.

(1) In this Act, except in so far as the context otherwise requires, the following expressions have the meanings hereby assigned to them respectively, that is to say:—

[F89"Advisory Body" has the meaning given to it by paragraph 1 of Schedule 1A to this Act;**]**

"analysis" includes micro-biological assay but no other form of biological assay, and "analyse" has a corresponding meaning;

F90 ...

F90 ...

F90 ...

"the appropriate committee" has the meaning assigned to it by section 4(6) of this Act;

F90 ...

"assemble", in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and "assembly" has a corresponding meaning;

"business" includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate;

F91 ...

[F92"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004;**]**

"the Commission" means the **[**F93Commission for Human Medicines**]** established under this Act;

"composition", in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degrees of strength, quality and purity, in which those ingredients are contained in it respectively;

"container", in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

"contravention" includes failure to comply and "contravene" has a corresponding meaning;

"dentist" means a person registered in the dentists register under the **[**F94Dentists Act 1984 F95...;**]**

F96 . . .

F90 ...

[F97 "the 2001 Directive" means Directive 2001/83/ EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use **][**F98 , as amended **][**F99by—

(a) Directive 2002/98/ EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components,

(b) Commission Directive 2003/63/ EC amending Directive 2001/83/ EC on the Community code relating to medicinal products for human use,

(c) Directive 2004/24/ EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/ EC on the Community code relating to medicinal products for human use; F100...

(d) Directive 2004/27/ EC of the European Parliament and of the Council amending Directive 2001/83/ EC on the Community code relating to medicinal products for human use; **][**F101and

(e) Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004;**]**

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

[F102 " doctor " means a registered medical practitioner person within the meaning of Schedule 1 to the Interpretation Act 1978 **]**

[F103 " drugs authority " has the meaning assigned to it by section 108(12) of this Act; **]**

[F104 " EEA State " means a Member State, Norway, Iceland or Liechtenstein; and **]**

"enforcement authority" means any Minister or body on whom a duty or power to enforce any provisions of this Act or of any regulations or order

made thereunder is imposed or conferred by or under sections 108 to 110 of this Act;

[F105“Expert Advisory Group” means an Expert Advisory Group established under paragraph 3 or 4 of Schedule 1A to this Act;**]**

“export” means export from the United Kingdom, whether by land, sea or air, and “import” has a corresponding meaning;

“the first appointed day” has the meaning assigned to it by section 16(1) of this Act;

[F106 “ food and drugs authority ” has the meaning assigned to it for the purposes of the M8 Food and Drugs Act 1955 by **[**F107 section 198 of the M9 Local Government Act 1972 **]** ; **]**

“the Gazette” means the London, Edinburgh and Belfast Gazettes;

“health centre” means a health centre maintained under **[**F108 section 2 or 3 of the National Health Service Act 2006, section 2 or 3 of the National Health Service (Wales) Act 2006, **][**F109section 36 of the M10National Health Service (Scotland) Act 1978**]** or **[**F110Article 5 of the M11Health and Personal Social Services (Northern Ireland) Order 1972**]**;

[F111“the Herbal Regulations” means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;**]**

“herbal remedy” means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance;

F90...

[F112“the Homoeopathic Regulations” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994**]**

“hospital” includes a clinic, nursing home or similar institution;

“hover vehicle” means a vehicle designed to be supported on a cushion of air;

[F104 “import from a third country” means import from any country other than an EEA State ; and **]**

“ingredient”, in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared;

“labelling”, in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and “label” has a corresponding meaning;

“leaflet” includes any written information;

“the licensing authority” has the meaning assigned to it by section 6 of this Act;

“licence of right” has the meaning assigned to it by section 25(4) of this Act;

“manufacture”, in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it F113...;

[F114“the Marketing Authorisation Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;**]**

[F115“the Ministers” shall be construed in accordance with section 1(1) of this Act;**]**

F90...

“offence under this Act” includes an offence under any regulations or order made under this Act;

“package”, in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question;

“Pharmaceutical Society” in relation to Great Britain means the Pharmaceutical Society of Great Britain, and in relation to Northern Ireland**[**F116or the register of visiting pharmaceutical chemists from a relevant European State**]** means the Pharmaceutical Society of Northern Ireland;

“pharmacist” in relation to Great Britain means a person registered in **[**F117Part 1**[**F118or 3**]** of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007,**]** and in relation to Northern Ireland (subject to any order made under paragraph 1 of Schedule 4 to this Act) means a person registered in the register of pharmaceutical chemists for Northern Ireland made out and maintained under **[**F119Articles 6 and 9 of the M12Pharmacy (Northern Ireland) Order 1976**]**;

“plant” includes any part of a plant;

F90...

“practitioner" (except where that word occurs as part of the expression “veterinary practitioner") means a doctor, dentist, veterinary surgeon or veterinary practitioner;

“prescribed” means prescribed by regulations under this Act;

“product licence”, “manufacturer’s licence” and “wholesale dealer’s licence” have the meanings assigned to them by sections 7 and 8 of this Act;

“registered pharmacy” has the meaning assigned to it by section 74 of this Act;

“retail pharmacy business” means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not);

“substance” means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour;

“the time allowed", in Part II of, and Schedule 2 to, this Act has the meaning assigned to it by **[**F120section 21(12)**]** of this Act;

“treatment”, in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not;

F90...

“veterinary practitioner” means a person registered in the supplementary veterinary register kept under section 8 of the M13Veterinary Surgeons Act 1966;

“veterinary surgeon” means a person registered in the register of veterinary surgeons kept under section 2 of the M14Veterinary Surgeons Act 1966;

"writing" includes any form of notation, whether by hand or by printing, typewriting or any similar process, and "written" has a corresponding meaning.

(2) For the purposes of this Act considerations of safety, in relation to any substance or article, shall be taken to include consideration of the extent (if any) to which the substance or article—

(a) if used without proper safeguards, is capable of causing danger to the health of the community[F121]..., or

[F122](b) . . . . . .

(c) may interfere with the treatment, prevention or diagnosis of disease, or

(d) may be harmful to the person administering it or (in the case of an instrument, apparatus or appliance) the person operating it,

and any reference in this Act to safety or to the interests of safety shall be construed accordingly.

(3) In this Act any reference to doing anything in accordance with a licence under Part II of this Act shall be construed as a reference to doing it in pursuance of such a licence and in compliance with any conditions and any limitations (whether as to area or otherwise) to which the licence is subject, and so as not to fall within any exceptions to which it is subject[F123]...[F124F123]....

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

(5) For the purposes of this Act medicinal products of any description shall be taken to be effectively on the market in the United Kingdom at a particular time if (but only if) during the whole of the period of one month ending with that time adequate stocks of medicinal products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in the United Kingdom as were likely to require them.

(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

F89 Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(a)**

F90 Words in s. 132(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(a)(i)** (with regs. 2(4), 3)

F91 Words in s. 132(1) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(i)**

F92 Words in s. 132(1) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(ii)**

F93 Words in s. 132(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(b)**

F94 Words substituted by virtue of Dentists Act 1984 (c. 24, SIF 83:1), s. 54(1), **Sch. 5 para. 2**

F95 Words in s. 132(1) omitted (3.12.2007) by virtue of The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **151**

F96 S. 132: definition of "the 1965 Directive"deleted (28.2.2002) by virtue of S.I. 2002/236, **reg. 2(d)(i)**

F97 S. 132: definition of "the 2001 Directive"inserted (28.2.2002) by S.I. 2002/236, **reg. 2(d)(ii)**

F98 Words in s. 132(1) inserted (31.10.2003) by Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003 (S.I. 2003/2321), regs. 1(2)(b), **2**

F99 Words in s. 132 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. 10(a)** (with Sch. 6)

F100 Word in s. 132(1) omitted (29.12.2008) by virtue of The Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2008 (S.I. 2008/3097), regs. 1(1), **4(b)(i)**

F101 Words in s. 132(1) inserted (29.12.2008) by The Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2008 (S.I. 2008/3097), regs. 1(1), **4(b)(ii)**

F102 Definition substituted by Medical Act 1983 (c. 54, SIF 83:1), **Sch. 5 para. 5**

F103 Words inserted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 11**

F104 Words in s. 132 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. 10(b)** (with Sch. 6)

F105 Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(c)**

F106 Definition repealed (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1)(4), Sch. 3 para. 11, **Sch. 5**

F107 Words substituted by Local Government Act 1972 (c. 70), **s. 198(2)**

F108 Words in s. 132(1) substituted (1.3.2007) by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 8(2), **Sch. 1 para. 45** (with Sch. 3 Pt. 1)

F109 Words substituted by National Health Service (Scotland) Act 1978 (c. 29), **Sch. 16 para. 31**

F110 Words substituted by National Health Service Reorganisation Act 1973 (c. 32), **Sch. 4 para. 128(3)**

F111 Words in s. 132 inserted (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(a), **Sch. 1 para. 3**

F112 Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(d)**

F113 Words in s. 132(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(a)(ii)** (with regs. 2(4), 3)

F114 Words in s. 132(1) inserted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(e)**

F115 Words in s. 132(1) inserted (1.10.2006) by The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(a)(iii)** (with regs. 2(4), 3)

F116 Words in s. 132(1) inserted (N.I.) (22.5.2008) by The European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), regs. 1(2), **13(c)**

F117 Words in s. 132(1) substituted (7.2.2007 coming into force in accordance with art. 1(2)(3)) by Pharmacists and Pharmacy Technicians Order 2007 (S.I. 2007/289), art. 1(2)(3), **Sch. 1 para. 2(16)**

F118 Words in s. 132(1) inserted (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **98(d)**

F119 Words substituted by S.I. 1976/1213 (N.I. 22), **Sch. 5 para. 7**

F120 Words in s. 132(1) substituted (30.10.2005) by Medicines (Advisory Bodies) Regulations 2005 (S.I. 2005/1094), reg. 1(1), **Sch. 1 para. 14(f)**

F121 Words in s. 132(2)(a) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(b)(i)** (with regs. 2(4), 3)

F122 S. 132(2)(b) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(b)(ii)** (with regs. 2(4), 3)

F123 Words in s. 132(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 67(c)** (with regs. 2(4), 3)

F124 Words in s. 132(3) omitted (1.5.2004) by virtue of Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 19(a)(ii)**

Modifications etc. (not altering text)

C105 Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

C106 S. 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**

C107 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**

C108 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**

Marginal Citations

M8 1955 c. 16 (4 & 5 Eliz. 2).
M9 1972 c. 70.
M10 1978 c. 29.
M11 S.I. 1972 No. 1265.
M12 S.I. 1976/1213 (N.I. 22)
M13 1966 c. 36.
M14 1966 c. 36.

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 [M15]Interpretation 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)

C109 Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**

C110 S. 133 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

C111 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
M15 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) F125

(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) **[**F126Sections 16(1) and 17(2)(a) of the M16Interpretation 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
F125 S. 134(2) repealed by Northern Ireland Constitution Act 1973 (c. 36), **Sch. 6 Pt. I**
F126 Words substituted by virtue of Interpretation Act 1978 (c. 30), **s. 25(2)**

Modifications etc. (not altering text)
C112 Pt. VIII (ss. 104–136) extended by S.I.s 1982/425, art. 3, 1984/187 art. 2; and extended with modifications by S.I. 1985/403, **art. 3(1)**
C113 S. 134 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.
C114 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
M16 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 :
F127 …

(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

F127 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)

C115 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)**

C116 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.

(2) 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).

Modifications etc. (not altering text)

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

C118 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

C119 S. 136(3) extended (E.W.S.) by Animal Health Act 1981 (c. 22, SIF 4:4), **s. 95(4)**

Status:
Point in time view as at 01/10/2009.

Changes to legislation:
Medicines Act 1968, Part VIII is up to date with all changes known to be in force on or before 07 July 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.