STATUTORY INSTRUMENTS

1997 No. 1830

MEDICINES

The Prescription Only Medicines (Human Use) Order 1997

Made	25th July 1997
Laid before Parliament	28th July 1997
Coming into force	18th August 1997

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred on them by sections 58(1), (4) and (5), 59(1) and 129(4) of the Medicines Act 1968(1) or, as the case may be, those conferred by the said provisions and now vested in them(2), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Medicines Commission pursuant to sections 58(6) and 129(7) of that Act, hereby make the following Order:

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Order 1997 and shall come into force on 18th August 1997.

- (2) In this Order, unless the context otherwise requires-
 - "the Act" means the Medicines Act 1968;

"aerosol" means a product which is dispersed from its container by a propellent gas or liquid;

[^{F1}"clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates,

^{(1) 1968} c. 67. Section 58 has been amended by the Prescription by Nurses Etc. Act 1992 (c. 28), section 1. The expression "the appropriate Ministers" is defined in section 1(2) of the Medicines Act 1968.

⁽²⁾ In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Secretary of State concerned with Agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

[^{F2}"clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003;]

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[^{F4}"Common Services Agency" means the Common Services Agency for the Scottish Health Service established under section 10 of the National Health Service (Scotland) Act 1978;]

[^{F4}"Community marketing authorization" means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93;]

"controlled drug" has the meaning assigned to it by section 2 of the Misuse of Drugs Act 1971(3);

"cyanogenetic substances" means preparations which-

- (a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17, or
- (b) contain more than 0.1 per cent by weight of any substance having the formula either α -Cyanobenzyl-6-O- β -d-glucopyranosyl- β -d-glucopyranoside or α -Cyanobenzyl- β -d-glucopy ranosiduronic acid;

[^{F5}··district nurse/health visitor prescriber'' means a first level nurse, or a registered midwife, against whose name in the professional register there is an annotation that he is qualified to order drugs, medicines and appliances from the Nurse Prescriber's Formulary for District Nurses and Health Visitors Appendix in the current edition of the British National Formulary];

"dosage unit" means-

- (a) where a medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other article, or
- (b) where a medicinal product is not in any such form, the unit of measurement which is used as the unit by reference to which the dose of the medicinal product is measured;

[^{F6}"Extended Formulary" means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;]

[^{F6}"extended formulary nurse prescriber" means a person—

- (a) [^{F7}who is a first level nurse [^{F8}or registered midwife], and]
- (b) against whose name is recorded in [^{F9}the professional register] an annotation signifying that he is qualified to order drugs, medicines and appliances from the Extended Formulary;]

"external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

[^{F10}"first level nurse" means a person registered in Sub-Part 1 of the Nurses' Part of the professional register;]

[^{F4}"Health Authority"—

⁽**3**) 1971 c. 38.

- (a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977;
- (b) in relation to Scotland, means a Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and
- (c) in relation to Northern Ireland, means a Health and Social Services Board established under Article 16 of the Health and Personal Social Services (Northern Ireland) Order 1972;]

[^{F11}"health care" means services for or in connection with the prevention, diagnosis or treatment of disease;]

"health prescription" means a prescription issued by a doctor, dentist $[^{F12}$, supplementary prescriber] $[^{F13}$, a district nurse/health visitor prescriber or an extended formulary nurse prescriber] under or by virtue of–

- (a) in England and Wales, the National Health Service Act 1977(4),
- (b) in Scotland, the National Health Service (Scotland) Act 1978(5), and
- (c) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(6);

[^{F14}"health record" has the meaning given by section 68(2) of the Data Protection Act 1998(6);]

[^{F4}"homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;]

[^{F15}"independent clinic"—

- (a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000(8), and
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;]
- [^{F15}"independent hospital"—
- (a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and
- (b) in relation to Scotland, means-
 - (i) an independent hospital, or
 - (ii) a private psychiatric hospital,

as defined by section 77(1) of the Regulation of Care (Scotland) Act 2001;]

[^{F15}"independent medical agency"—

- (a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;]

"inhaler" does not include an aerosol;

[^{F4}"marketing authorization" includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;]

⁽**4**) 1977 c. 49.

^{(5) 1978} c. 29.

⁽⁶⁾ S.I. 1972/1265 (N.I. 14).

⁽⁶⁾ S.I. 1972/1265 (N.I. 14).

⁽⁸⁾ S.I. 1985/2066.

"master" has the same meaning as in section 313(1) of the Merchant Shipping Act 1995(7);

"maximum daily dose" or "MDD" means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered in a period of 24 hours;

"maximum dose" or "MD" means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered at any one time;

"maximum strength" means-

- (a) the maximum quantity of a substance by weight or volume contained in a dosage unit of a medicinal product;
- (b) the maximum percentage of a substance contained in a medicinal product calculated in any of the following ways-
 - (i) weight in weight,
 - (ii) weight in volume,
 - (iii) volume in weight, or
 - (iv) volume in volume,

and if the maximum percentage calculated in those ways differs, the higher or highest such percentage;

"medicinal product" includes any article or substance in respect of which section 58 of the Act has effect by virtue of an order made under section 104 of the Act, but does not include–

- (a) a medicinal product which is a veterinary drug as defined in section 132(1) of the Act or
- (b) an article or substance in respect of which section 58 has such effect where that article or substance is only to be administered to animals;

"the Misuse of Drugs Regulations" means, in relation to England, Wales and Scotland, the Misuse of Drugs Regulations 1985(8) and in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986(9);

[^{F4}"NHS trust"—

- (a) in relation to England and Wales, has the same meaning as in the National Health Service and Community Care Act 1990;
- (b) in relation to Scotland, has the same meaning as in the National Health Service (Scotland) Act 1978; and
- (c) in relation to Northern Ireland, means a Health and Social Services trust established under article 10 of the Health and Social Services (Northern Ireland) Order 1991;]

[^{F16}"NHS foundation trust" has the same meaning as in section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003;]

[^{F17}"nursing home" has the meaning given by article 16 of the Registered Homes (Northern Ireland) Order 1992;]

"occupational health scheme" means a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease;

^{(7) 1995} c. 21.

⁽⁸⁾ S.I. 1985/2066.

⁽⁹⁾ SR 1986 No. 52.

"offshore installation" means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(10) which is within–

- (a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(11);

"operator", in relation to an aircraft, means the person for the time being having the management of the aircraft;

"parenteral administration" means administration by breach of the skin or mucous membrane;

[^{F4}"Patient Group Direction" means—

- (a) in connection with the supply of a prescription only medicine as referred to in article 12A(2), [^{F18}12B, 12C, 12D or 12E], a written direction relating to the supply and administration of a description or class of prescription only medicine; or
- (b) in connection with the administration of a prescription only medicine as referred to in article 12A(2), 12B or 12C, a written direction relating to the administration of a description or class of prescription only medicine,

and which, in the case of either (a) or (b)-

- (i) is signed by a doctor or dentist, and by a pharmacist; and
- (ii) relates to supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction);]

"prescription only medicine" means a medicinal product of a description or falling within a class specified in article 3 of this Order;

[^{F4}"Primary Care Trust" has the same meaning as in the National Health Service Act 1977;]

[^{F19}"prison service" means—

- (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952),
- (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989), and
- (c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953);]

[^{F20}"professional register" means the register maintained by the Nursing and Midwifery Council [^{F21}under article 5 of] the Nursing and Midwifery Order 2001;]

"prolonged release" in relation to a medicinal product means a formulation of that product which-

- (a) is used to reduce the rate at which the active ingredient in that product is released after administration, and
- (b) is sold or supplied as a prolonged, controlled or sustained release medicinal product;

[^{F22}"registered chiropodist" means a person who is registered in Part 2 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;];

[^{F23}"registered dietitian" means a person who is registered in Part 4 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

^{(10) 1971} c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).

^{(11) 1964} c. 29.

[^{F24}"registered midwife" means a person registered in the Midwives' Part of the professional register;]

[^{F25}"registered nurse" means a person registered in the Nurses' Part of the professional register;]

[^{F23}"registered occupational therapist" means a person who is registered in Part 6 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

"registered ophthalmic optician" means a person who is registered in either of the Registers of ophthalmic opticians maintained under section 7(a) of the Opticians Act 1989(**12**);

[^{F22}"registered orthoptist" means a person who is registered in Part 7 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;];

[^{F23}"registered orthotist and prosthetist" means a person who is registered in Part 10 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[^{F22}"registered paramedic" means a person who is registered in Part 8 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[^{F22}"registered physiotherapist" means a person who is registered in Part 9 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[^{F26}"registered provider" means—

- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
 - (i) in relation to England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency,
 - (ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and
- (b) in relation to a nursing home, the person registered under Part III of the Registered Homes (Northern Ireland) Order 1992 as the person carrying on the nursing home, other than a manager who is to be treated as carrying on the home by virtue of article 17(2) of that order;

[^{F22}"registered radiographer" means a person who is registered in Part 11 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[^{F23}"registered speech and language therapist" means a person who is registered in Part 12 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

"relevant manager" means-

- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
 - (i) in relation to England and Wales—
 - (aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or

- (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,
- (ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of Regulation of Care (Scotland) Act 2001, and
- (b) in relation to a nursing home, the manager of the nursing home, unless they are the registered provider for that home;

"relevant register" means-

- (a) in relation to a first level nurse [^{F27}or registered midwife], the professional register, and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;]

"repeatable prescription" means a prescription which contains a direction that it may be dispensed more than once;

"sell" means sell by retail as defined in section 131 of the Act and "sale" has a corresponding meaning;

"soap" means any compound of a fatty acid with an alkali or amine;

[^{F4}"Special Health Authority"—

- (a) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977;
- (b) in relation to Scotland, means a Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978; and
- (c) in relation to Northern Ireland, means a Special Health and Social Services Agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990;]

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[^{F29}"Strategic Health Authority" means a Strategic Health Authority established under section 8 of the National Health Service Act 1977;]

[^{F30}"supplementary prescriber" means—

- (a) a first level nurse, ^{F31}...
- (b) a pharmacist, [^{F32}or
- (c) a registered midwife,] a pharmacist,

against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;]

"supply" means supply in circumstances corresponding to retail sale as defined in section 131 of the Act;

"unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances.

[^{F4}"United Kingdom marketing authorization" means a marketing authorization granted by the licensing authority under the Medicines For Human Use (Marketing Authorisations Etc.)

Regulations 1994 (including a product licence having effect as such an authorization by virtue of Schedule 6 to those Regulations).]

(3) For the purposes of this Order, the equivalence of a substance to a reference material shall be determined by calculating the amount of that reference material which is contained in that substance either by weight or, where the amount of the reference material is specified in terms of international units of activity, those units.

(4) In this Order, unless the context otherwise requires, a reference-

- (a) to a numbered section is to the section of the Act which bears that number,
- (b) to a numbered article or Schedule is to the article of, or Schedule to, this Order which bears that number,
- (c) in an article or in a Part of a Schedule to a numbered paragraph is to the paragraph of that article or Part of that Schedule which bears that number, and
- (d) in a paragraph to a lettered sub-paragraph is to the sub-paragraph of that paragraph which bears that letter.
- (5) In [^{F33}Schedules 1, 2, 3A and 5]-
 - (a) entries specified in columns 2 to 5 relate to the substances listed in column 1 against which they appear and where, in relation to a particular substance listed in column 1, an entry in columns 2 to 5 bears a number or letter it relates only to such entries in the other of those columns as bear the same number or letter;
 - (b) the following abbreviations are used:

"g" for gram,

"iu" for international unit of activity,

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

(6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

 $^{F34}(7)$ In articles 12 to [$^{F35}12E$], a reference to a prescription only medicine being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a particular person, or in accordance with a Patient Group Direction, includes a reference to it being sold or supplied in accordance with such directions or such a Direction.

(8) In articles 12A and 12C, a reference to an arrangement for the supply or administration of prescription only medicines includes a reference to an arrangement which covers such supply or administration and other matters.

(9) In Schedule 7, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.]]

Textual Amendments

- F1 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(a)**
- F2 Words in art. 1(2) substituted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, Sch. 10 Pt. 2 para. 13(a)
- **F3** Words in art. 1 omitted (1.4.2002) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(a)**

- F4 Words in art. 1(2) inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(a)**
- F5 Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(i)
- **F6** Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(c)**
- F7 Words in art. 1(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(b)(i)
- **F8** Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(ii)
- **F9** Words in art. 1(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(b)(ii)**
- **F10** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(iii)
- F11 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(d)
- F12 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(e)
- **F13** Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(d)**
- F14 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(f)
- F15 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(g)**
- F16 Words in art. 1(2) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(8), Sch. 8
- F17 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(h)
- **F18** Words in art. 1 substituted (10.12.2003) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2003 (S.I. 2003/2915), arts. 1(1), **2**
- F19 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(i)
- **F20** Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(e)**
- F21 Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(iv)
- F22 Words in art. 1 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(2)(a)
- F23 Words in art. 1(2) inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 2
- F24 Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(v)
- F25 Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(vi)
- **F26** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(j)**
- F27 Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(vii)
- F28 Words in art. 1 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(2)(b)

- F29 Words in art. 1(2) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), regs. 1, 7, Sch. 4
- **F30** Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(2)(k)**
- F31 Word in art. 1(2) omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(viii)
- F32 Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(viii)
- **F33** Words in art. 1(5) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(3)**
- **F34** Words in art. 1(7)-(9) inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(b)**
- **F35** Word in art. 1(7) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(3)**

Appropriate practitioners

2. For the purposes of section 58 (medicinal products on prescription only), the following shall be appropriate practitioners–

- (a) in relation to the descriptions and classes of medicinal products specified in article
 3, doctors, dentists [^{F36}, supplementary prescribers], veterinary surgeons and veterinary practitioners;
- [^{F37}(b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, district nurse/health visitor prescribers;
 - (c) in relation to the descriptions and classes of medicinal products specified in article 3A(1), extended formulary nurse prescribers.]

Textual Amendments

- **F36** Words in art. 2(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **3**
- **F37** Art. 2(b)(c) substituted for art. 2(b) (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **3**

[^{F38}Medicinal products on prescription only

3. The following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—

- (a) medicinal products in respect of which a marketing authorization has been granted, which in the marketing authorization are classified as being prescription only medicines;
- (b) medicinal products in respect of which no marketing authorization has been granted consisting of or containing a substance listed in column 1 of Schedule 1;
- (c) medicinal products that are for parenteral administration;
- (d) medicinal products that are controlled drugs unless a marketing authorization has been granted in respect of that medicinal product in which the product is classified as being a pharmacy only or on general sale list medicine;
- (e) cyanogenetic substances, other than preparations for external use;

- (f) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used.
- [^{F39}(g) medicinal products in respect of which a marketing authorization has been granted consisting of or containing aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules which in the marketing authorization are classified as being pharmacy only or general sale list medicines.]]

Textual Amendments

- **F38** Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4
- F39 Art. 3(g) added (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 4

[^{F40}Prescribing by extended formulary nurse prescribers

3A.—(1) Subject to paragraph (2), the description and classes of medicinal products in relation to which extended formulary nurse prescribers are appropriate practitioners are those prescription only medicines which consist of, or contain, one or more of the substances specified in column 1 of Schedule 3A, but which do not contain any other substance or combination of substances which is a prescription only medicine not included in Schedule 3A.

- (2) [^{F41}Subject to paragraph (4),] an extended formulary nurse prescriber may—
 - (a) give a prescription for a medicinal product referred to in paragraph (1); or
 - (b) if that medicinal product is for parenteral administration—

(i) administer that medicinal product, or

(ii) give directions for the administration of that medicinal product,

only where he complies with any condition as to the cases or circumstances in which he may do so that is specified by virtue of paragraph (3).

(3) If the entry in column 2 of Schedule 3A relating to a substance specifies one or more requirements as to use, route of administration or pharmaceutical form, it is a condition for the purposes of paragraph (2) that a medicinal product which consists of, or contains, that substance is administered, or is prescribed or directed for administration, in accordance with the specified requirements.

^{F42}(4) An extended formulary nurse prescriber may prescribe or administer a medicinal product referred to in paragraph (1), or give directions for administration of such a product, without complying with any condition specified by virtue of paragraph (3) if—

- (a) he is a supplementary prescriber; and
- (b) he complies with the applicable conditions set out in article 3B(3).]]

Textual Amendments

- F40 Art. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 5
- **F41** Words in art. 3A(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **5(a)**

F42 Art. 3A(4) added (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 5(b)

[^{F43}Prescribing and administration by supplementary prescribers

- **3B.**—(1) Subject to paragraph (2), a supplementary prescriber may—
 - (a) give a prescription for a medicinal product referred to in article 3; or
 - (b) if that medicinal product is for parenteral administration—
 - (i) administer that medicinal product, or
 - (ii) give directions for the administration of that medicinal product,

only where he complies with the conditions as to the cases or circumstances in which he may do so specified in paragraph (3).

- (2) Paragraph (1) does not apply if-
 - (a) the supplementary prescriber is a district nurse/health visitor prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3; or
 - (b) the supplementary prescriber is an extended formulary nurse prescriber and—
 - (i) the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in article 3A(1), and
 - (ii) he satisfies any applicable condition specified by virtue of article 3A(3).
- (3) The conditions referred to in paragraph (1) are that—
 - (a) the supplementary prescriber is acting in accordance with the terms of a clinical management plan which—
 - (i) relates to the patient for whom the product is prescribed or to whom it is, or is to be, administered,
 - (ii) is in effect at the time the prescription or direction is given or, as the case may be, the product is administered, and
 - (iii) includes the particulars specified in Schedule 3B;
 - (b) at the time the prescription or directions are given or, as the case may be, the product is administered—
 - (i) a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of the product, or
 - (ii) the product is, or is to be, administered in the course of a clinical trial [^{F44}which has been authorised, or is to be treated as having been authorised, by the licensing authority in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2003];
 - (c) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan.

Textual Amendments

F43 Arts. 3B, 3C inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **6**

F44 Words in art. 3B(3)(b)(ii) substituted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, Sch. 10 Pt. 2 para. 13(b)

Exemptions from conditions in respect of the cases or circumstances in which an extended formulary nurse prescriber or supplementary prescriber may administer a medicinal product

3C. The conditions specified by virtue of article 3A(3) and in article 3B(3) shall not apply in relation to the administration of a medicinal product by an extended formulary nurse prescriber or a supplementary prescriber where—

- (a) that person is acting in accordance with the directions of another person who is an appropriate practitioner, or
- (b) that administration is exempt from the restriction in section 58(2)(b) (restriction on administration) by virtue of any of the subsequent provisions of this Order.]

Textual Amendments

F43 Arts. 3B, 3C inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **6**

Duration of special provisions in relation to new medicinal products

Textual Amendments

F45 Art. 4 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 11

Exempt medicinal products

5.—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there-

- (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or
- (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.

(2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.

(3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.

(4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use-

- (a) where a purpose for which it may be used is so specified, for that purpose;
- (b) where the class of persons in whom it may be used is so specified, in persons of that class I^{F46} .

provided that, where the entry in column 3 contains a condition to the effect that the product is to be wholly or mainly for use in a specified class of persons, the product satisfies that condition where it is sold or supplied wholly or mainly for use in persons of that class].

(5) Where a pharmaceutical form is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied in that pharmaceutical form.

(6) Where a maximum dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum dose which does not exceed that specified maximum dose.

(7) Subject to paragraph (8), where a maximum daily dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum daily dose which does not exceed that specified maximum daily dose.

(8) A medicinal product which contains more than one of the substances-

Atropine Atropine Methobromide Atropine Methonitrate Atropine Oxide Hydrochloride Atropine Sulphate Hyoscine Hyoscine Butylbromide Hyoscine Hydrobromide Hyoscine Methonitrate Hyoscyamine Hyoscyamine

Hyoscyamine Sulphate,

satisfies the condition only where it is sold or supplied for use at a maximum daily dose which does not exceed 1 milligram in total of the alkaloids derived from belladonna, hyoscyamus, stramonium or other solanaceous plant which are contained in that medicinal product.

(9) Where a maximum period of use or a maximum frequency of use is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use for a maximum period or frequency, as the case may be, which does not exceed the maximum period of use or the maximum frequency of use which is so specified.

(10) Where a maximum quantity is specified in column 5 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it, or where so specified in that column, the medicinal product which contains that substance is sold or supplied in a quantity which does not exceed that specified maximum quantity.

(11) In paragraphs (2) to (7) and (9) and (10) a reference to a numbered column is a reference to the column bearing that number in Schedule 1.

Textual Amendments

F46 Words in art. 5(4) added (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **2**

[^{F47}Exemption for products consisting of or containing aloxiprin, aspirin or paracetamol

5A. A medicinal product falling within article 3(g) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the quantity of that product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.]

Textual Amendments

F47 Art. 5A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 7

Circumstances in which controlled drugs and medicinal products authorized by the European Community are not prescription only medicines

Textual Amendments

F48 Art. 6 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 11

Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines

7. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of any of the following medicinal products for parenteral administration–

Adrenaline Injection 1 in 1000 (1 mg in 1 ml)

Atropine Sulphate Injection

Chlorpheniramine Injection

Cobalt Edetate Injection

Dextrose Injection Strong B.P.C.

Diphenhydramine Injection

Glucagon Injection

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum

Sodium Nitrite Injection Sodium Thiosulphate Injection Sterile Pralidoxime

where the administration is for the purpose of saving life in an emergency.

Exemptions for emergency sale or supply

8.—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.

- (2) The conditions referred to in paragraph (1) are-
 - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor [^{F49}, a supplementary prescriber][^{F50}, a district nurse/health visitor prescriber or an extended formulary nurse prescriber] who by reason of an emergency is unable to furnish a prescription immediately;
 - (b) that the doctor [^{F51}, supplementary prescriber][^{F52}, district nurse/health visitor prescriber or extended formulary nurse prescriber] has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;
 - (c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor [^{F53}, supplementary prescriber][^{F54}, district nurse/health visitor prescriber or extended formulary nurse prescriber] requesting it;
 - (d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
 - (e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(13) within the time specified in that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.

(3) The restrictions imposed by section 58(2)(a) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (4) are satisfied.

- (4) The conditions referred to in paragraph (3) are-
 - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself-
 - (i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,
 - (ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor [^{F55}, supplementary prescriber][^{F56}, district nurse/health visitor prescriber or extended formulary nurse prescriber] for the person requesting it, and
 - (iii) as to the dose which in the circumstances it would be appropriate for that person to take;

⁽¹³⁾ S.I. 1980/1923, amended by S.I. 1997/1831.

- (b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment is sold or supplied except that where the prescription only medicine–
 - (i) is [^{F57}a preparation of insulin,] an aerosol for the relief of asthma, an ointment or cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply may be sold or supplied,
 - (ii) is an oral contraceptive, a quantity sufficient for a full treatment cycle may be sold or supplied,
 - (iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment may be sold or supplied;
- (c) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;
- (e) that the container or package of the prescription only medicine is labelled so as to show-
 - (i) the date on which the prescription only medicine is sold or supplied,
 - (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,
 - (iii) the name of the person requesting the prescription only medicine,
 - (iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and
 - (v) the words "Emergency Supply".

(5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.

Textual Amendments

- F49 Words in art. 8(2)(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(i)
- **F50** Words in art. 8(2)(a) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(a)(i)**
- **F51** Words in art. 8(2)(b) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(ii)
- **F52** Words in art. 8(2)(b) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(a)(ii)**
- **F53** Words in art. 8(2)(c) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(iii)
- **F54** Words in art. 8(2)(c) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(a)(iii)**
- **F55** Words in art. 8(4)(a)(ii) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(b)
- **F56** Words in art. 8(4)(a)(ii) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(b)**

F57 Words in art. 8(4)(b)(i) inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **2**

Exemption for non-parenteral administration to human beings

9. The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration.

Exemption for medicinal products at high dilutions

10.— $[^{F58}(1)]$ The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains, any of the substances listed in column 1 of Schedule 1 or 2, only one or more unit preparation of such substances, if–

- (a) each such unit preparation has been diluted to at least one part in a million (6x), and the person selling, supplying or administering the medicinal product has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required; or
- (b) each such unit preparation has been diluted to at least one part in a million million (6c).

[^{F59}(2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains solely one or more unit preparations of the following substances—

Aconite Arsenic Trioxide Belladonna Herb Ignatia Bean Nux Vomica Seed, if each such unit preparation has been diluted to at least one part in a million (6x)]

Textual Amendments

- **F58** Art. 10 renumbered as art. 10(1) (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **9**
- **F59** Art. 10(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 9

Exemptions for certain persons

11.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply–

- (a) to the sale or supply by a person listed in column 1 of Part I of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied;
- (b) to the supply by a person listed in column 1 of Part II of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

(2) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration by a person listed in column 1 of Part III of Schedule 5 of the prescription only medicines for parenteral administration listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

[^{F60}Exemption for sale or supply in hospitals

12.—(1) Subject to paragraph (3), the restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine in the course of the business of a hospital where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) to a particular person in accordance with directions satisfying the conditions specified in paragraph (2).

(2) The conditions specified in paragraph (1) are that the directions—

- (a) are in writing;
- (b) relate to the particular person to whom the medicine is to be administered; and
- (c) are given by a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine.

(3) Such directions may be given by an extended formulary nurse prescriber or a supplementary prescriber only where he complies with any condition as to the cases or circumstances in which he may give a prescription for that medicine specified by virtue of article 3A or 3B, as if the directions are a prescription.

(4) The exemption in paragraph (1) applies notwithstanding that the directions do not satisfy the conditions specified in article 15(2).]

Textual Amendments

F60 Art. 12 substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), **2**

[^{F61}Exemptions for the supply and administration of prescription only medicines by national health service bodies

12A.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by—

- (a) the Common Services Agency;
- (b) a [^{F62}Strategic Health Authority,] Health Authority or Special Health Authority;
- (c) an NHS trust [^{F63} or NHS foundation trust];
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply of prescription only medicines,

where the medicine is supplied for the purpose of being administered to a particular person in accordance with the written directions of a doctor or dentist relating to that person notwithstanding that those directions do not satisfy the conditions specified in article 15(2).

(2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by—

- (a) the Common Services Agency;
- (b) a [^{F64}Strategic Health Authority,] Health Authority or Special Health Authority;
- (c) an NHS trust [^{F65}or NHS foundation trust];
- (d) a Primary Care Trust; or
- (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply or, as the case may be, the administration of prescription only medicines,

where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (3) are satisfied.

- (3) The conditions referred to are that—
 - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
 - (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
 - (c) the Patient Group Direction is signed on behalf of the person specified in column 2 of the Table in Part II of Schedule 7 to this Order ("the authorising person") against the entry in column 1 of that Table for the class of person by whom the medicine is supplied or administered;
 - (d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing, on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
 - (e) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (4) In this article, "excepted person" means-
 - (a) a doctor or dentist; or
 - (b) a person lawfully conducting a retail pharmacy business within the meaning of section 69.

Textual Amendments

- **F61** Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(d)**
- **F62** Words in art. 12A(1)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, Sch. 1 para. 73(2)(a)
- F63 Words in art. 12A(1)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), Sch. 2
- F64 Words in art. 12A(2)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, Sch. 1 para. 73(2)(b)

F65 Words in art. 12A(2)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), Sch. 2

Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist doctors or dentists in providing national health services

12B.—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—

- (a) the individual supplies or, as the case may be, administers the medicine in order to assist a doctor or dentist in the provision of, respectively, NHS primary medical services or NHS primary dental services;
- (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
 - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the doctor or dentist in question in providing the services referred to in paragraph (1)(a) (whether or not it also relates to such supply or administration in order to assist any other doctor or dentist);
 - (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
 - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
 - (d) the Patient Group Direction is signed—
 - (i) by the doctor or dentist in question or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
 - (ii) on behalf of the health authority [^{F66}or Primary Care Trust]—
 - (a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or
 - (b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;
 - (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
 - (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

- (3) In this article—
 - (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
 - (i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997;
 - (ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
 - (iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997;
 - (b) a reference to the provision of NHS primary medical services shall be construed as a reference to—
 - [^{F67}(i) in relation to England and Wales, the provision of primary medical services under Part I of the National Health Service Act 1977;]
 - [^{F68}(ii) in relation to Scotland, the provision of primary medical services under Part I of the National Health Service (Scotland) Act 1978; and]
 - [^{F69}(iii) in relation to Northern Ireland, the provision of primary medical services under Part VI of the Health and Personal Social Services (Northern Ireland) Order 1972;]

Textual Amendments

- F61 Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(d)
- F66 Words in art. 12B(2)(d)(ii) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), regs. 1, 8, Sch. 5
- F67 Art. 12B(3)(b)(i) substituted (E.) (1.4.2004) by The General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004 (S.I. 2004/865), art. 1(1), Sch. 1 para. 18(2); and substituted (W.) by The General Medical Services Transitional and Consequential Provisions (Wales) (No. 2) Order 2004 (S.I. 2004/1016), art. 1(1), Sch. 1 para. 18(2)
- **F68** Art. 12B(3)(b)(ii) substituted (S.) (31.5.2004) by The Primary Medical Services (Consequential and Ancillary Amendments) (Scotland) Order 2004 (S.S.I. 2004/212), art. 1, sch. 1 para. 5
- F69 Art. 12B(3)(b)(iii) substituted (N.I.) (1.4.2004) by The General Medical Services Transitional and Consequential Provisions (No. 2) (Northern Ireland) Order 2004 (S.R. 2004/156), art. 1(1), Sch. 1 para. 10(2) (with art. 88)

Exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction

12C.—(1) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by a person lawfully conducting a retail pharmacy business within the meaning of section 69 where—

- $[^{F70}(a)$ the medicine is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—
 - (i) a body referred to in article 12A(a) to (d),
 - (ii) an authority or person carrying on the business of an establishment or agency referred to in article 12D(1),
 - (iii) a force or service referred to in article 12E(1)(a)(i) to (iii), or
 - (iv) Her Majesty's Forces,

for the supply or, as the case may be, the administration of prescription only medicines;]

- (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
 - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine by the person lawfully conducting a retail pharmacy business who supplies or, as the case may be, administers the prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
 - (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- [^{F71}(c) the Patient Group Direction is signed—
 - (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
 - (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider and, if there is a relevant manager for the establishment or agency, that manager,
 - (iii) in the case of an arrangement with a prison service, by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that service,
 - (iv) in the case of an arrangement with a police force or the Police Service of Northern Ireland—
 - (a) by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, and
 - (b) a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland, and
 - (v) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces;]
 - [where the prescription only medicine is administered by the person lawfully conducting a
- ^{F72}(cc) retail pharmacy business within the meaning of section 69, the individual who administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is [^{F73}designated in writing—

- (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
- (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider or, if there is a relevant manager for the establishment or agency, that relevant manager,
- (iii) in the case of an arrangement with a force or service referred to in article 12E(1)(a)
 (i) to (iii), by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, or
- (iv) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces,

for the purpose of the administration of prescription only medicines under the Patient Group Direction; and]]

(d) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

Textual Amendments

- **F61** Arts. 12A-12C inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **2(d)**
- **F70** Art. 12C(1)(a) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **10(a)**
- F71 Art. 12C(2)(c) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **10(b)(i)**
- **F72** Art. 12C(2)(cc) inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **3(1)**
- **F73** Words in art. 12C(2)(cc) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **10(b)(ii)**

[^{F74}Exemption for the supply and administration of prescription only medicines by independent hospitals, clinics and agencies

12D.—(1) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine in the course of the business of—

- (a) in England, Wales or Scotland—
 - (i) an independent hospital,
 - (ii) an independent clinic, or
 - (iii) an independent medical agency; or
- (b) in Northern Ireland, a nursing home,

where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to are that—

- (a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
- (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- (c) the Patient Group Direction is signed—
 - (i) by or on behalf of the registered provider, and
 - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager;
- (d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing—
 - (i) by or on behalf of the registered provider, or
 - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager,

for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and

(e) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

Textual Amendments

F74 Arts. 12D, 12E inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 11

Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces

12E.—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—

- (a) the individual supplies or, as the case may be, administers the medicine in order to assist the provision of health care by, on behalf of, or under arrangements made by—
 - (i) a police force in England, Wales or Scotland,
 - (ii) the Police Service of Northern Ireland,
 - (iii) a prison service, or
 - (iv) Her Majesty's Forces;
- (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—

- (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the provision of health care by, or on behalf of, or under arrangements made by the police force or service, the prison service or, as the case may be, Her Majesty's Forces;
- (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
- (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- (d) the Patient Group Direction is signed—
 - (i) by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order ("the authorising person") against the entry in column 1 of that Table for the police force or service, the prison service or Her Majesty's Forces by whom, or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care; and
 - (ii) in the case of a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;
- (e) the individual referred to in paragraph (1) is designated in writing, by or on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
- (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

Textual Amendments

F74 Arts. 12D, 12E inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 11

Exemption in cases involving another's default

13. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person who, having exercised all due diligence, believes on reasonable grounds that the product sold or supplied is not a prescription only medicine.

[^{F75}Exemptions relating to prescriptions given by nurses

13A.— $[^{F76}(1)$ The restrictions imposed by section 58(2)(a) (restrictions in sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by—

- (a) another pharmacist,
- (b) a registered nurse, or
- (c) a registered midwife,

who is not an appropriate practitioner in relation to that medicine where the pharmacist selling or supplying the medicine, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.]

(2) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by an extended formulary nurse prescriber [^{F77}or supplementary prescriber] where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the extended formulary nurse prescriber [^{F77}or supplementary prescriber] has complied with any condition with which he is required to comply by virtue of [^{F78}articles 3A(2) and (3) or 3B].]

Textual Amendments

- F75 Art. 13A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 7
- F76 Art. 13A(1) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 12(a)
- **F77** Words in art. 13A(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **12(b)(i)**
- **F78** Words in art. 13A(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **12(b)(ii)**

Exemption in the case of a forged prescription

14. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

Prescriptions

15.—(1) For the purposes of section 58(2)(a) [^{F79}, and subject to paragraph (2A),] a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

- (2) The conditions referred to in paragraph (1) are that the prescription-
 - (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
 - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;
 - (c) shall contain the following particulars-
 - (i) the address of the appropriate practitioner giving it,
 - (ii) the appropriate date,
 - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist [^{F80}, a supplementary prescriber], [^{F81}a district nurse/health visitor prescriber, an extended formulary nurse prescriber], a veterinary surgeon or a veterinary practitioner,
 - (iv) where the appropriate practitioner giving it is a doctor, dentist [^{F82}, a supplementary prescriber][^{F83}, a district nurse/health visitor prescriber or an extended formulary nurse prescriber], the name, address and the age, if under 12, of the person for whose treatment it is given, and

- (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
- (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
- (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.

 $[^{F84}(2A)$ For the purposes of paragraph (1), where a prescription is issued and dispensed in England and the conditions specified in paragraph (2C) are fulfilled, the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (2B).

- (2B) The conditions referred to are that the prescription shall be-
 - (a) created in an electronic form and signed with an electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries); or
 - (b) entered on a document where-
 - (i) the prescription is created electronically and signed with an electronic signature and both the data and the signature are entered on the document in a non-legible manner;
 - (ii) the prescription is created in writing on the document, as referred to in paragraph (2)(b), and is signed with an electronic signature which is entered on the document in a non-legible manner; or
 - (iii) the prescription is created in an electronic form which is entered on the document in a non-legible manner, and is signed as referred to in paragraph (2)(a),
 - and transferred to the person by whom it is dispensed by physical means.
- (2C) The conditions referred to are that-
 - (a) the prescription is issued by a doctor—
 - (i) under or by virtue of the National Health Service Act 1997; or
 - (ii) as part of the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1977,

and dispensed by a person lawfully conducting a retail pharmacy business within the meaning of section 69; and

- (b) the Secretary of State is satisfied that—
 - (i) the use of electronic means in order to create, sign and transfer prescriptions (or whichever of those purposes is applicable) is appropriate for the purposes of a pilot scheme on the use of electronic prescribing, in relation to both the doctor and the person lawfully conducting a retail pharmacy business concerned, and in relation to the premises at which the prescription is dispensed; and
 - (ii) the particular electronic means used by both the doctor and the person lawfully conducting a retail pharmacy business concerned are suitable for the purposes of such a pilot scheme.]

(3) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to a sale or supply of a prescription only medicine which is not in accordance with a prescription given by an appropriate practitioner by reason only that a condition specified in paragraph (2) [^{F85}or, where applicable, paragraph (2B)] is not satisfied where the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that that condition is satisfied in relation to that sale or supply.

- (4) In paragraph (2) "the appropriate date" means-
 - (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
 - (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it;

and, for the purposes of sub-paragraphs (d) and (e) of that paragraph, where a health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.

 $[^{F86}(5)$ In paragraphs (2B) and (2C)—

"doctor" has the same meaning as in section 132(1);

"electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000;

"electronic signature" has the same meaning as in section 7 of the Electronic Communications Act 2000.]

Textual Amendments

- **F79** Words in art. 15(1) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(a)**
- **F80** Words in art. 15(2)(c)(iii) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **13(a)**
- **F81** Words in art. 15(2)(c)(iii) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 8(a)
- **F82** Words in art. 15(2)(c)(iv) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **13(b**)
- **F83** Words in art. 15(2)(c)(iv) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **8(b)**
- **F84** Art. 15(2A)-(2C) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(b)**
- **F85** Words in art. 15(3) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(c)**
- **F86** Art. 15(5) added (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(d)**

Revocations

16.—(1) The Orders specified in Schedule 6 are revoked.

(2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(14) articles 2 to 6 and Schedules 1 and 2 are revoked.

(14) S.I. 1989/1852.

Signed by authority of the Secretary of State for Health

Baroness Jay Minister of State, Department of Health

Win Griffiths Parliamentary Under Secretary of State, Welsh Office

Sam Galbraith Parliamentary Under Secretary of State, The Scottish Office

Jeff Rooker Minister of State, Ministry of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd July 1997.



D. C. Gowdy Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th July 1997.



P. Small Permanent Secretary

SCHEDULE 1

Articles 3(a), 5(1) and 10

SUBSTANCES WHICH IF INCLUDED IN MEDICINAL PRODUCTS MAKE THOSE PRODUCTS PRESCRIPTION ONLY MEDICINES AND EXEMPTIONS FROM RESTRICTIONS ON THE SALE AND SUPPLY OF PRESCRIPTION ONLY MEDICINES

Exemptions from the restrictions on the sale and supply of prescription only medicines				ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
[^{F87} Acampro	sate]			
Acarbose				
Acebutolol Hydrochlorie	de			
[^{F87} Aceclofe	nac]			
Acemetacin				
Acetarsol				
Acetazolami	de			
Acetazolami Sodium	de			
Acetohexam	ide			
Acetylcholin Chloride	e0.2 per cent	External		
Acetylcystei	ne			
Acipimox				
Aciclovir	5.0 per cent	External For treatment of herpes simplex virus infections of the lips and face (Herpes labialis)		Container or package containing not more than 2g of medicinal product
Acitretin				
Aclarubicin Hydrochlori	de			
Aconite	1.3 per cent	External		

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Acrivastine		-	24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine	
Acrosoxacin					
Actinomycin C					
Actinomycin D					
[^{F88} Adapalene	;]				
Adenosine					
Adrenaline		(1) By inhaler			
		(2) External [^{F89} (except ophthalmic)]			
Adrenaline Acid		(1) By inhaler			
Tartrate		(2) External			
Adrenaline Hydrochlorid	e	(1) By inhaler			
		(2) External			
Adrenocortica Extract	al				
Albendazole					
Alclofenac					
Alclometason Dipropionate	e				
Alcuronium Chloride					
Aldesleukin					
Aldosterone					

		from the restrictions on the sale and supply of a non-constant of the sale and supply of the sale and supply of			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
[^{F87} Alendron Sodium]	ate				
Alfacalcidol					
Alfuzosin Hydrochlorid	de				
Allergen Extracts					
Allopurinol					
Allyloestren	ol				
[^{F90} Aloxiprin	(1) 620 mg	(1) Non- effervescent tablets and capsules		(1) The quantity sold or supplied in one container or package shall not exceed 32	
				The quantity of non- effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100	
		(2) All preparations other than non- effervescent tablets or capsules]			

		Exemptions from the restrictions on the sale and supply of prescription only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Alphadolone Acetate					
Alphaxalone					
Alprenolol					
Alprenolol Hydrochlorid	e				
Alprostadil					
Alseroxylon					
[^{F88} Altretamin	ne]				
Amantadine Hydrochlorid	e				
Ambenonium Chloride					
Ambutonium Bromide					
Amcinonide					
Ametazole Hydrochlorid	e				
Amethocaine		Non- ophthalmic use			
Amethocaine Gentisate		Non- ophthalmic use			
Amethocaine Hydrochlorid	e	Non- ophthalmic use			
Amikacin Sulphate					
Amiloride Hydrochlorid	e				
Aminocaproio Acid	2				
Aminogluteth	imide				

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Aminopterin Sodium					
Amiodarone Hydrochlorid	e				
Amiphenazol Hydrochlorid					
[^{F91} Amisulprie	de]				
Amitriptyline					
Amitriptyline Embonate					
Amitriptyline Hydrochlorid					
Amlodipine Besylate					
Ammonium Bromide					
Amodiaquine Hydrochlorid					
Amorolfine Hydrochlorid	e				
Amoxapine					
Amoxycillin					
Amoxycillin Sodium					
Amoxycillin Trihydrate					
Amphomycin Calcium					
Amphotericin					
Ampicillin					
Ampicillin Sodium					
Ampicillin Trihydrate					

		from the restric only medicine	ctions on the sale and sup s	pply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutio form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Amsacrine				
Amygdalin				
Amyl Nitrite				
Amylocaine Hydrochloride	e	Non- ophthalmic use		
[^{F87} Anastrozol	e]			
Ancrod				
Androsterone				
Angiotensin Amide				
Anistreplase				
Anterior Pituitary Extract				
Antimony Barium Tartrate				
Antimony Dimercaptosu	ccinate			
Antimony Lithium Thiomalate				
Antimony Pentasulphide				
Antimony Potassium Tartrate				
Antimony Sodium Tartrate				
Antimony Sodium Thioglycollate	2			

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity	
Antimony Sulphate					
Antimony Trichloride					
Antimony Trioxide					
Antimony Trisulphide					
Apiol					
Apomorphine	e				
Apomorphine Hydrochlorid					
[^{F88} Apracloni Hydrochlorid					
Aprotinin					
Arecoline Hydrobromid	e				
Argipressin					
Aristolochia					
Aristolochia Clematitis					
Aristolochia Contorta					
Aristolochia Debelis					
Aristolochia Fang-chi					
Aristolochia Manshuriensi	S				
Aristolochia Serpentaria					
Arsenic					
Arsenic Triiodide					

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratic use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
Arsenic Trioxide						
Arsphenami	ne					
[^{F92} Aspirin	[^{F93} (1) 75mg]	[^{F93} (1) Non- effervescent tablets and capsules]		[^{F93} (1) The quantity sold or supplied in one container or package shall not exceed 100 The quantity of non- effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100]		
	[^{F94} [^{F95} 309] mg]	[^{F95} (2)]on- effervescent tablets and capsules		[^{F95} (2)]The quantity sold or supplied in one container or package		

		from the restri 1 only medicine	ctions on the sale and sup es	oply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
				shall not exceed 32
		[^{F95} (3)]All preparations other than non- effervescent tablets or capsules		The quantity of non- effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100]
Astemizole		F96	F96	F96
		F96 F96 F96		
Atenolol				
Atracurium Besylate				
Atropine		(1) Internal(a) byinhaler		
		(b) otherwise	(b) 300mcg (MD)	

		from the restr n only medicine	ictions on the sale and suppers	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form		Column 5 Maximum quantity	
		than by inhaler			
		(2) External (except ophthalmic)	1mg (MDD)		
Atropine		(1) Internal			
Methobromi	de	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		Internal			
Methonitrate		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
Atropine Oxide		(1) Internal			
Hydrochloric	le	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			

	prescription	only medicine		
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Atropine Sulphate		(1) Internal		
Sulphute		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD)	
		(2) External (except ophthalmic)		
Auranofin				
Azapropazon	e			
Azathioprine				
Azathioprine Sodium				
Azelaic Acid				
Azelastine Hydrochlorid	e	For nasal administratio	140mcg per nostril (MD) on	Container or package
		For the treatment of seasonal allergic rhinitis [^{F97} or perennial allergic rhinitis] For use in adults and children not less than [^{F98} 5 years] As a non- aerosol,	280mcg per nostril (MDD)	containing not more than 5,040mcg of Azelastine Hydrochloride

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratic use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity			
		aqueous form					
Azidocillin Potassium							
Azithromycin							
Azlocillin Sodium							
Aztreonam							
Bacampicillin Hydrochloride							
Bacitracin							
Bacitracin Methylene Disalicylate							
Bacitracin Zinc							
Baclofen							
[^{F91} Balsalazide Sodium]	e						
Bambuterol Hydrochloride	2						
Barium Carbonate							
Barium Chloride							
Barium Sulphide							
Beclamide							
Beclomethaso	ne						
Beclomethaso Dipropionate	ne	For nasal administration (non- aerosol)	100mcg per nostril (MD)	Container or package containing not more than [^{F99} 20,000 mcg] of			

		from the restr 1 only medicine	ictions on the sale and supp es	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati	Column 4 Treatment limitations	Column 5 Maximum quantity
	2. U.g.	use or pharmaceut form		
		For the prevention	200 mcg per nostril (MDD)	Beclomethasone Dipropionate
		and treatment of allergic rhinitis	[^{F100} For a maximum period of 3 months]	
		[^{F101} For use in persons aged 18 years and over]		
Belladonna Herb		(1) Internal	(1) 1mg of the alkaloids (MDD)	
		(2) External		
Belladonna Root		(1) Internal	(1) 1mg of the alkaloids (MDD)	
		(2) External		
Bemegride				
Bemegride Sodium				
Benapryzine Hydrochlorie				
Bendrofluaz	ide			
Benethamine Penicillin	2			
Benoxaprofe	n			
Benperidol				
[^{F91} Benseraz	ide]			
Benserazide Hydrochlorie	le			
Bentiromide				
Benzathine Penicillin				
Benzbromar	one			

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
Benzhexol Hydrochlorid	le					
Benzilonium Bromide						
Benzocaine		Any use except ophthalmic use				
Benzoctamin Hydrochloric						
Benzoyl Peroxide	10.0 per cent	External				
N-Benzoyl Sulphanilami	ide					
Benzquinami	ide					
Benzquinami Hydrochlorid						
Benzthiazide	;					
Benztropine Mesylate						
Benzylpenici Calcium	illin					
Benzylpenici Potassium	illin					
Benzylpenici Sodium	illin					
Beractant						
Betahistine Hydrochloric	le					
Betamethaso	ne					
Betamethaso Adamantoate						
Betamethaso Benzoate	ne					

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Betamethason Dipropionate	e					
Betamethason Sodium Phosphate	e					
Betamethason Valerate	e					
Betaxolol Hydrochloride	9					
Bethanechol Chloride						
Bethanidine Sulphate						
Bezafibrate						
[^{F88} Bicalutami	de]					
Biperiden Hydrochloride	2					
Biperiden Lactate						
Bismuth Glycollylarsa	nilate					
Bisoprolol Fumarate						
Bleomycin						
Bleomycin Sulphate						
Bretylium Tosylate						
[^{F91} Brimonidin Tartrate]	ne					
Bromhexine Hydrochloride	2					
Bromocriptine Mesylate	2					
Bromperidol						

		from the restri only medicine	ictions on the sale and supples	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Bromvaleton	e			
Brotizolam				
Budesonide		For nasal administratio	200mcg per nostril (MD)	Container or package
		For the prevention or treatment of seasonal allergic rhinitis	[^{F100} For a maximum period of 3 months]	containing not more than 10mg of Budesonide
		200 mcg per nostril (MDD)		
		[^{F101} For use in persons aged 18 years and over]		
		As a non- aerosol, aqueous form		
Bufexamac				
Bumetanide				
Buphenine			6mg (MD)	
Hydrochlorid	e		18mg (MDD)	
Bupivacaine		Any use except ophthalmic use		
Bupivacaine Hydrochlorid	e	Any use except ophthalmic use		
Buserelin Acetate				

		Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Buspirone Hydrochlorie	de					
Busulphan						
Butacaine Sulphate		Any use except ophthalmic use				
Butorphanol Tartrate						
Butriptyline Hydrochlori	de					
[^{F102} Cabergo	line]					
Calcipotriol						
[^{F88} Calcipotr Hydrate]	iol					
Calcitonin						
Calcitriol						
Calcium Amphomyci	n					
Calcium Benzamidos	alicylate					
Calcium Bromide						
Calcium Bromidolact	obionate					
Calcium Carbimide						
Calcium Folinate						
Calcium Metrizoate						
Calcium Sulphaloxate	•					
[^{F103} Candesa Cilexetil]	rtan					
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	prescription	from the restring from the restrict from the res	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Candicidin				
Canrenoic Acid				
Cantharidin	0.01 per cent	External		
Capreomycir Sulphate	1			
Captopril				
Carbachol				
Carbamazepi	ine			
Carbaryl				
[^{F91} Carbasala Calcium]	ite			
Carbenicillin Sodium	l			
Carbenoxolo	ne	(1) Pellet	(1) 5mg (MD)	
Sodium			25mg (MDD)	
	(2) 2.0 per cent	(2) Gel		
	(3) 1.0 per cent	(3) Granules for mouthwash in adults and children not less than 12 years	(3) 20mg (MD) 80mg (MDD)	(3) Container or package containing not more than [^{F104} 560mg] of Carbenoxolone Sodium
Carbidopa				
Carbimazole				
Carbocistein	e			
Carbon Tetrachloride	2			
Carboplatin				

		from the restri only medicine	ictions on the sale and suppers	vly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Carboprost Trometamol				
Carbuterol Hydrochlorid	e			
Carfecillin Sodium				
Carindacillin Sodium				
Carisoprodol				
Carmustine				
Carperidine				
Carteolol Hydrochlorid	e			
Cefaclor				
Cefadroxil				
Cefazedone Sodium				
[^{F91} Cefdinir]				
Cefixime				
Cefodizime Sodium				
Cefotaxime Sodium				
Cefoxitin Sodium				
Cefpodoxime Proxetil				
[^{F102} Cefprozil]]			
Cefsulodin Sodium				
Ceftazidime				
Ceftizoxime Sodium				

		from the restri	ctions on the sale and supp	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Ceftriaxone Sodium				
Cefuroxime Axetil				
Cefuroxime Sodium				
Celiprolol Hydrochlorid	e			
Cephalexin				
Cephalexin Sodium				
Cephaloridin	e			
Cephalothin Sodium				
Cephamando Nafate	le			
Cephazolin Sodium				
Cephradine				
Cerium Oxalate				
Cerivastatin				
[^{F91} Cerivastat Sodium]	in			
Ceruletide Diethylamine	;			
Cetirizine Hydrochlorid	e		10mg (MDD)	F105
Chenodeoxyo Acid	cholic			
Chloral Hydrate		External		
Chlorambuci	l			
Chlorampher	icol			

		from the restruction only medicine	ictions on the sale and sup es	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Chlorampher Cinnamate	nicol			
Chlorampher Palmitate	nicol			
Chlorampher Sodium Succinate	nicol			
Chlorhexado	ol			
Chlormadino Acetate	one			
Chlormerodi	rin			
Chlormethia	zole			
Chlormethia Edisylate	zole			
Chlormezan	one			
Chloroform(15)) 5.0 per cent	(1) Internal		
		(2) External		
Chloroquine Phosphate		Prophylaxis of malaria		
Chloroquine Sulphate		Prophylaxis of malaria		
Chlorothiazi	de			
Chlorotrianis	sene			
Chlorphenox Hydrochlorid				
Chlorpromaz	zine			
Chlorpromaz Embonate	zine			
Chlorpromaz Hydrochlorid				
Chlorpropan	nide			

 $^{(15) \} See S.I. \ 1979/382 \ amended \ by \ S.I. \ 1980/263 \ and \ S.I. \ 1989/1124.$

Column 1 Substance	Column 2		S	
	Maximum strength	Column 3 Route of administration use or pharmaceution form		Column 5 Maximum quantity
Chlorprothix	ene			
Chlorprothix Hydrochlorid				
Chlortetracy	cline			
Chlortetracy Calcium	cline			
Chlortetracy Hydrochlorid				
Chlorthalido	ne			
Chlorzoxazo	ne			
Cholestyram	ine			
Ciclacillin				
Ciclobendaz	ole			
Cilastatin Sodium				
Cilazapril				
Cimetidine		(a) For the	(a) 200mg (MD)	
		short-term symptomatic	800mg (MDD)	
		relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity and for the prophylaxis of meal- induced heartburn	For a maximum period of 14 days	
		(b) For the prophylactic management of nocturnal heartburn by a single	-	

		from the restri only medicine	ctions on the sale and sup	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		dose taken at night			
Cimetidine Hydrochlorid	le	C			
Cinchocaine	3.0 per cent	Non- ophthalmic use			
Cinchocaine Hydrochlorid		Non- ophthalmic use			
Cinchophen					
Cinoxacin					
Ciprofibrate					
Ciprofloxacia	1				
Ciprofloxacin Hydrochlorid					
Cisapride					
Cisplatin					
[^{F88} Citalopran Hydrobromic					
Clarithromyc	in				
Clavulanic Acid					
Clidinium Bromide					
Clindamycin					
Clindamycin Hydrochlorid					
Clindamycin Palmitate Hydrochlorid					
Clindamycin Phosphate					

			ctions on the sale and sup	ply of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrativ use or pharmaceuth form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Clioquinol		(1) External (other than treatment of mouth ulcers)		
	(2) 35mg	(2) Treatment of mouth ulcers	(2) 350mg (MDD)	
Clobetasol Propionate				
Clobetasone Butyrate	[^{F106} 0.05 per cent]	[^{F106} Cream for use in adults and in children aged 12 years and over, for external use for the short term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis)]		[^{F106} Container or package containing not more than 15g of medicinal product]
Clofazimine				
Clofibrate				
Clomiphene Citrate				
Clomipramin				
Clomipramin Hydrochlorid	le			
Clomocycline	e			

		from the restruction only medicine	ictions on the sale and sup es	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Clomocycline Sodium	2			
Clonidine				
Clonidine Hydrochlorid	e			
Clopamide				
Clopenthixol Decanoate				
Clopenthixol Hydrochlorid	e			
Clorexolone				
Clotrimazole		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Cloxacillin Benzathine				
Cloxacillin Sodium				
Clozapine				
Cocculus Indicus				
Co- dergocrine Mesylate				
Colaspase				
Colchicine				
Colestipol Hydrochlorid	e			
Colfosceril Palmitate				

		from the restrictions on the sale and sup only medicines	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
Colistin Sulphate			
Colistin Sulphometha	ite		
Colistin Sulphometha Sodium	ite		
Coniine			
Conium Leaf	7.0 per cent	External	
Corticotroph	in		
Cortisone			
Cortisone Acetate			
Co- tetroxazine			
Co- trimoxazole			
Cropropamic	le		
Crotethamid	e		
Croton Oil			
Croton Seed			
Curare			
Cyclofenil			
Cyclopenthia	azide		
Cyclopentola Hydrochlorid			
Cyclophosph	amide		
Cycloserine			
Cyclosporin			
Cyclothiazid	e		
Cyproterone Acetate			

		from the restruction only medicine	ictions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Cytarabine				
Cytarabine Hydrochloride	5			
Dacarbazine				
Dalteparin Sodium				
Danazol				
Danthron				
Dantrolene Sodium				
Dapsone				
Dapsone Ethane Ortho Sulphonate				
Daunorubicin Hydrochloride				
Deanol Bitartrate			26mg (MDD)	
Debrisoquine Sulphate				
Demecarium Bromide				
Demeclocycli	ne			
Demeclocycli Calcium	ne			
Demeclocycli Hydrochloride				
Deoxycortone Acetate	;			
Deoxycortone Pivalate	;			
Deptropine Citrate				

		from the restric only medicines	ctions on the sale and sup s	oply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutio form		Column 5 Maximum quantity
Dequalinium Chloride	(1) 0.25mg	(1) Internal: throat lozenges or throat pastilles		
	(2) 1.0 per cent	(2) External: paint		
Deserpidine				
Desferrioxam Mesylate	nine			
Desflurane				
Desipramine Hydrochlorid	e			
Deslanoside				
Desmopressi	n			
Desmopressin Acetate	n			
Desogestrel				
Desonide				
Desoxymetha	isone			
Dexamethaso	one			
Dexamethaso Acetate	one			
Dexamethaso Isonicotinate	one			
Dexamethaso Phenylpropio				
Dexamethaso Pivalate	one			
Dexamethaso Sodium Metasulphob				
Dexamethaso Sodium Phosphate	one			

	prescription	n only medicine		
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity
Dexamethaso Troxundate	one			
Dexfenflurar Hydrochloric				
Dextrometho Hydrobromio		Internal	(a) In the caseof a prolongedrelease preparation:equivalent of 30mg ofDextromethorphan (MD)	
			equivalent of 75mg of Dextromethorphan (MDD)	
			(b) in any other case: equivalent of 15mg of Dextromethorphan (MD)	
			equivalent of 75mg of Dextromethorphan (MDD)	
Dextrothyrox Sodium	kine			
Diazoxide				
Dibenzepin Hydrochloric	le			
Dichloralphe	enazone			
Dichlorphena	amide			
Diclofenac Diethylamme	1.16 per owienti	External For local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product

		from the restriction only medicine	ctions on the sale and sup s	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form soft tissue	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		rheumatism		
		For use in adults and children not less than 12 years		
Diclofenac Potassium				
Diclofenac Sodium				
Dicyclomine			10mg (MD)	
Hydrochloride	2		60mg (MDD)	
[^{F87} Didanosine	e]			
Dienoestrol				
Diethanolamir Fusidate	ne			
Diflucortolone Valerate	e			
Diflunisal				
Digitalin				
Digitalis Leaf				
Digitalis Prepared				
Digitoxin				
Digoxin				
Dihydralazine Sulphate	;			
Dihydroergota Mesylate	amine			
Dihydrostrept	omycin			
Dihydrostrept Sulphate	omycin			

	prescription	from the restri only medicine		ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuth form		Column 5 Maximum quantity
Diloxanide Furoate				
Diltiazem Hydrochloric	le			
Dimercaprol				
Dimethisoqu Hydrochloric		Non- ophthalmic use		
Dimethistero	ne			
Dimethothia Mesylate	zine			
Dimethyl Sulphoxide				
Dimethyltub Bromide	ocurarine			
Dimethyltub Chloride	ocurarine			
Dimethyltub Iodide	ocurarine			
Dinoprost				
Dinoprost Trometamol				
Dinoproston	e			
[^{F90} Diphenhy Hydrochloric	dAlhine Apreparations except liquid-filled capsules]			
[^{F107} Dipheno: Hydrochloric	x∳fåf2.5 mg] le]	[^{F107} In combination with Atropine Sulphate for short term use as an adjunctive therapy to	[^{F107} 25 mg (MDD)]	[^{F107} Container or package containing not more than 20 tablets]

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	prescription	only medicine		v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		pharmaceuti form	ical	
		appropriate rehydration in acute diarrhoea		
		For use in persons aged 16 years and over		
		Tablets]		
Dipivefrin Hydrochlorid	e			
Dipyridamole	e			
Disodium Etidronate				
Disodium Pamidronate				
Disopyramid	e			
Disopyramide Phosphate	e			
Distigmine Bromide				
Disulfiram				
Dithranol	1.0 per cent			
Dobutamine Hydrochlorid	e			
[^{F107} Dolasetro Mesilate]	on			
Domperidone	3	[^{F108} For the relief of post- prandial symptoms of excessive fullness, nausea, epigastric	[^{F108} 10mg of Domperidone (MD)] [^{F108} 40mg of Domperidone (MDD)]	[^{F108} Container or package containing not more than 200mg of Domperidone]

		from the restri only medicine	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]		
Domperidone Maleate	•	[^{F109} For the relief of post- prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,]	[^{F110} 10 mg of Domperidone as Domperidone Maleate (MD)] [^{F110} 40 mg of Domperidone as Domperidone Maleate (MDD)]	[^{F109} Container or package containing not more than [^{F111} 200mg] of Domperidone as Domperidone Maleate;]
[^{F91} Donepezil Hydrochlorid	e]			
Dopamine Hydrochlorid	e			
Dopexamine Hydrochlorid	e			
[^{F88} Dorzolam Hydrochlorid				
Dothiepin				
Dothiepin Hydrochlorid	e			
Doxapram Hydrochlorid	e			
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	prescription	from the restruction only medicine	ictions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Doxazosin Mesylate				
Doxepin Hydrochlorid	e			
Doxorubicin				
Doxorubicin Hydrochlorid	e			
Doxycycline				
Doxycycline Calcium Chelate				
Doxycycline Hydrochlorid	e			
Droperidol				
Dydrogestero	ne			
Dyflos				
Econazole		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Econazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Ecothiopate Iodide				
Edrophonium Chloride				

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity	
Eflornithine Hydrochloric	le				
[^{F87} Eformoter Fumarate]	rol				
Embutramide	2				
Emepronium Bromide					
Emetine	1.0 per cent				
Emetine Bismuth Iodide					
Emetine Hydrochloric	Equivalent leof 1.0 per cent of Emetine				
Enalapril Maleate					
Encephalitis Virus, Tick- borne, Cent Eur					
Enoxacin					
Enoxaparin Sodium					
Enoximone					
Ephedrine		(1) Internal (other than nasal sprays or nasal drops)	(1) 30mg (MD)		
			60mg (MDD)		
	(2) 2.0 per cent	(2) Nasal sprays or nasal drops			

		from the restring from the restrict from the res	ctions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Ephedrine Hydrochlori	de	(1) Internal (other than	(1) Equivalent of 30mg of Ephedrine (MD)	
-		nasal sprays or nasal drops)	Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Ephedrine Sulphate		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD)	
			Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Epicillin				
Epirubicin				
Epirubicin Hydrochlori	de			
Epithiazide				
Epoetin Alfa				
Epoetin Beta				
Epoprosteno Sodium	1			
Ergometrine Maleate				

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Ergometrine Tartrate						
Ergot, Prepared						
Ergotamine Tartrate						
Erythromycin						
Erythromycin Estolate						
Erythromycin Ethylcarbonat						
Erythromycin Ethyl Succinate						
Erythromycin Lactobionate						
Erythromycin Phosphate						
Erythromycin Stearate						
Erythromycin Thiocyanate						
Esmolol Hydrochloride	e					
Estramustine Phosphate						
[^{F112} Estramust Sodium Phosphate]	ine					
Etafedrine Hydrochloride	e					
Ethacrynic Acid						
Ethambutol Hydrochloride	e					

		from the restrient from the restrient from the restrict from the r	ctions on the sale and supp	ply of
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Ethamivan				
Ethamsylate				
Ethiazide				
Ethinyl Androstened	iol			
Ethinyloestra	adiol			
Ethionamide				
Ethisterone				
Ethoglucid				
Ethoheptazir Citrate	ie			
Ethopropazin Hydrochloric				
Ethosuximid	e			
Ethotoin				
Ethyl Biscoumacet	ate			
Ethynodiol Diacetate				
Etodolac				
Etomidate				
Etomidate Hydrochlorid	de			
Etoposide				
Etretinate				
[^{F88} Exemesta	ine]			
Famciclovir				
Famotidine		For the	10mg (MD)	
		short-term symptomatic	20mg (MDD)	
		relief of heartburn, dyspepsia, indigestion,	For maximum period of 14 days	
		<i></i> ,	69	

		from the restri	ctions on the sale and suppl	y of
Column 1	Column 2	Column 3	s Column 4	Column 5
Substance	Maximum	Route of	Treatment limitations	Maximum
Substance	strength	administratio		quantity
	sirengin	use or	<i>on,</i>	quantity
		pharmaceuti	ical	
		form		
		acid		
		indigestion		
		and		
		hyperacidity,		
		and		
		prevention		
		of these		
		symptoms		
		when		
		associated with food		
		and drink,		
		including		
		nocturnal		
		symptoms		
Fazadinium Bromide				
Felbinac	3.17 per	External	For maximum period of 7	Container
	cent	[^{F114} For the	days	or package
		101010		containing
		relief of		not more
		relief of rheumatic		not more than
				than
		rheumatic pain, pain of non-serious		than [^{F113} 50g] of
		rheumatic pain, pain of non-serious arthritic		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions		than [^{F113} 50g] of
		rheumatic pain, pain of non-serious arthritic conditions and soft		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains,		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions]		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not less than 12		than [^{F113} 50g] of medicinal
Felodipine		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not		than [^{F113} 50g] of medicinal
Felodipine		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not less than 12		than [^{F113} 50g] of medicinal
Felypressin		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not less than 12		than [^{F113} 50g] of medicinal
		rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and children not less than 12		than [^{F113} 50g] of medicinal

		from the restri	ctions on the sale and sup	pply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Fenfluramine Hydrochlorid				
Fenofibrate				
Fenoprofen				
Fenoprofen Calcium				
Fenoterol Hydrobromic	le			
Fenticonazol Nitrate	e	[^{F106} External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)]		
Feprazone				
Ferrous Arsenate				
[^{F88} Ferumoxs	il]			
[^{F91} Fexofenac Hydrochloric				
Filgrastim				
Finasteride				
Flavoxate Hydrochloric	le			
Flecainide Acetate				
Flosequinan				
Fluanisone				
Flubendazole	•			
Fluclorolone Acetonide				
Flucloxacillin Magnesium	1			

		from the restruction only medicine	ictions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Flucloxacilli Sodium	n			
Fluconazole		For oral administratic for the treatment of vaginal candidiasis [^{F115} or associated candidal balanitis] in persons aged not less than 16 but less than 60 years	150mg (MD) m	Container or package containing not more than 150mg of Fluconazole
Flucytosine				
Fludrocortise Acetate	one			
Flufenamic Acid				
Flumazenil				
Flumethason	ie			
Flumethason Pivalate	le			
Flunisolide	0.025 per cent	(a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever [^{F116} For use	(a) 50mcg per nostril (MD) 100mcg per nostril (MDD) [^{F117} For a	(a) Container or package containing not more than 6,000mcg of Flunisolide
		in persons aged 18	maximum period of 3 months]	

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	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrat use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
		years and over]				
		In the form of a non- pressurised nasal spray				
		F118	F118	F118		
			F118			
		E110				
		F118				
		F118				
Fluocinolone Acetonide						
Fluocinonide						
Fluocortin Butyl						
Fluocortolone	e					
Fluocortolone Hexanoate	e					
Fluocortolone Pivalate	2					
Fluorescein Dilaurate						
Fluoromethol	lone					
Fluorouracil						
Fluorouracil Trometamol						
Fluoxetine Hydrochlorid	e					
Flupenthixol Decanoate						

		from the restr only medicin	ictions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrat use or pharmaceut form		Column 5 Maximum quantity
Flupenthixol Hydrochlorid	le			
Fluperolone Acetate				
Fluphenazine Decanoate	;			
Fluphenazine Enanthate				
Fluphenazine Hydrochlorid				
Flupredniden Acetate	e			
Fluprednisolo	one			
Fluprostenol Sodium				
Flurandrenol	one			
Flurbiprofen	[^{F119} 8.75 mg]	[^{F120} Throat lozenges]	[^{F121} 43.75 mg (MDD)]	[^{F122} Container or package containing not more than 140 mg of Flurbiprofen]
Flurbiprofen Sodium				
Fluspirilene				
Flutamide				
Fluticasone Propionate				
[^{F91} Flutrimaz	ole]			
Fluvastatin Sodium				
Fluvoxamine Maleate				
Folic Acic			500mcg (MDD)	

		from the restric only medicines	ctions on the sale and support	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratic use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Formestane				
Formocortal				
Foscarnet Sodium				
Fosfestrol Sodium				
Fosfomycin Trometamol				
Fosinopril Sodium				
Framycetin Sulphate				
Frusemide				
Furazolidone				
Fusafungine				
Fusidic Acid				
Gabapentin				
Gadoteridol				
Gallamine Triethiodide				
Ganciclovir				
Ganciclovir Sodium				
Gelsemine	0.1 per cent			
Gelsemium			25mg (MD)	
			75mg (MDD)	
Gemeprost				
Gemfibrozil				
Gentamicin				
Gentamicin Sulphate				
Gestodene				

		from the restriction only medicine	ctions on the sale and support	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Gestrinone				
Gestronol				
Gestronol Hexanoate				
Glibenclamic	de			
Glibornuride				
Gliclazide				
Glipizide				
Gliquidone				
Glisoxepide				
Glucagon				
Glycopyrron Bromide	ium		1mg (MD)	
			2mg (MDD)	
Glymidine				
Gonadorelin				
Goserelin Acetate				
Gramicidin	0.2 per cent	External		
Granisetron Hydrochloric	le			
Griseofulvin				
Growth Hormone				
Guanethidine Monosulpha				
Guanfacine Hydrochlorid	le			
Guanoclor Sulphate				
Guanoxan Sulphate				
Halcinonide				

		from the restruction only medicine	ictions on the sale and supp	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Halofantrine Hydrochlorid				
Haloperidol				
Haloperidol Decanoate				
Heparin		External		
Heparin Calcium		External		
Heparin Sodium				
Hexachlorop	hane	External		
	(a) 2.0 per cent	(a) Soaps		
	(b) 0.1 per cent	(b) Aerosols		
	(c) 0.75 per cent	(c) preparations other than soaps and aerosols		
Hexamine Phenylcinch	oninate			
Hexobarbito	ne			
Hexobarbito Sodium	ne			
Hexoestrol				
Hexoestrol Dipropionate	2			
L-Histidine Hydrochlorid	de	Dietary supplementa	tion	
Homatropine	2	(1) Internal	(1) 0.15mg (MD) 0.45mg (MDD)	
		(2) External (except ophthalmic)		

		from the restrictions on the sale and sup	vly of
		only medicines	
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration,	Column 5 Maximum quantity
		use or pharmaceutical form	
Homatropine		0.2mg (MD)	
Hydrobromi	ae	0.6mg (MDD)	
Homatropine		2mg (MD)	
Methylbrom	lue	6mg (MDD)	
Hydralazine Hydrochlorid	de		
Hydrargaphe	en	Local application to skin	
Hydrobromio Acid	с		
Hydrochloro	thiazide		
Hydrocortisc	one [^{F123} (1)0.5 per cent]	[^{F123} (1) External (a) For use in combination with Nystatin of maximum strength 3.0 per cent for intertrigo (b) For use in adults and children not less than 10 years]	(Containing or package containing not more than 15g of medicinal product]
	[^{F124} (2)].0 per cent	[^{F124} (2)] External (a) For use either alone 78	(Fon(a))) er or package containing not more than 15g

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrat use or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity			
		form					
		-	ction niton fitis, t ctitis, t ctitis, ns, ate a, nation nazole azole e] 's al go nation aine	of medicinal product (cream or ointment) or 30ml (spray)			

		from the restrictions of only medicines	on the sale and supp	ply of
Column 1 Substance	Column 2 Maximum strength	administration, use or pharmaceutical	mn 4 ment limitations	Column 5 Maximum quantity
Hydrocortiso Acetate	onEquivalent to 1.0 per cent Hydrocortiso	contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination with one or more of the following: Benzyl Benzoate, Bismuth Oxide, Bismuth Subgallate, Peru Balsam, Pramoxine Hydrochloride, Zinc Oxide, for haemorrhoids	30	Container or package containing not more than 15g of medicinal product In the case of suppositories, container or package containing no more than 12

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity		
		[^{F126} or in combination with Miconazole Nitrate, for athlete's foot and candidal intertrigo]				
		For use in adults and children not less than 10 years				
		Cream, ointment or suppositories				
Hydrocortisc Butyrate Hydrocortisc						
Caprylate						
Hydrocortiso Hydrogen Succinate	ne					
Hydrocortisc Sodium Phosphate	ne					
Hydrocortisc Sodium Succinate	nEquivalent to 2.5mg Hydrocortiso	External For aphthous ulceration of the mouth for adults and children not less than 12 years In the form of pellets		Container or package containing not more than equivalent to 50mg of Hydrocortisone		

	-	from the restrient from the restrient from the restrict from the r	ctions on the sale and sup s	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity
[^{F90} Hydrocya Acid]	anic			
Hydroflumet	thiazide			
Hydroxychlo Sulphate	oroquine	Prophylaxis of malaria		
Hydroxyprog	gesterone			
Hydroxyprog Enanthate	gesterone			
Hydroxyprog Hexanoate	gesterone			
Hydroxyurea	ı			
Hydroxyzine Embonate	2			
Hydroxyzine Hydrochlorie		(a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride
		(b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis,	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride
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		from the restriction only medicine	ictions on the sale and suppers	vly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or		Column 5 Maximum quantity
		pharmaceut form	ical	
		in children not less than 6 years but less than 12 years		
Hyoscine	(1) 0.15 per cent	(1) Internal		
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Butylbromid	e	(a) by inhaler		
		(b) otherwise than by inhaler	(b) 20mg (MD) 80mg (MDD)	(b) Container or package containing not more than 240mg of Hyoscine Butylbromide
		(2) External		
Hyoscine		(1) Internal		
Hydrobromi	de	(a) by inhaler		
		(b)	(b) 300mcg (MD)	
		otherwise than by inhaler	900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Methobromi	de	(a) by inhaler		
		(b) otherwise	(b) 2.5mg (MD) 7.5mg (MDD)	

		from the restrict from the restrict from the restrict from the second se	ictions on the sale and supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
		<i>form</i> than by inhaler		
		(2) External		
Hyoscine		(1) Internal		
Methonitrate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscyamine	e	(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 1mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Hydrobromid	le	(a) by inhaler		
		(b) otherwise	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
		than by inhaler	Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine	•	(1) Internal		
Sulphate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD)Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		

		only medicine		y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form		Column 5 Maximum quantity
Ibuprofen		Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrho feverishness, symptoms of colds and influenza		
		(1) Internal	(1)(a) In the case of a prolonged release preparation 600mg (MD)	
			1,200mg (MDD)	
			(b) in any other case 400mg (MD)	
			1,200mg (MDD)	
	(2) 5.0 per cent	(2) External		
	[^{F127} (3) 10.0 per cent]	[^{F127} (3) External]	[^{F127} (3) 125 mg (MD) 500 mg (MDD)]	[^{F127} (3) Container or package containing not more than [^{F128} 50g] of medicinal product]
[^{F90} Ibuprofen Lysine		Rheumatic and muscular pain, pain of non-serious arthritic	(a) in the case of a prolonged release preparation 600 mg (MD) 1,200 mg (MDD)	

			ictions on the sale and supp	ly of	
		n only medicine			
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum	Route of	Treatment limitations	Maximum	
	strength	administrat	ion,	quantity	
		use or	ing 1		
		pharmaceut	ical		
		form			
		conditions, backache,			
		neuralgia,			
		migraine,			
		headache,			
		dental pain,			
		dysmenorrho			
		feverishness	,		
		symptoms			
		of colds and			
		influenza			
		Internal	(b) in any other case 400 mg (MD) 1,200 mg		
			(MDD)]		
Idarubicin Hydrochloride					
Idoxuridine					
Ifosfamide					
Ignatius Bean					
[^{F87} Imidapril Hydrochloride	;]				
Imipenem					
Hydrochloride					
Imipramine					
Imipramine Hydrochloride	;				
Imipramine					
Ion					
Exchange					
Resin					
Bound Salt					
or Complex					
[^{F102} Indapamic	le				
Indapamide Hemibydrate					
Hemihydrate					
Indomethacin					

		from the restri	ctions on the sale and sup	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Indomethacir Sodium	1				
Indoprofen					
Indoramin Hydrochlorid	e				
Inosine Pranobex					
[^{F129} Insulin]					
Iodamide					
Iodamide Meglumine					
Iodamide Sodium					
Iohexol					
Iomeprol					
Iopamidol					
Iopentol					
Iothalamic Acid					
Ioversol					
Ioxaglic Acid					
Ipratropium Bromide					
Iprindole Hydrochlorid	e				
Iproniazid Phosphate					
[^{F91} Irbesartan]				
Isoaminile					
Isoaminile Citrate					
Isocarboxazio	1				

		from the restri only medicine	ctions on the sale and suppl	'y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity
Isoconazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Isoetharine				
Isoetharine Hydrochloride	9			
Isoetharine Mesylate				
Isoniazid				
Isoprenaline Hydrochloride	2			
Isoprenaline Sulphate				
Isopropamide Iodide			Equivalent of 2.5mg of Isopropamide ion (MD)	
			Equivalent of 5.0mg of Isopropamide ion (MDD)	
Isotretinoin				
Isradipine				
Itraconazole				
Jaborandi		External		
Kanamycin Acid Sulphate				
Kanamycin Sulphate				
Ketamine Hydrochloride	e			

	from the restri only medicine	ctions on the sale and suppl	y of
Column 1 Column 2 Substance Maximum strength	Column 3 Route of administration use or pharmaceution form		Column 5 Maximum quantity
Ketoconazole 2.0 per cent	[^{F130} (a)][^{F131} E For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	xtern(a)] Maximum frequency of application of once every 3 days	[^{F130} (a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole
	[^{F132} (b) For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo]		
Ketoprofen 2.5 per cent	External For rheumatic and muscular pain in adults and children not less than 12	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
Ketorolac Trometamol			
ITometamoi			
Ketotifen Fumarate			

		from the restric only medicines	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutio form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Lachesine Chloride				
Lacidipine				
Lamotrigine				
Lanatoside C				
Lanatoside Complex A, B and C				
[^{F102} Lansopra	zole]			
Latamoxef Disodium				
[^{F102} Lercanidi Hydrochlorid				
Levallorphan Tartrate				
Levobunolol Hydrochlorid	e			
[^{F90} Levocaba: Hydrochlorid		(1) Nasal sprays For the symptomatic treatment of seasonal allergic rhinitis		(1) Container or package containing not more than 10 ml of medicinal product
		(2) Aqueous eye drops		(2) Container
		For the symptomatic treatment of seasonal allergic conjunctivitis		or package containing not more than 4 ml of medicinal product]
[^{F133} Levocarn	itine]	[^{F133} For dietary supplementat	ion]	

pre	scription	from the restrie only medicine	ctions on the sale and sup s	ply of
Substance Ma	lumn 2 ximum ength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity
Levodopa				
[^{F91} Levofloxacin]				
Levonorgestrel ^{F134}	0.75mg]	[^{F134} for use as an emergency contraceptive in women aged 16 years and over]		
Lidoflazine				
Lignocaine		Non- ophthalmic use		
Lignocaine Hydrochloride		Non- ophthalmic use		
Lincomycin				
Lincomycin Hydrochloride				
Liothyronine Sodium				
Lisinopril				
Lithium Carbonate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lithium Citrate				
Lithium Succinate				
Lithium Sulphate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lobeline		(1) Internal	(1) 3mg (MD)	
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			ctions on the sale and suppl	ly of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine. Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		JOIM	9mg (MDD)	
		(2) External		
Lobeline Hydrochloric	le	(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lobeline Sulphate		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lodoxamide Trometamol	[^{F135} equivaler of 0.1 per cent Lodoxamide]	treatment of ocular	·,	
Lofepramine				
Lofepramine Hydrochlorid	le			
Lofexidine Hydrochlorid	le			
Lomefloxaci Hydrochlorid				
Lomustine				
Loperamide Hydrochlorid	le	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	F137

	1	from the restr	ictions on the sale and suppersive the sale and supper	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administrat use or pharmaceut form		Maximum quantity

. . .

[^{F103}Lornoxicam]

[^{F103} Losartan Potassium]	
Loxapine Succinate	
Lung Surfactant Porcine	
Luteinising Hormone	
Lymecycline	
Lynoestrenol	
Lypressin	
Lysuride Maleate	
Mafenide	
Mafenide Acetate	
Mafenide Hydrochloride	
Mafenide 5.0 per cent Eye drops Propionate	
Magnesium Fluoride	
Magnesium Metrizoate	
Mandragora Autumnalis	
Mannomustine Hydrochloride	
Maprotiline Hydrochloride	
Mebanazine	

		from the restri	ctions on the sale and supp s	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Mebendazole		For oral use in the treatment of enterobiasis in adults and in children not less than 2 years	100mg (MD)	Container or package containing not more than 800mg of Mebendazole
Mebeverine Hydrochloride		[^{F138} (a)For the symptomatic relief of irritable bowel syndrome	[^{F138} (a) 135 mg (MD) 405 mg (MDD)]	
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[^{F138} (b) 100 mg (MD) 300 mg (MDD)]	
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride	;			
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyproge: Acetate	sterone			

		from the restri	ictions on the sale and supp	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Mefenamic Acid					
Mefloquine Hydrochloride	e				
Mefruside					
Megestrol					
Megestrol Acetate					
Meglumine Gadopentetate	e				
Meglumine Iodoxamate					
Meglumine Ioglycamate					
Meglumine Iothalamate					
Meglumine Iotroxate					
Meglumine Ioxaglate					
[^{F102} Meloxican	n]				
Melphalan					
Melphalan Hydrochloride	e				
Menotrophin					
Mepenzolate Bromide			25mg (MD) 75mg (MDD)		
Mephenesin					
Mephenesin Carbamate					
Mepivacaine Hydrochloride	2	Any use except ophthalmic use			

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	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
Meptazinol Hydrochlorid	le					
Mequitazine						
[^{F91} Mercapta Bitartrate]	mine					
Mercaptopur	ine					
Mersalyl						
Mersalyl Acid						
Mesalazine						
Mesna						
Mestranol						
Metaraminol Tartrate						
Metergoline						
Metformin Hydrochlorid	de					
Methacyclin	e					
Methacycline Calcium	e					
Methacycline Hydrochlorid						
Methallenoe	stril					
Methicillin Sodium						
Methixene						
Methixene Hydrochlorid	le					
Methocarbar	nol					
Methocidin		Throat lozenges and throat pastilles				

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Methohexito Sodium	ne				
Methoin					
Methoserpid	ine				
Methotrexate	e				
Methotrexate Sodium	2				
Methotrimep	orazine				
Methotrimep Hydrochlorid					
Methotrimep Maleate	orazine				
Methoxamin Hydrochlorid		Nasal sprays or nasal drops not containing liquid paraffin as a vehicle			
Methsuximic	le				
Methyclothia	azide				
Methyldopa					
Methyldopat Hydrochlorid					
Methylepheo			30mg (MD)		
Hydrochlorid	de		60mg (MDD)		
Methylpredn	isolone				
Methylpredn Acetate	isolone				
Methylpredn Sodium Succinate	isolone				
Methylthiou	racil				
Methysergid Maleate	e				

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Metipranolo	1					
Metirosine						
Metoclopran Hydrochlorid						
Metolazone						
Metoprolol Fumarate						
Metoprolol Succinate						
Metoprolol Tartrate						
Metronidazo	le					
Metronidazo Benzoate	le					
Metyrapone						
Mexiletine Hydrochlorid	de					
Mezlocillin Sodium						
Mianserin Hydrochlorid	de					
Miconazole		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis				
Miconazole Nitrate		External but in the case of vaginal use only external use for the treatment				

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity	
		of vaginal candidiasis			
Mifepristone					
Miglitol					
Milrinone					
Milrinone Lactate					
Minocycline					
Minocycline Hydrochloric	le				
Minoxidil	[^{F139} (1) 2.0 per cent]	[^{F139} (1) External			
	[^{F139} (2) 5.0 per cent	(2) External use for the treatment of alopecia androgenetic in men aged 18 to 65 (but not in women);]	a,		
[^{F87} Mirtazapi	ne]				
Misoprostol					
Mitobronitol					
Mitomycin					
Mitozantrone Hydrochloric					
Mivacurium Chloride					
[^{F112} Mizolasti	ine]				
Moclobemid	e				
[^{F91} Modafinil]				
[^{F88} Moexipril Hydrochlorid					

		from the restrion only medicine	ictions on the sale and sup	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Molgramostin	m				
Molindone Hydrochlorid	e				
Mometasone Furoate					
Moracizine Hydrochlorid	e				
Morazone Hydrochlorid	e				
[^{F87} Moxonidin	ne]				
Mupirocin					
Mupirocin Calcium					
Mustine Hydrochlorid	e				
Nabilone					
Nabumetone					
Nadolol					
Nafarelin Acetate					
Naftidrofuryl Oxalate					
Naftifine Hydrochlorid	e				
Nalbuphine Hydrochlorid	e				
Nalidixic Acid					
Nalorphine Hydrobromid	le				
Naloxone Hydrochlorid	e				
Naltrexone Hydrochlorid	e				

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Naphazoline Hydrochlorid	(1) 0.05 per læent	(1) Nasal sprays or nasal drops not containing liquid paraffin as a vehicle			
	(2) 0.015 per cent	(2) Eye drops			
Naphazoline Nitrate	0.05 per cent	Nasal sprays or nasal drops not containing liquid paraffin as a vehicle			
Naproxen					
Naproxen Sodium					
[^{F91} Naratripta Hydrochlorid					
Natamycin					
[^{F103} Nebivolo Hydrochlorid					
Nedocromil Sodium	[^{F140} 2.0 per cent]	[^{F140} For the prevention, relief and treatment of seasonal and perennial allergic conjunctiviti		[^{F140} Container or package containing not more than 3 ml of medicinal product]	
Nefazodone Hydrochlorid	le				
Nefopam Hydrochlorid	le				
Neomycin					

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity	
Neomycin Oleate					
Neomycin Palmitate					
Neomycin Sulphate					
Neomycin Undecanoate					
Neostigmine Bromide					
Neostigmine Methylsulpha	te				
Netilmicin Sulphate					
Nicardipine Hydrochlorid	e				
Nicergoline					
[^{F112} Niceritrol]				
Nicotinic Acid		Any use, except for the treatment of hyperlipidaen	600mg (MDD) mia		
Nicoumalone					
Nifedipine					
Nifenazone					
Nikethamide					
[^{F90} Nilutamid	e]				
Nimodipine					
Niridazole					
[^{F103} Nisoldipin	ne]				
Nitrendipine					
Nitrofurantoin	1				

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Nitrofurazon	e				
Nizatidine		For the prevention [^{F141} and treatment] of the symptoms of food- related heartburn [^{F141} and meal- induced indigestion] For use in	75mg (MD) [^{F142} 150mg (MDD)] [^{F143} For a maximum period of 14 days]		
		adults and children not less than 16 years			
Nomifensine Maleate					
Noradrenalin	e				
Noradrenalin Acid Tartrate	e				
Norethisteron	ne				
Norethisteroi Acetate	ne				
Norethisteron Enanthate	ne				
Norethynodr	el				
Norfloxacin					
Norgestimate	;				
Norgestrel					
Nortriptyline Hydrochloric					
Noscapine					

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Noscapine Hydrochlorid	le				
Novobiocin Calcium					
Novobiocin Sodium					
Nux Vomica Seed					
Nystatin	[^{F144} 3.0 per cent]	[^{F144} External For use in combination with Hydrocortise of maximum strength 0.5 per cent for intertrigo For use in adults and children not less than 10 years]		[^{F144} Container or package containing not more than 15g of medicinal product]	
Octacosactrin	1				
Octreotide					
Oestradiol Oestradiol Benzoate					
Oestradiol Cypionate					
Oestradiol Dipropionate					
Oestradiol Diundecanoa	te				
Oestradiol Enanthate					

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrativ use or pharmaceuti form		Column 5 Maximum quantity	
Oestradiol Phenylpropic	onate				
Oestradiol Undecanoate					
Oestradiol Valerate					
Oestriol					
Oestriol Succinate					
Oestrogenic Substances Conjugated					
Oestrone					
Ofloxacin					
Olsalazine Sodium					
Omeprazole					
[^{F87} Omeprazo Magnesium]	ole				
Ondansetron Hydrochlorid	le				
Orciprenaline Sulphate	2				
Orphenadrine Citrate	2				
Orphenadrine Hydrochlorid					
Ouabain					
Ovarian Gland Dried					
Oxamniquine	2				
Oxantel Embonate					
Oxaprozin					

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Oxatomide						
Oxedrine Tartrate						
Oxethazaine			10mg (MD)	Container		
		cont not i than 400r	or package containing not more than 400mg of Oxethazaine			
Oxitropium Bromide						
Oxolinic Acid						
Oxpentifyllin	ie					
Oxprenolol Hydrochlorid	le					
Oxybuprocai Hydrochloric		Non- ophthalmic use				
Oxybutynin Hydrochlorid	le					
Oxypertine						
Oxypertine Hydrochloric	le					
Oxyphenbuta	zone					
Oxyphencycl Hydrochlorid						
Oxyphenoniu Bromide	ım		5mg (MD) 15mg (MDD)			
Oxytetracycl	ine					
Oxytetracycl Calcium	ine					
Oxytetracycl Dihydrate	ine					

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
Oxytetracycl Hydrochlori						
Oxytocin, natural						
Oxytocin, synthetic						
Pancreatin	(1) 21,000 European Pharmacopo units of lipase per capsule	(1) capsules eia				
	(2) 25,000 European Pharmacopo units of lipase per gram	(2) powder eia				
Pancuroniun Bromide	1					
[^{F102} Pantopra Sodium]	zole					
Papaverine		(1) By inhaler				
		(2)	(2) 50mg (MD)			
		Otherwise than by inhaler	150mg (MDD)			
Papaverine Hydrochlorie	de	(1) By inhaler				
		(2) Otherwise	(2) Equivalent of 50mg of Papaverine (MD)			
		than by inhaler	Equivalent of 150mg of Papaverine (MDD)			
[^{F92} Paracetar	nol (1) [^{F145} 2	50mg]) Non- effervescent tablets and capsules		(1) The quantity sold or supplied in		
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	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>		
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
	(2) 500 mg	[^{F146} wholly or mainly] for use in children aged less than 12 years (2) Non- effervescent tablets and capsules [^{F147} wholly or mainly] for use in adults and children not less than 12 years	one container or package shall not exceed 32 The quantity of non- effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100
		(3) All preparations other than non- effervescent tablets and capsules	(2) The quantity sold or supplied in one container or package shall not exceed 32 The quantity of non- effervescent tablets, capsules or a

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratiuse or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
				combination of both sold or supplied to a person at any one time shall not exceed 100]		
Paraldehyde				100]		
Paramethadic	ne					
Paramethasor Acetate						
Parathyroid Gland						
Pargyline Hydrochlorid	e					
Paroxetine Hydrochlorid	e					
Pecilocin						
Penamecillin						
Penbutolol Sulphate						
[F102Penciclov	vir]					
Penicillamine	;					
Penicillamine Hydrochlorid						
Pentamidine Isethionate						
Penthienate Bromide			5mg (MD) 15mg (MDD)			

I	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Substance I	Column 2 Maximum trength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity		
Pentolinium Tartrate						
Perfluamine						
Pergolide Mesylate						
Perhexiline Maleate						
Pericyazine						
Perindopril						
Perindopril Erbumine						
Perphenazine						
Phenacetin 0	.1 per cent					
Phenazone		External				
Phenazone Salicylate						
Phenbutrazate Hydrochloride						
Phenelzine Sulphate						
Phenethicillin Potassium						
Phenformin Hydrochloride						
Phenglutarimid Hydrochloride	e					
Phenindione						
[^{F148} Phenolphth	alein.]					
Phenoxybenzar Hydrochloride	nine					
Phenoxymethy	penicillin					
Phenoxymethyl Calcium	penicillin					

		from the restri only medicine	ctions on the sale and support	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Phenoxymethy Potassium	lpenicillin			
Phenprocoumo	n			
Phensuximide				
Phentolamine Hydrochloride				
Phentolamine Mesylate				
Phenylbutazon	e			
Phenylbutazon Sodium	e			
Phenylpropano	lamine	Internal		
Hydrochloride		(1) all preparations except prolonged release capsules, nasal sprays and nasal drops	(1) 25mg (MD) 100mg (MDD)	
		(2) prolonged release	(2) 50mg (MD) 100mg (MDD)	
		capsules		
	3) 2.0 per cent	(3) nasal sprays and nasal drops		
Phenytoin				
Phenytoin Sodium				
Phthalylsulpha	thiazole			
Physostigmine				
Physostigmine Aminoxide Salicylate				

		from the restr n only medicin	ictions on the sale and supp es	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrat use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Physostigmi Salicylate	ne			
Physostigmi Sulphate	ne			
[^{F90} Phytomer	nadione	Any use except the prevention or treatment of haemorrhagi disorders]		
Picrotoxin				
Pilocarpine				
Pilocarpine Hydrochlorie	de			
Pilocarpine Nitrate				
Pimozide				
Pindolol				
Pipenzolate			5mg (MD)	
Bromide			15mg (MDD)	
Piperacillin Sodium				
Piperazine Oestrone Sulphate				
Piperidolate	1.		50mg (MD)	
Hydrochlori	ae		150mg (MDD)	
Pipothiazine Palmitate				
Piracetam				
Pirbuterol Acetate				
Pirbuterol Hydrochlori	de			

	Exemptions	from the restri	ctions on the sale and suppl	ly of
Column 1 Substance		only medicine Column 3 Route of administrati use or pharmaceuti	column 4 Treatment limitations on,	Column 5 Maximum quantity
[^{F149} Pirenzep Dihydrochlo Monohydrat	ride	form		
Pirenzepine Hydrochlori	de			
Piretanide				
Piroxicam	0.5 per cent	External For the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries For use in adults and children not less than 12 years	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
[^{F112} Piroxica Beta- cyclodextrin				
Pituitary Gland (Whole Dried)		By inhaler		
Pituitary Powdered (Posterior Lobe)		By inhaler		

	prescription	from the restri n only medicine	ctions on the sale and suppos	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity	
Pivampicilli	1				
Pivampicillin Hydrochlorid					
Pivmecillina	m				
Pivmecillina Hydrochlorid					
Pizotifen					
Pizotifen Malate					
Plicamycin					
Podophylloto	oxin				
Podophyllun	1				
Podophyllun Indian	1				
Podophyllun		External			
Resin	cent	Ointment or impregnated plaster			
Poldine			2mg (MD)		
Methylsulph	ate		6mg (MDD)		
Polidexide					
Polyestradio Phosphate	1				
Polymyxin B Sulphate					
Polythiazide					
Poppy Capsule					
Potassium Arsenite	0.0127 per cent				
Potassium Bromide					
Potassium Canrenoate					
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Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Potassium Clavulanate					
Potassium Perchlorate					
Practolol					
Pralidoxime Chloride					
Pralidoxime Iodide					
Pralidoxime Mesylate					
[^{F91} Pramipex] Hydrochloric					
Pravastatin Sodium					
Prazosin Hydrochlorid	le				
Prednisolone					
Prednisolone Acetate					
Prednisolone Butylacetate					
Prednisolone Hexanoate					
Prednisolone Metasulphob					
Prednisolone Metasulphob Sodium					
Prednisolone Pivalate					
Prednisolone Sodium Phosphate					

		from the restric only medicine	ctions on the sale and sup s	pply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Prednisolone Steaglate				
Prednisone				
Prednisone Acetate				
Prenalterol Hydrochlorid	e			
Prenylamine Lactate				
Prilocaine Hydrochlorid	e	Non- ophthalmic use		
Primidone				
Probenecid				
Probucol				
Procainamide Hydrochlorid				
Procaine Hydrochlorid	e	Non- ophthalmic use		
Procaine Penicillin				
Procarbazine Hydrochlorid	e			
Prochlorperaz	zine			
Prochlorperaz Edisylate	zine			
Prochlorperaz Maleate	z i^{ft@6}3mg]	[^{F106} Buccal tablets for the treatment of nausea and vomiting in cases of previously diagnosed migraine	[^{F106} 12mg (MDD)]	[^{F106} Container or package containing not more than 8 tablets]

		Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
		<i>form</i> only. For				
		use in				
		persons aged 18				
		years and				
		over.]				
Prochlorperaz Mesylate	zine					
Procyclidine Hydrochlorid	e					
Progesterone						
Prolactin						
Proligestone						
Prolintane Hydrochlorid	e					
Promazine Embonate						
Promazine Hydrochlorid	e					
Propafenone						
Propafenone Hydrochlorid	e					
Propanidid						
Propantheline	e		15mg (MD)			
Bromide			45mg (MDD)			
[^{F103} Propiveri: Hydrochlorid	ne e]		,			
Propofol						
Propranolol Hydrochlorid	e					
Propylthioura	cil					
Proquazone						
Protamine						
Proquazone	icil					

	-	from the restri only medicine	ctions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity
Prothionamic	le			
Protirelin				
Protriptyline Hydrochloric	le			
Proxymetaca Hydrochloric		Non- ophthalmic use		
Pseudoephedrine Hydrochloride		Internal	(a) In the case of a prolonged release preparation	
			120mg (MD)	
			240mg (MDD)	
			(b) in any other case 60mg (MD)	
			240mg (MDD)	
Pseudoephed	lrine		60mg (MD)	
Sulphate			180mg (MDD)	
Pyrantel Embonate		(a) For the treatment of enterobiosis, in adults and children not less than 12 years	(a) 750mg MDD (as a single dose)	(a) Container or package containing not more than 750mg of Pyrantel Embonate
		(b) For the treatment of enterobiosis, in children less than 12 years but not less than 6 years	(b) 500mg MDD (as a single dose)	(b) Container or package containing not more than 750mg of Pyrantel Embonate
		(c) For the treatment of enterobiosis in children less than 6	(c) 250mg MDD (as a single dose)	(c) Container or package containing not more

		from the restri n only medicine	ctions on the sale and supp s	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form	,	Column 5 Maximum quantity
		years but not less than 2 years		than 750mg of Pyrantel Embonate
Pyrantel Tartrate				
Pyrazinamide	e			
Pyridostigmi Bromide	ne			
Pyrimethami	ne			
[^{F103} Quetiapin Fumarate]	ne			
[^{F88} Quinagoli Hydrochloric				
Quinapril				
[^{F149} Quinapri Hydrochloric				
Quinestradol				
Quinestrol				
Quinethazon	e			
Quinidine				
Quinidine Bisulphate				
Quinidine Polygalacture	onate			
Quinidine Sulphate				
Quinine			100mg (MD)	
			300mg (MDD)	
Quinine Bisulphate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Cinchophen			Equivalent of 100mg of Quinine (MD)	
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	-	from the restrictions o only medicines	n the sale and suppl	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Colum Route of Treatm administration, use or pharmaceutical form	nn 4 nent limitations	Column 5 Maximum quantity
		-	lent of 300mg of e (MDD)	
Quinine Dihydrochlo	ride	-	lent of 100mg of e (MD)	
		-	lent of 300mg of e (MDD)	
Quinine Ethyl		-	lent of 100mg of e (MD)	
Carbonate		-	lent of 300mg of e (MDD)	
Quinine Glycerophosphate			llent of 100mg of e (MD)	
		-	llent of 300mg of e (MDD)	
Quinine Hydrobromi	de	-	lent of 100mg of e (MD)	
-		-	lent of 300mg of e (MDD)	
Quinine Hydrochlorid	le	-	lent of 100mg of e (MD)	
			lent of 300mg of e (MDD)	
Quinine Iodobismuth	ate		lent of 100mg of e (MD)	
		Equiva	lent of 300mg of e (MDD)	
Quinine Phosphate		Equiva	lent of 100mg of e (MD)	
		Equiva	lent of 300mg of e (MDD)	
Quinine Salicylate		Equiva	lent of 100mg of e (MD)	
2		Equiva	lent of 300mg of e (MDD)	
Quinine Sulphate		Equiva	lent of 100mg of e (MD)	

		from the restri only medicine	ctions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutit form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
			Equivalent of 300mg of Quinine (MDD)	
Quinine Tannate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine in combination with Urea Hydrochloride	;			
Ramipril [^{F87} Ranitidine Bismuth Citrate]				
Ranitidine Hydrochloride	•	For the short term	Equivalent to 75mg of Ranitidine (MD)	
5		symptomatic relief of	Equivalent to 300mg of Ranitidine (MDD)	
		heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity [^{F150} or the prevention of these symptoms when associated with consuming food and drink]	For a maximum period of 14 days	
Rauwolfia Serpentina				
Rauwolfia Vomitoria				

		from the restrictions on the sale a only medicines	nd supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitate administration, use or pharmaceutical form	Column 5 ions Maximum quantity
Razoxane			
[^{F91} Reboxetin Mesilate]	ne		
Remoxipride Hydrochlorid			
Reproterol Hydrochlorid	de		
Rescinnamir	ne		
Reserpine			
Rifabutin			
Rifampicin			
Rifampicin Sodium			
Rifamycin			
[^{F87} Rimexolo	one]		
Rimiterol Hydrobromi	de		
Risperidone			
Ritodrine Hydrochlorid	de		
Rolitetracycl Nitrate	line		
[^{F107} Ropiniro Hydrochlorio			
Sabadilla			
Salbutamol			
Salbutamol Sulphate			
Salcatonin			
Salcatonin Acetate			
Salmefamol			

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Salmeterol Xinafoate					
Salsalate					
Saralasin Acetate					
Selegiline Hydrochlorid	e				
Semisodium Valproate					
[^{F91} Sertindole]				
[^{F87} Sertraline Hydrochlorid	e]				
Serum Gonadotroph	in				
[^{F87} Sevoflurat	ne]				
Silver Sulphadiazine	e				
Simvastatin					
Sissomicin					
Sissomicin Sulphate					
Snake Venoms					
Sodium Acetrizoate					
Sodium Aminosalicyl	ate				
Sodium Antimonylglu	iconate				
Sodium Arsanilate					
Sodium Arsenate					

		from the restrictions on the sale and sup only medicines	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
Sodium Arsenite	0.013 per cent		
Sodium Bromide			
Sodium Clodronate			
Sodium Cromoglyca	te	(a) For nasal admistration	
	(b) 2.0 per cent	(b) For the treatment of acute seasonal allergic conjunctivitis [^{F151} or perennial allergic conjunctivitis]	(b) Container or package containing not more than 10ml of medicinal product
		In the form of aqueous eye drops	
	(c) 4.0 per cent	(c) For the treatment of acute seasonal allergic conjunctivitis In the form	(c) Container or package containing not more than 5g of medicinal
		of an eye ointment	product
Sodium Ethacrynate			
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices	
		(2) Other preparations for use in the prevention	
		124	

		from the restri only medicine	ctions on the sale and suppos	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceute form of dental		Column 5 Maximum quantity	
		caries In the form			
		of (a) tablets or drops	(a) 2.2 mg (MDD)		
	(b) 0.2 per cent	(b) mouth rinses other than those for daily use			
	(c) 0.05 per cent	(c) mouth rinses for daily use			
Sodium Fusidate					
Sodium Metrizoate					
Sodium Monofluoro	1.14 per phæspthate	Dentrifrice			
Sodium Oxidronate					
Sodium Stiboglucon	ate				
Sodium Valproate					
Somatorelin Acetate					
Sotalol Hydrochlori	de				
[^{F88} Sparfloxa	acin]				
Spectinomy	cin				
Spectinomy Hydrochlori					
Spiramycin					
Spiramycin Adipate					
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		from the restruction only medicine	ictions on the sale and sup	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Spironolacto	ne				
Stannous Fluoride	([^{F152} 1]) 0.62 per cent	([^{F152} 1]) Dentifrice			
	[^{F152} (2) 0.4 per]	[^{F152} (2) Dental gels for use in the prevention and treatment of dental caries and decalcification of the teeth]	Dn		
Stilboestrol					
Stilboestrol Dipropionate	2				
Streptodorna	se	External			
Streptokinas	e	External			
Streptomycin	1				
Streptomycir Sulphate	1				
Strychnine					
Strychnine Arsenate					
Strychnine Hydrochlorid	le				
[^{F90} Strychnin Nitrate]	e				
Styramate					
Succinylsulp	hathiazole				
Sucralfate					
Sulbactam Sodium					

		from the restric only medicine	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Sulbenicillin				
Sulbenicillin Sodium				
Sulconazole Nitrate		External (except vaginal)		
[^{F90} Sulfabenz	amide]			
Sulfacytine				
Sulfadoxine				
Sulfamerazin	e			
Sulfamerazin Sodium	e			
Sulfametopy	azine			
Sulfamonom	ethoxine			
Sulindac				
Sulphacetam	ide			
Sulphacetam Sodium	ide			
Sulphadiazin	e			
Sulphadiazin Sodium	e			
Sulphadimeth	noxine			
Sulphadimidi	ne			
Sulphadimidi Sodium	ne			
Sulphafurazo	le			
Sulphafurazo Diethanolam				
Sulphaguanic	line			
Sulphaloxic Acid				
Sulphamethiz	zole			

		from the restri only medicine	ictions on the sale and supper	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
Sulphametho	oxazole				
Sulphametho	oxydiazine				
Sulphametho	xypyridazine				
Sulphametho Sodium	xypyridazine				
Sulphamoxol	le				
Sulphanilami	ide				
Sulphaphena	zole				
Sulphapyridi	ne				
Sulphapyridi Sodium	ne				
Sulphasalazi	ne				
Sulphathiazo	le				
Sulphathiazo Sodium	le				
Sulphaurea					
Sulphinpyraz	zone				
Sulpiride					
Sultamicillin					
Sultamicillin Tosylate					
Sulthiame					
Sumatriptan Succinate					
Suprofen					
Suxamethoni Bromide	um				
Suxamethoni Chloride	um				
Suxethonium Bromide	l				

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity			
[^{F103} Tacalcito Monohydrate							
Tacrine Hydrochlorid	de						
Talampicillir	ı						
Talampicillir Hydrochlorid							
Talampicillir Napsylate	1						
Tamoxifen							
Tamoxifen Citrate							
[^{F102} Tamsulo Hydrochlorid							
[^{F87} Tazaroter	ne]						
Tazobactam Sodium							
Teicoplanin							
[^{F91} Temocaph Hydrochlorid							
Temocillin Sodium							
Tenoxicam							
Terazosin Hydrochlorid	de						
Terbinafine	[^{F153} 1.0 per cent]	[^{F154} External use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel]		[^{F155} Container or package containing not more than 30 grams of medicinal product]			

		ns from the restrictions on the sale and supply of on only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
[^{F156} Terbinafin∉ ^{F156} 1.0 per Hydrochloride]ent]		([^{F157} 1]) [^{F158} Preparation other than spray solutions, for][^{F156} exter use for the treatment of tinea pedis and tinea cruris]		([^{F157} 1]) [^{F156} Container or package containing not more than 15 g of medicinal product.]	
		[^{F159} (2) Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis]		[^{F159} (2) Container containing not more than 30ml of medicinal product]	
Terbutaline					
Terbutaline Sulphate					
Terfenadine			F160	F160	
Terlipressin					
Terodiline Hydrochlorid	e				
[^{F91} Testostero	ne]				
Tetrabenazine	e				
Tetracosactrii	1				
Tetracosactrii Acetate	1				

		from the restric only medicine.	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratic use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Tetracycline Hydrochlorid	le			
Tetracycline Phosphate Complex				
Tetroxoprim				
Thallium Acetate				
Thallous Chloride				
Thiabendazo	le			
Thiambutosi	ne			
Thiethylpera: Malate	zine			
Thiethylpera Maleate	zine			
Thiocarlide				
Thioguanine				
Thiopentone Sodium				
Thiopropazat Hydrochloric				
Thioproperaz Mesylate	zine			
Thioridazine				
Thioridazine Hydrochlorid				
Thiosinamine	e			
Thiotepa				
Thiothixene				
Thiouracil				
Thymoxamir Hydrochloric				
Thyroid				

	prescription	only medicine	ictions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity
Thyrotrophin	1			
Thyroxine Sodium				
Tiamulin Fumarate				
Tiaprofenic Acid				
Tibolone				
Ticarcillin Sodium				
[^{F102} Ticlopid Hydrochlorid				
Tigloidine Hydrobromi	de			
[^{F102} Tiludron Disodium]	ate			
Timolol Maleate				
Tinidazole				
Tinzaparin				
Tioconazole	(1) 2.0 per cent	(1) External (except vaginal)		
		(2) Vaginal for treatment of vaginal candidiasis		
[^{F88} Tizanidin Hydrochlorid Tobramycin				
Tobramycin Sulphate				
Tocainide Hydrochlorid	de			

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Tofenacin Hydrochlorid	e				
Tolazamide					
Tolazoline Hydrochlorid	e	External			
Tolbutamide					
Tolbutamide Sodium					
Tolfenamic Acid					
Tolmetin Sodium					
[^{F87} Topiramat	e]				
[^{F112} Torasemi	de]				
[^{F102} Toremifer	ne]				
Tramadol Hydrochlorid	e				
Trandolapril					
Tranexamic Acid					
Tranylcypron Sulphate	nine				
Trazodone Hydrochlorid	e				
Treosulfan					
Tretinoin					
Triamcinolon	e				
Triamcinolon Acetonide	¶ ^{F161} (1)] 0.1 per cent	[^{F161} (1)] For the treatment of common mouth ulcers		[^{F161} (1)] Container or package containing not more than 5g of	

		from the restri	ctions on the sale and suppl	y of
Column 1	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
				medicinal product
		[^{F162} (2) In the form of a non- pressurised nasal spray, for the treatment of symptoms of seasonal allergic rhinitis in persons aged 18 years and over]	[^{F162} (2) 110mcg per nostril (MD) 110mcg per nostril (MDD) For a maximum period of 3 months]	[^{F162} Container or package containing not more than 3.575mg of Triamcinolone Acetonide]
Triamcinolone Diacetate				
Triamcinolone Hexacetonide				
Triamterene				
Tribavirin				
Triclofos Sodium				
Trientine Dihydrochlori	le			
Trifluoperazin	e			
Trifluoperazin Hydrochloride				
Trifluperidol				
Trifluperidol Hydrochloride				
Trilostane				
Trimeprazine				
Trimeprazine Tartrate				

<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>			ply of		
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Trimetaphan Camsylate					
Trimetazidine	e				
Trimetazidine Hydrochlorid					
Trimethoprim	1				
Trimipramine Maleate	2				
Trimipramine Mesylate	2				
Tropicamide					
Tropisetron Hydrochlorid	e				
Troxidone					
L- Tryptophan		(1) Oral Dietary supplementat	ion		
Tubocurarine Chloride		(2) External			
Tulobuterol					
Tulobuterol Hydrochlorid	e				
Tyrothricin		Throat lozenges or throat pastilles			
Uramustine					
Urea Stibamine					
Urethane					
Uridine 5'- triphosphate					
Urofollitroph	in				

		from the restric only medicine.	ctions on the sale and sup s	vly of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Urokinase					
Ursodeoxycl Acid	noic				
Vaccine: Bacillus Salmonella Typhi					
Vaccine: Poliomyelitis (Oral)	5				
[^{F88} Valaciclo Hydrochlorid					
Valproic Acid					
[^{F91} Valsartan]				
Vancomycin Hydrochlorid	le				
Vasopressin					
Vasopressin Tannate					
Vecuronium Bromide					
[^{F88} Venlafaxi Hydrochlorid	ne le]				
Verapamil Hydrochlorid	le				
Veratrine					
Veratrum, Green					
Veratrum, White					
Vidarabine					
Vigabatrin					
Viloxazine Hydrochlorid	le				
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		from the restrict only medicine	ictions on the sale and supples	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Vinblastine Sulphate				
Vincristine Sulphate				
Vindesine Sulphate				
Viomycin Pantothenate				
Viomycin Sulphate				
Vitamin A		(1) Internal	(1) 7,500iu (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Acetate		(1) Internal	(1) Equivalent to 7,500iuVitamin A (2,250mcgRetinol equivalent)(MDD)	
		(2) External		
Vitamin A Palmitate		(1) Internal	(1) Equivalent to 7,500iuVitamin A (2,250mcgRetinol equivalent)(MDD)	
		(2) External		
Warfarin				
Warfarin Sodium				
Xamoterol Fumarate				
Xipamide				
Yohimbine Hydrochlorid	e			
[^{F88} Zalcitabin Zidovudine	e]			

	<i>Exemptions from the restrictions on the sale and supply of prescription only medicines</i>			ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratuuse or pharmaceut form	,	Column 5 Maximum quantity
Zimeldine Hydrochlorid	de			
Zolpidem Tartrate				
Zomepirac Sodium				
Zopiclone				
Zuclopenthix Acetate	col			
Zuclopenthix Decanoate	kol			
Zuclopenthix Hydrochlorid				

extu	al Amendments
F87	Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment
	Order 2000 (S.I. 2000/1917), arts. 1(1), 3(c)
F88	Words in Sch. 1 inserted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendmer
	(No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), 2(c)
F89	Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendmer
	Order 2001 (S.I. 2001/2777), arts. 1(1), 3(a)
F90	Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment
	(No. 3) Order 1998 (S.I. 1998/2081), art. 1(1), Sch.
F91	Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order
	2001 (S.I. 2001/2777), arts. 1(1), 3(g)
F92	Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment
	Order 1997 (S.I. 1997/2044), art. 1(1), Sch. 1
F93	Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment
	Order 1999 (S.I. 1999/1044), arts. 1(1), 2(a)
F94	Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment
	(No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(a)
F95	Sch. 1: entries renumbered (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment
	Order 1999 (S.I. 1999/1044), arts. 1(1), 2(a)
F96	Words in Sch. 1 omitted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use
	Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(b)
F97	Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendme
	(No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(a)
F98	Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment
	(No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(a)

- **F99** Word in Sch. 1 substituted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(b**)
- **F100** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(c)(ii)**
- **F101** Words in Sch. 1 substituted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(c)(i)**
- F102 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(h)
- F103 Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), 2(e)
- F104 Word in Sch. 1 substituted (16.9.1997) by The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), 2(a)
- F105 Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(a)
- F106 Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(f)
- F107 Sch. 1 entries inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(e)
- **F108** Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **4(b)**
- F109 Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), 2(a)
- F110 Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(d)
- F111 Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(c)
- F112 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(e)(i)
- F113 Word in Sch. 1 substituted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), 2(a)
- F114 Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(e)
- F115 Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(b)**
- F116 Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(f)(i)
- F117 Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(f)(ii)**
- F118 Words in Sch. 1 omitted (16.9.1998) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(f)(iii)
- F119 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(b)(i)
- F120 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(b)(ii)
- F121 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(b)(iii)
- F122 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(b)(iv)
- **F123** Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(c)**
- F124 Sch. 1: entries renumbered (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), 2(c)

- F125 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(a)
- F126 Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(c)
- F127 Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **3(a)**
- **F128** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(d)
- F129 Word in Sch. 1 inserted (13.8.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(e)(ii)
- **F130** Word in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(ii)**
- **F131** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(i)**
- **F132** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(g)(iii)**
- F133 Words in Sch. 1 inserted (19.1.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 (S.I. 1999/3463), arts. 1(1), 2(b)
- F134 Sch. 1 entries inserted (1.1.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2000 (S.I. 2000/3231), arts. 1(1), 2
- F135 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(e)(i)
- F136 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(e)(ii)
- F137 Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(c)
- **F138** Words in Sch. 1 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(b)**
- F139 Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), 2(b)
- **F140** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **3(h)**
- **F141** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(i)**
- **F142** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(ii)**
- F143 Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), 2(c)(iii)
- F144 Words in Sch. 1 inserted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), 2(d)
- F145 Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(i)
- **F146** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(ii)
- F147 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(iii)
- **F148** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(d)(ii)**
- **F149** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(d)(i)**
- F150 Words in Sch. 1 added (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(c)

- F151 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(d)
- **F152** Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(d)**
- **F153** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(d)(i)**
- F154 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(d)(ii)
- F155 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(d)(iii)
- F156 Words in Sch. 1 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), **3(b)**
- **F157** Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- **F158** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- F159 Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(e)
- F160 Words in Sch. 1 omitted (16.9.1997) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), 2(b)
- F161 Sch. 1 entries re-numbered (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)
- F162 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)

	<i>Circumstances excluding medicinal products from the class of prescription only medicines</i>			
Column 1	Column 2	Column 3	Column 4	
Substance	Maximum strength	Pharmaceutical Form	Maximum Dose	
Codeine and its salts	Equivalent of 1.5 per cent of codeine monohydrate		Equivalent of 20 mg of codeine monohydrate	
Dihydrocodeine and its salts	Equivalent of 1.5 per cent of dihydrocodeine		Equivalent of 10 mg of dihydrocodeine	
Ethylmorphine andits salts	Equivalent of 0.2 per cent of ethylmorphine		Equivalent of 7.5 mg of ethylmorphine	
Morphine and its salts	(1) Equivalent of 0.02 per cent anhydrous morphine	(1) Liquid	(1) Equivalent of3 mg of anhydrousmorphine	
	(2) Equivalent of 0.04 per cent of anhydrous morphine; equivalent of 300	(2) Solid	(2) Equivalent of 3 mg of anhydrous morphine	

SCHEDULE 2

Articles 6(1) and 10

	<i>Circumstances excluding medicinal products from the class of prescription only medicines</i>			
Column 1	Column 2	Column 3	Column 4	
Substance	Maximum strength	Pharmaceutical Form	Maximum Dose	
	mcg of anhydrous morphine			
Medicinal Opium	(1) Equivalent of 0.02 per cent of anhydrous morphine	(1) Liquid	(1) Equivalent of 3 mg of anhydrous morphine	
	(2) Equivalent of 0.04 per cent of anhydrous morphine	(2) Solid	(2) Equivalent of 3 mg of anhydrous morphine	
Pholcodine and its salts	Equivalent of 1.5 per cent of pholcodine monohydrate		Equivalent of 20 mg of pholcodine monohydrate	

SCHEDULE 3

Article 2(b)

DESCRIPTIONS AND CLASSES OF PRESCRIPTION ONLY MEDICINES IN RELATION TO WHICH APPROPRIATE NURSE PRACTITIONERS ARE APPROPRIATE PRACTITIONERS

[^{F163}Co-danthramer Capsules NPF]

[^{F163}Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[^{F163}Co-danthrusate Oral Suspension NPF]

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

[^{F164}Water for Injections]

Textual Amendments

F163 Words in Sch. 3 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 4

F164 Words in Sch. 3 inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 14

[^{F165}SCHEDULE 3A

Article 3A

SUBSTANCES WHICH MAY BE PRESCRIBED, ADMINISTERED OR DIRECTED FOR ADMINISTRATION BY EXTENDED FORMULARY NURSE PRESCRIBERS AND CONDITIONS FOR SUCH PRESCRIPTION OR ADMINISTRATION

Textual Amendments

F165 Sch. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 9

Column 1 Substance	Column 2 Requirements as to use, route of
	administration, or pharmaceutical form
Aciclovir	External use
Acrivastine	Oral
Adapalene	External use
Alclometasone dipropionate	External use
Alimemazine tartrate (trimeprazine tartrate)	Oral
[^{F166} Amitriptyline hydrochloride	Oral]
Amorolfine hydrochloride	External use
Amoxycillin trihydrate	Oral
Aspirin	Oral
Azelaic acid	External use
Azelastine hydrochloride	Ophthalmic use or nasal
[^{F166} Azithromycin dihydrate	Oral]
Baclofen	Oral administration in palliative care
Beclometasone dipropionate	External use or nasal
Betamethasone dipropionate	External use
Betamethasone sodium phosphate	Aural or nasal
Betamethasone valerate	External use
Budesonide	Nasal
[^{F166} Carbamazepine	Oral or rectal]
Carbaryl	External use
Carbenoxolone sodium	Mouthwash
Cetirizine hydrochloride	Oral
Chloramphenicol	Ophthalmic use
Cimetidine	Oral
Cinchocaine hydrochloride	External use
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If*#*Clavulanic acid [****(as potassium clavulanate)]Oral]Clindamycin phosphateExternal useClobetasone butyrateExternal useClobetasone butyrateExternal useClotrimazoleExternal use[****Codeine PhosphateOral][****Codeine PhosphateOral][****Codeine PhosphateOral][****Codeine PhosphateOral][****Codeine PhosphateOral][****Codeine PhosphateOral]CyclizineParenteral administration in palliative careDantrolene sodiumOral administration in palliative careDantronOralDesogestrelOralDesogestrelOralDesamethasone (Desoxymethasone)External useDexamethasone isonicotinateNasal[***DiazepamOral, parenteral or rectal administration in palliative care]Diclofenac diethylammoniumExternal use[***Diclofenae sodiumOral or rectal][***Diclofenae sodiumOral or rectal][***Diclofenae sodiumOral or rectal administration in palliative careDomperidoneOral or care administration in palliative careDomperidoneOral or care administration in palliative careDomperidone maleateOral]Econazole nitrateExternal use[***Diromycin ethyl succinateOral][***Diromycin ethyl succinateOral][***Erythromycin ethyl succinateOral][***Erythromycin stearateOral][***Erythromycin stearateOral][***Eryth	Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
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Iydrocortisone butyrate Exte	ernal use [^{F173} or aural]
Iydrocortisone sodium succinate Loz	ernal use
	zenges
^{F174} Hyoscine Tra	nsdermal administration in palliative care
•	enteral

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form F175
	administration in palliative care
Hyoscine hydrobromide	[^{F176} Oral or parenteral administration in palliative care]
Ibuprofen	External use or oral
Ibuprofen lysine	Oral
[^{F166} Imipramine hydrochloride	Oral]
Ipratropium bromide	Nasal
Isotretinoin	External use
Ketoconazole	External use
Ketoprofen	External use
Levocabastine hydrochloride	Ophthalmic use or nasal
Levomepromazine (methotrimeprazine) maleate	Oral administration in palliative care
Levomepromazine (methotrimeprazine) hydrochloride	Parenteral administration in palliative care
Levonorgestrel	Oral
[^{F166} Lignocaine hydrochloride	External use or parenteral]
Lithium succinate	External use
Lodoxamide trometamol	Ophthalmic use
Loperamide hydrochloride	Oral
Loratadine	Oral
[^{F168} Lorazepam	Oral or parenteral administration in palliative care]
[^{F166} Lymecycline	Oral]
Mebendazole	Oral
Medroxyprogesterone acetate	Parenteral
Mestranol	Oral
Metoclopramide hydrochloride	Oral or parenteral administration in palliative care
Metronidazole	[^{F177} External use, oral or rectal]
Metronidazole benzoate	Oral
Miconazole	Dental lacquer
Miconazole nitrate	External use

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form	
[^{F168} Midazolam	Parenteral administration in palliative care]	
Minocycline	Oral	
[^{F170} Mizolastine	Oral]	
[^{F170} Minocycline hydrochloride	Oral	
Mometasone furoate	External use or nasal	
Nedocromil sodium	Ophthalmic use	
Nefopam hydrochloride	Oral	
Neomycin sulphate	Aural	
Neomycin undecenoate	Aural	
Nitrofurantoin	Oral	
Nizatidine	Oral	
Norethisterone 9	Oral	
Norethisterone acetate	Oral	
Norethisterone enanthate	Parenteral	
Norgestimate	Oral	
Norgestrel	Oral	
[^{F166} Nortriptyline hydrochloride	Oral]	
Nystatin	External use	
Oxytetracycline dihydrate	Oral	
Paracetamol	Oral	
Penciclovir	External use	
Piroxicam	External use	
[^{F166} Prednisolone	Oral]	
Prednisolone hexanoate	External use	
Prednisolone sodium phosphate	Aural [^{F178} or oral]	
Ranitidine hydrochloride	Oral	
[^{F166} Salbutamol sulphate	Inhalation]	
Silver sulphadiazine	External use	
Sodium cromoglycate	Ophthalmic use	
[^{F166} Sodium fusidate	External use]	
Streptodornase	External use	
Streptokinase	External use	

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
Sulconazole nitrate	External use
Terbinafine hydrochloride	External use
[^{F166} Terbutaline sulphate	Inhalation]
Tetracycline hydrochloride	External use or oral
Tretinoin	External use
Triamcinolone acetonide	External use, aural, nasal or oral paste
Trimethoprim	Oral
Tuberculin PPD	Parenteral
Vaccine, Adsorbed Diphtheria	Parenteral
Vaccine, Adsorbed Diphtheria And Tetanus	Parenteral
Vaccine, Adsorbed Diphtheria And Tetanus For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis (Acellular Component)	Parenteral
Vaccine, BCG	Parenteral
Vaccine, BCG Percutaneous	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib)	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib) with Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Haemophilus Influenzae Type B, Diphtheria, Tetanus And Acellular Pertussis	Parenteral
Vaccine, Hepatitis A	Parenteral
Vaccine, Hepatitis A With Typhoid	Parenteral
Vaccine, Hepatitis A, Inactivated, With Recombinant (DNA) Hepatitis B	Parenteral
Vaccine, Hepatitis B	Parenteral
Vaccine, Influenza	Parenteral
Vaccine, Live Measles, Mumps And Rubella (MMR)	Parenteral
Vaccine, Meningococcal Group C Conjugate	Parenteral
Vaccine, Meningococcal Polysaccharide A and C	Parenteral

Column 1	Column 2
Substance	Requirements as to use, route of
	administration, or pharmaceutical form
Vaccine, Pneumococcal	Parenteral
F179	F179
Vaccine, Poliomyelitis, Live (Oral)	Oral
Vaccine, Rubella, Live	Parenteral
Vaccine, Tetanus, Adsorbed	Parenteral
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Parenteral
[^{F170} Water for Injections	Parenteral]]

Textual Amendments

- F166 Sch. 3A entries inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(g)
- F167 Words in Sch. 3A added (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 3(a)
- **F168** Words in Sch. 3A inserted (10.12.2003) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2003 (S.I. 2003/2915), arts. 1(1), **3**
- F169 Words in Sch. 3A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 15(a)
- F170 Words in Sch. 3A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 15(c)
- F171 Words in Sch. 3A inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(a)
- F172 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), **3(b)**
- **F173** Words in Sch. 3A added (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), **3(b)**
- F174 Words in Sch. 3A inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 3(d)
- F175 Words in Sch. 3A omitted (18.5.2004) by virtue of The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 3(c)
- F176 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(d)
- F177 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(e)
- **F178** Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), **3(f)**
- F179 Words in Sch. 3A omitted (4.4.2003) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 15(b)

[^{F180}SCHEDULE 3B

Regulation 3B(3)(a)(iii)

PARTICULARS FOR CLINICAL MANAGEMENT PLANS

Textual Amendments

F180 Sch. 3B inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 16

A clinical management plan shall contain the following particulars-

- (a) the name of the patient to whom the plan relates;
- (b) the illnesses or conditions which may be treated by the supplementary prescriber;
- (c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;
- (d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;
- (e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;
- (f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;
- (g) the arrangements for notification of-
 - (i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and
 - (ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and
- (h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.]

SCHEDULE 4

Article 8(4)(c)

SUBSTANCES NOT TO BE CONTAINED IN A PRESCRIPTION ONLY MEDI CINE SOLD OR SUPPLIED UNDER THE EXEMPTION CONFERRED BY ARTICLE 8(3)

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

- Hexobarbitone
- Hexobarbitone Sodium
- Hydrobromic Acid
- Meclofenoxate Hydrochloride

Methohexitone Sodium Pemoline Piracetam Potassium Bromide Prolintane Hydrochloride Sodium Bromide Strychnine Hydrochloride Tacrine Hydrochloride Thiopentone Sodium

SCHEDULE 5

Article 11(1)(a)

EXEMPTION FOR CERTAIN PERSONS FROM SECTION 58(2) OF THE ACT

PART I

EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions		
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines	1.	The sale or supply shall be- (a) subject to the presentation of an order signed by the principal of the institution concerned with education or research or the appropriate head of department in charge of a specified course of research stating- (i) the name of the institution for which the prescription only medicine is required, (ii) the purpose for which the prescription only medicine	
	151			

Column 1 Persons exempted			Column 2 Prescription only medicines to which the exemption applies	Column Z Condition	ns
				(b)	is required, and (iii) the total quantity required, and for the purposes of the education or research with which the institution is concerned.
2.	supp only	ons selling or olying prescription medicines to any of following— a public analyst appointed under section 27 of the Food Safety Act 1990(16) or article 36 of the Food (Northern Ireland) Order 1989(17), an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990,	2. All prescription only medicines.	subject to an order s of any per 1 of this p status of t and the ar only medi shall be o with the e	e or supply shall be the presentation of igned by or on behalf rson listed in column paragraph stating the he person signing it nount of prescription icine required, and nly in connection xercise by those f their statutory
	(3)	a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989,			
	(4)	a person duly authorized by an enforcement authority under sections 111 and 112,			
	(5)	a sampling officer within the meaning of Schedule 3 to the Act.			

^{(16) 1990} c. 16. (17) S.I. 1989/846 (N.I. 6).

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions	
3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(18), the National Health Service (Scotland) Act 1978(19) and the Health and Personal Social Services (Northern Ireland) Order 1972(20), or under any subordinate legislation made under those Acts or that Order.	3. All prescription only medicines.	 3. The sale or supply shall be- (a) subject to the presentation of an order signed by or on behalf of the person so employe or engaged stating the status of the person signing it and the amount of prescription only medicine required, and (b) for the purposes of a scheme referred to in column 1 in this paragraph. 	
4. Registered midwives.	 Prescription only medicines containing any of the following substances– Chloral hydrate Ergometrine maleate Pentazocine hydrochloride [^{F181}Phytomenadion Triclofos sodium. 	 4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is no for parenteral administration. 	
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	 5. Prescription only medicines which are not for parenteral administration and which– (a) are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or 	5. The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.	

^{(18) 1977} c. 49. (19) 1978 c. 29. (20) S.I. 1972/1265 (N.I. 14).

Column 1	Column 2	Column 3	
Persons exempted	Prescription only medicines to which the exemption applies	Conditions	
	 (b) are eye ointments and are prescriptio only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any of the following substances: Atropine sulphate Bethanecol chloride Carbachol Cyclopentola hydrochlorid Homatropine hydrochlorid Naphazoline hydrochlorid Naphazoline nitrate Physostigmin salicylate Physostigmin sulphate Pilocarpine hydrochlorid Pilocarpine nitrate Tropicamide 	te e e ue ue	
6. Registered ophthalmic opticians.	6. Prescription only medicineslisted in column 2 of paragrap5.		
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.	 7. The sale or supply shall be– (a) subject to the presentation of 	

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
		 on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and (b) only for the purpose of testing containers of medicinal products or determining the standards for such containers.
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	 8. The sale or supply shall be only– (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(21) or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons)	9. Amyl nitrite.	9. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.

(**21**) 1972 c. 66.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(22).		
[^{F182} 10. ^{F183} registered chiropodists who hold a certificate of competence in the use of the medicines specified in Column 2 issued by or with the approval of the Chiropodists Board [^{F184} or the Health Professions Council].	 10. The following prescription only medicines— (a) Co-dydramol 10/500 tablets; (b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight; (c) Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume; and (d) Topical hydrocortisone where the maximum strength of the Amorolfine in the lacquer does not exceed 1 per cent by weight in volume; and 	10. The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.]

Textual Amendments

- **F181** Word in Sch. 5 Pt. 1 para. 4 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 4(a)
- F182 Sch. 5 Pt. 1 para. 10 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), art. 1, Sch.
- F183 Word in Sch. 5 Pt. 1 para. 10 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(a)(i)

⁽²²⁾ S.I. 1976/1214 (N.I. 23).

F184 Words in Sch. 5 Pt. 1 para. 10 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(a)(ii)

Article 11(1)(b)

PART II

Column 1 Column 2 Column 3 Persons exempted Prescription only medicines Conditions to which the exemption applies 1. Royal National Lifeboat 1. All prescription only 1. The supply shall be only so Institution and certified first medicines. far as is necessary for the the aiders of the Institution. treatment of sick or injured persons in the exercise of the functions of the Institution. 2. The owner or the master of 2. All prescription only 2. The supply shall be only a ship which does not carry a medicines. so far as is necessary for the doctor on board as part of her treatment of persons on the complement. ship. 3. Persons authorized by 3. Such prescription only 3. The supply shall be subject licences granted under to such conditions and in such medicines, being controlled regulation 5 of the Misuse of drugs, as are specified in the circumstances and to such an Drugs Regulations to supply a licence. extent as may be specified in controlled drug. the licence. 4. Persons requiring 4. Such prescription only 4. The supply shall beprescription only medicines medicines as may be specified for the purpose (a) for the purpose of enabling in the relevant enactment of enabling them them, in the course of any to comply with business carried on by them, to any requirements comply with any requirements made by or in made by or in pursuance of pursuance of any any enactment with respect to such enactment, the medical treatment of their and (b) employees. subject to such conditions and in such circumstances as may be specified in the relevant enactment. 5. Persons operating an 5. Prescription only medicines 5. occupational health scheme. sold or supplied to a person The supply shall be (1)operating an occupational in the course of an health scheme in response to

EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

occupational health scheme.

(2)The individual supplying the prescription only

an order in writing signed by a

doctor or a registered nurse.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
		medicine, if not a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons employed as qualified first-aid personnel on offshore installations.	7. All prescription only medicines.	7. The supply shall be only so far as is necessary for the treatment of persons on the installation.

Article 11(2)

PART III

EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1 Persons exempted	Pre to v	lumn 2 escription only medicines which the exemption blies	Column 3 Conditions
1. F185 registered chiropodists who hold a certificate of competence in the use of	1.	Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than	1. The administration shall be only in the course of their professional practice.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
analgesics issued by or with the approval of the Chiropodists Board [^{F186} or the Health Professions Council].	one of the following substances– [^{F187} Bupivacaine hydrochloride Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride Lignocaine hydrochloride uignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride [^{F188} Mepivacaine hydrochloride] Prilocaine hydrochloride]	
2. Registered midwives.	 Prescription only medicines for parenteral administration containing any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order– [^{F189}Diamorphine] Ergometrine maleate Lignocaine hydrochloride [^{F189}Morphine] Naloxone hydrochloride [^{F189}Morphine] Naloxone hydrochloride Oxytocins, natural and synthetic Pentazocine lactate 	2. The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
	Pethidine hydrochloride Phytomenadione Promazine hydrochloride.	
3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of her complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.
5. Persons operating an occupational health scheme.	5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	 5. — (1) The administration shall be in the course of an occupational health scheme. (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or	6. The administration shall be only so far as is necessary for the immediate treatment

which have been sold or supplied to the operator or 160

for the immediate treatment of sick or injured persons on

Column 1 Persons exempted	Column 2 Prescription of to which the ex applies		Column 3 Conditions
	commander of response to an o signed by a doc	order in writing	the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.	7. Medicinal pr prescription onl by reason only within the class in article 3(c) (p parenteral admi	ly medicines that they fall specified products for	7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgement as to the treatment required.
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescript medicines that parenteral admi	are for	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State [^{F190} or persons who are [^{F191} registered] paramedics].	administra (a) Diaz ml e injer (b) Succ Moo Gela cent infu (bb) [^{F192} com subs Erge Mal per Oxy ml, actir (d) pres only com	on only s for parenteral	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption	Conditions
	applies	
	substances, but no	
	active ingredient-	
	Adrenaline	
	Acid Tartrate	
	Anhydrous	
	Glucose	
	[^{F193} Benzylper	nicillin]
	[^{F194} Bretylium	1
	Tosylate	
	Compound	
	Sodium	
	Lactate	
	Intravenous	
	Infusion	
	(Hartmann's	
	Solution)	
	Ergometrine	
	Maleate	
	[^{F193} Frusemide	e]
	Glucose	
	Heparin	
	Sodium	
	Lignocaine	
	Hydrochlorid	
	[^{F193} Metoclop:	
	[^{F193} Morphine	
	Sulphate]	
	Nalbuphine	
	Hydrochlorid	e
	Naloxone	
	Hydrochlorid	8
	Polygeline	
	[^{F195} Reteplase	
]	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride	
	[^{F193} Streptokin	nase
	[^{F195} Tenectepl	ase.]

Textual Amendments

F185 Word in Sch. 5 Pt. 3 para. 1 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(i)(aa)
F186 Words in Sch. 5 Pt. 3 para. 1 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(i)(bb)

- F187 Words in Sch. 5 Pt. 3 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 5(2)
- **F188** Words in Sch. 5 Pt. 3 para. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), **4(b)**
- **F189** Words in Sch. 5 Pt. 3 para. 2 inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 4
- **F190** Words in Sch. 5 Pt. 3 para. 9 added (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(a)**
- F191 Word in Sch. 5 Pt. 3 para. 9 substituted for words (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(ii)
- **F192** Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(b)**
- **F193** Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(c)**
- F194 Words in Sch. 5 Pt. 3 para. 9 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **3**
- F195 Words in Sch. 5 Pt. 3 para. 9 inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 4

SCHEDULE 6

Article 16(1)

ORDERS REVOKED

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Order 1983	S.I. 1983/1212
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1984	S.I. 1984/756
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1986	S.I. 1986/586
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1987	S.I. 1987/674
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1987	S.I. 1987/1250
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1988	S.I. 1988/2017
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1991	S.I. 1991/962

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1992	S.I. 1992/1534
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1992	S.I. 1992/2937
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1993	S.I. 1993/1890
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993	S.I. 1993/3256
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1994	S.I. 1994/558
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994	S.I. 1994/3016
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 3) Order 1994	S.I. 1994/3050
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1995	S.I. 1995/1384
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995	S.I. 1995/3174
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1996	S.I. 1996/1514
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1996	S.I. 1996/3193

[^{F196}SCHEDULE 7

Articles 12A to 12C

Textual Amendments
F196 Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000
(S.I. 2000/1917), arts. 1(1), 2(e)

PART I

PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;
- (d) the clinical situations which prescription only medicines of that description or class may be used to treat;
- (e) the clinical criteria under which a person shall be eligible for treatment;
- (f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;
- (g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;
- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;
- (i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;
- (j) the applicable dosage or maximum dosage;
- (k) the route of administration;
- (l) the frequency of administration;
- (m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;
- (n) whether there are any relevant warnings to note, and, if so, what warnings;
- (o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- (p) arrangements for referral for medical advice;
- (q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.

PART II

PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED

Column 1 Class of person by whom a prescription only medicine is supplied or administered	Column 2 Person on whose behalf the Direction must be signed
Common Services Agency	The Agency
[^{F197} Strategic Health Authority]	[^{F197} The Strategic Health Authority]
Health Authority	The Health Authority
Special Health Authority	The Special Health Authority

Column 1 Class of person by whom a prescription only medicine is supplied or administered	Column 2 Person on whose behalf the Direction must be signed
NHS trust [^{F198} or NHS foundation trust]	The trust
Primary Care Trust	The Trust
A person who supplies or administers a prescription only medicine pursuant to an arrangement made with the Common Services Agency, a Health Authority, a Special Health Authority, an NHS trust, [^{F199} , an NHS foundation trust] or a Primary Care Trust	The Common Services Agency, where the arrangement has been made with the Agency; or the Health Authority, Special Health Authority, NHS trust [^{F200} or NHS foundation trust] or Primary Care Trust with which the arrangement has been made]

Textual Amendments

behalf the health care is provided

A police force in England or Wales

- F197 Words in Sch. 7 Pt. 2 inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, Sch. 1 para. 73(4)
- **F198** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), Sch. 2
- **F199** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(4), **Sch. 4**
- F200 Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(3), Sch. 3

[^{F201}PART IIA

PERSONS BY WHOM OR ON WHOSE BEHALF A PATIENT GROUP DIRECTION USED IN THE PROVISION OF HEALTH CARE BY OR ON BEHALF OF THE POLICE, THE PRISON SERVICES OR THE ARMED FORCES MUST BE SIGNED

Textual AmendmentsF201Sch. 7 Pt. 2A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order		
2003 (S.I. 2003/696), arts. 1(1), 17		
Column 1	Column 2	

Direction must be signed The chief officer of police for that police force (within the meaning of the Police Act 1996)

Column 1	Column 2
Force or service by whom or on whose behalf the health care is provided	Person by whom or on whose behalf the Direction must be signed
A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1997)
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	(i) the Surgeon General,
	(ii) a Medical Director General, or
	(iii) a chief executive of an executive agency of the Ministry of Defence]

PART III

CLASSES OF INDIVIDUAL [^{F202}BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

Textual Amendments

F202 Words in Sch. 7 Pt. 3 heading substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **3(2)**

[^{F203}Registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.]

Pharmacists.

F204

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

[^{F205}Registered] chiropodists.

[^{F206}Registered orthoptists.

Registered physiotherapists.

Registered radiographers.]

[^{F207}Registered dietitians.]

[^{F207}Registered occupational therapists.]

[^{F207}Registered orthotists and prosthetists.]

[^{F207}Registered speech and language therapists.]]

Textual Amendments

- F203 Words in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(a)
- F204 Words in Sch. 7 Pt. 3 omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(b)
- F205 Word in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(b)
- F206 Words in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(c)
- F207 Words in Sch. 7 Pt. 3 added (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 5

EXPLANATORY NOTE

(This note is not part of the Order)

This Order consolidates with amendments the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 as amended. That Order and the Orders amending it ("the 1983 Order as amended") are revoked by article 16 and Schedule 6.

This Order specifies the descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail only in accordance with a prescription given by an appropriate practitioner and which may be administered only by or in accordance with the directions of such a practitioner). Many medicinal products are included in a class of such medicines by reason of the substances contained in them (*see*Schedule 1) but others are included because of other criteria, such as their method of administration (*see*article 3). In many cases the provisions of the Act apply subject to exemptions (*see*articles 4 and 5 to 13 and Schedule 1).

The principal amendments relate to those medicines in respect of which marketing authorizations have been granted by the European Community. They include as prescription only medicines those medicines in respect of which such an authorization has been granted which classifies a medicine as being subject to medical prescription (article 3(f)). They exclude from the class of prescription only medicines those medicines in respect of which such an authorization provides for supply which is not subject to medical prescription (article 6(3)).

The differences between this Order and the 1983 Order as amended are in the main technical changes concerning the location of provisions such as the division of material in Schedule 1 to the 1983 Order as amended between the new Schedules 1 and 2. But within the new Schedule 1 there are changes which relate to-

- (a) the deletion from Column 1 of substances which are no longer used in those medicinal products which are on the market;
- (b) the use of current names for the substances which are specified in that Column where their names have changed;

- (c) the incorporation in that Schedule of provisions from article 4 of, and Part IV of Schedule 1 to, the 1983 Order as amended so that they may be found more easily;
- (d) a change in the legal base for the entries in Columns 2 to 4 so that those entries now form the criteria for exemptions from the sale or supply requirements of section 58(2) of the Medicines Act 1968 instead of the criteria for excluding medicinal products from the class of prescription only medicines (*see also*article 5);
- (e) the introduction of a fifth Column which specifies the maximum pack sizes to which exemptions apply.

As this order will impose no additional costs to business a compliance cost assessment has not been prepared.

Status:

Point in time view as at 01/08/2004.

Changes to legislation:

There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997.