Medicines Act 1968

1968 CHAPTER 67

PART VIII

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

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:—

[F1"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;

F2 …

F2 …

F2 …

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

F2 …

"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;

F3 …

[F4"the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004;**]**

"the Commission" means the **[**F5Commission 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 **[**F6Dentists Act 1984 F7... F7 ... F7... F7...;**]**

F8 . . .

F2 ...

[F9 "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 **][**F10 , as amended **][**F11by—

(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; F12...

(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; **]**

[F13and

(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;

[F14 " doctor " means a registered medical practitioner person within the meaning of Schedule 1 to the Interpretation Act 1978 **]**

[F15 " drugs authority " has the meaning assigned to it by section 108(12) of this Act; **]**

[F16 " 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;

[F17“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;

[F18 “ food and drugs authority ” has the meaning assigned to it for the purposes of the M1 Food and Drugs Act 1955 by **[**F19 section 198 of the M2 Local Government Act 1972 **]** ; **]**

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

“health centre” means a health centre maintained under **[**F20 section 2 or 3 of the National Health Service Act 2006, section 2 or 3 of the National Health Service (Wales) Act 2006, **][**F21section 36 of the M3National Health Service (Scotland) Act 1978**]** or **[**F22Article 5 of the M4Health and Personal Social Services (Northern Ireland) Order 1972**]**;

[F23“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;

F2...

[F24“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;

[F16 “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 F25...;

[F26“the Marketing Authorisation Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;**]**

[F27“the Ministers” shall be construed in accordance with section 1(1) of this Act;**]**

F2 …

"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 **[**F28the General Pharmaceutical Council**]**, and in relation to Northern Ireland**[**F29or 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 **[**F30a person registered as a pharmacist in the register maintained under article 19 of the Pharmacy Order 2010**]**F31**[**,**]** 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 **[**F32Articles 6 and 9 of the M5Pharmacy (Northern Ireland) Order 1976**]**;

"plant" includes any part of a plant;

F2 …

"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 **[**F33section 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;

F2 …

"veterinary practitioner" means a person registered in the supplementary veterinary register kept under section 8 of the M6Veterinary Surgeons Act 1966;

"veterinary surgeon" means a person registered in the register of veterinary surgeons kept under section 2 of the M7Veterinary 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[F34]..., or

[F35](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[F36]...[F37F36]....

(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

F1 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)**

F2 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)

F3 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)**

F4 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)**

F5 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)**

F6 Words substituted by virtue of Dentists Act 1984 (c. 24, SIF 83:1), s. 54(1), **Sch. 5 para. 2**

F7 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**

F8 S. 132: definition of "the 1965 Directive"deleted (28.2.2002) by virtue of S.I. 2002/236, **reg. 2(d)(i)**

F9 S. 132: definition of "the 2001 Directive"inserted (28.2.2002) by S.I. 2002/236, **reg. 2(d)(ii)**

F10 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**

F11 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)

F12 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)**

F13 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)**

F14 Definition substituted by Medical Act 1983 (c. 54, SIF 83:1), **Sch. 5 para. 5**

F15 Words inserted (E.W.S.) by Food Safety Act 1990 (c. 16, SIF 53:1, 2), ss. 54, 59(1), **Sch. 3 para. 11**

F16 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)

F17 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)**

F18 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**

F19 Words substituted by Local Government Act 1972 (c. 70), **s. 198(2)**

F20 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)

F21 Words substituted by National Health Service (Scotland) Act 1978 (c. 29), **Sch. 16 para. 31**

F22 Words substituted by National Health Service Reorganisation Act 1973 (c. 32), **Sch. 4 para. 128(3)**

F23 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**

F24 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)**

F25 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)

F26 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)**

F27 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)

F28 Words in s. 132(1) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(18)(a)**; S.I. 2010/1621, art. 2(1), Sch.

F29 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)**

F30 Words in s. 132(1) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 1(18)(b)**; S.I. 2010/1621, art. 2(1), Sch.

F31 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)**

F32 Words substituted by S.I. 1976/1213 (N.I. 22), **Sch. 5 para. 7**

F33 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)**

F34 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)

F35 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)

F36 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)

F37 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)

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)**

C2 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**

C3 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**

C4 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

M1 1955 c. 16 (4 & 5 Eliz. 2).

M2 1972 c. 70.

M3 1978 c. 29.

M4 S.I. 1972 No. 1265.

M5 S.I. 1976/1213 (N.I. 22)

M6 1966 c. 36.

M7 1966 c. 36.

Status:
Point in time view as at 27/09/2010. This version of this provision has been superseded.

Changes to legislation:
Medicines Act 1968, Section 132 is up to date with all changes known to be in force on or before 03 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.