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).

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- (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;

"clinical trial exemption" means an exemption conferred by—

- (a) section 31(5) of the Act,
- (b) article 4 of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972,
- (c) article 2 or 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974(3), or
- (d) article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995;] F2

[F3...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;]

[F3: 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;

[F4" district nurse/health visitor prescriber" means—

- (a) a person who—
 - (i) is registered in Part 1 or 12 of the professional register, and
 - (ii) has a district nursing qualification additionally recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983; or
- (b) a person who is registered in Part 11 of the professional register as a health visitor, against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients;]
- "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;

[F5":Extended Formulary" means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;]

[F5" extended formulary nurse prescriber" means a person—

(a) [F6who is a first level nurse, and]

⁽**3**) 1971 c. 38.

^{(3) 1971} c. 38.

against whose name is recorded in [F7the 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;

[F8": first level nurse" means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;]

[F3"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 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;]

[F9" 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 [F10, supplementary prescriber][F11, 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);

[F12"health record" has the meaning given by section 68(2) of the Data Protection Act 1998(6);]

[F3: homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;]

[F13"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;]

I^{F13}"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—

^{(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.

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- (i) an independent hospital, or
- (ii) a private psychiatric hospital,

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

[F13"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;

[F3"marketing authorization" includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;]

"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);

IF3"NHS trust"—

(a) in relation to England and Wales, has the same meaning as in the National Health Service and Community Care Act 1990;

^{(7) 1995} c. 21.

⁽⁸⁾ S.I. 1985/2066.

⁽⁹⁾ SR 1986 No. 52.

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- (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;

[F14"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:

"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; I^{F3}". Patient Group Direction" means—

- (a) in connection with the supply of a prescription only medicine as referred to in article 12A(2), 12B or 12C, 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;

[F3"Primary Care Trust" has the same meaning as in the National Health Service Act 1977;] [F15"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);]

[F16" professional register" means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001;]

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

^{(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.

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- (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;
- "registered midwife" means a person who is registered in Part 10 of [F17the professional register];

[F19" 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;

"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, 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;

[&]quot;registered nurse" means a person who is registered in [F18the professional register];

[&]quot;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);

"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;

[F3"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;]

"state registered chiropodist" means a person who is registered in [F20]the register of chiropodists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001];

[F3ccstate registered paramedic" means a person who is registered in [F21the register of paramedics maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001];]

[F22"Strategic Health Authority" means a Strategic Health Authority established under section 8 of the National Health Service Act 1977;]

[F23" supplementary prescriber" means—

- (a) a first level nurse, or
- (b) 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.

[F3. 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 [F24Schedules 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:

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"g" for gram,
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"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.
- [F25(7) In articles 12 to [F2612E], 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

- 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 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)
- 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)
- F4 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)(b)
- F5 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)
- **F6** 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)**
- 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)(ii)
- 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)(c)
- **F9** 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)**
- F10 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)

- F11 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)
- 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)(f)
- F13 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)
- 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)(h)
- 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)(i)
- F16 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)
- F17 Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(f)
- **F18** Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(g)
- 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)(j)
- **F20** Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(h)
- **F21** Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(i)**
- **F22** 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**
- F23 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)
- **F24** 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)**
- F25 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)
- **F26** 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 [F27, supplementary prescribers], veterinary surgeons and veterinary practitioners;
 - [F28(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

F27 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**

F28 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

[F29 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.
 - [F30(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

- F29 Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4
- **F30** 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

[F31Prescribing 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) [F32Subject 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

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is administered, or is prescribed or directed for administration, in accordance with the specified requirements.

- ,,[
- F33(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

- F31 Art. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 5
- F32 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)
- **F33** 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)**

[F34Prescribing 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;

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- (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 and—
 - (a) the trial is the subject of a clinical trial certificate, or
 - (b) a clinical trial exemption has effect in relation to the supply of the product for the purposes of the trial; and
- (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

F34 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

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

F34 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

F354.			

Textual Amendments

F35 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^{F36} .

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 Methobromide

Hyoscine Methonitrate

Hyoscyamine

Hyoscyamine Hydrobromide

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

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

F36 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

[F37 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

F37 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

F38 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)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

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 [F39, a supplementary prescriber][F40, 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 [F41, supplementary prescriber] [F42, 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 [F43, supplementary prescriber][F44, 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 [F45, supplementary prescriber][F46, 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;
- (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 [F47a 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

- **F39** 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)
- **F40** 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)**

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- 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)
- **F42** 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)
- **F43** 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)
- **F44** 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)
- F45 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)
- **F46** 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)**
- **F47** 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.**—[F⁴⁸(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).
- [^{F49}(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

F48 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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

F49 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.

[F50 Exemption for sale or supply in hospitals

12. 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 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).]

Textual Amendments

F50 Art. 12 substituted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(c)

[F51]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 [F52Strategic Health Authority,] Health Authority or Special Health Authority;
 - (c) an NHS 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).

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- (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 [F53Strategic Health Authority,] Health Authority or Special Health Authority;
 - (c) an NHS 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

- **F51** 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)**
- **F52** 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)**
- **F53** 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)**

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 [F54 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

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- 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—
 - (i) in relation to England and Wales, the provision of general medical services under Part II of the National Health Service Act 1977, or the performance of personal medical 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 medical services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal medical 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 medical services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal medical services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997.

Textual Amendments

- F51 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)
- **F54** 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**

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—
 - [F55(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);
- [F56(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 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 [F58] 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

- **F51** 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)
- F55 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)
- F56 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)
- F57 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)
- **F58** 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)**

[F59 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

F59 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—

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- (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

F59 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.

[F60 Exemptions relating to prescriptions given by nurses

- **13A.**—[^{F61}(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 [F62 or supplementary prescriber] where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the extended formulary nurse prescriber [F62 or supplementary prescriber] has complied with any condition with which he is required to comply by virtue of [F63 articles 3A(2) and (3) or 3B].]

Textual Amendments

- **F60** Art. 13A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 7
- F61 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)
- **F62** 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)
- **F63** 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) [^{F64}, 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 [F65, a supplementary prescriber], [F66 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 [F67, a supplementary prescriber][F68, 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

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- 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.
- [^{F69}(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) [F70 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—

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- (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.

[F71(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

- **F64** 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)**
- **F65** 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)
- **F66** 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)
- **F67** 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)**
- **F68** 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)**
- F69 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)
- **F70** 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)
- F71 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.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

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

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

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



P. Small Permanent Secretary

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

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 Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Maximum Treatment limitations strength administration, quantity use or pharmaceutical form

[F72Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F72Aceclofenac]

Acemetacin

Acetarsol

Acetazolamide

Acetazolamide

Sodium

Acetohexamide

Acetylcholine 0.2 per cent External

Chloride

Acetylcysteine

Acipimox

Aciclovir 5.0 per cent External

For treatment of herpes simplex virus infections of the lips and

infections of the lips and face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

31

Container or package containing not more than 2g of

than 2g of medicinal product

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	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 pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
Acrivastine			24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine		
Acrosoxacin						
Actinomycin C						
Actinomycin D						
[F73Adapalene]					
Adenosine						
Adrenaline		(1) By inhaler				
		(2) External [F ⁷⁴ (except ophthalmic)]				
Adrenaline Acid Tartrate		(1) By inhaler				
		(2) External				
Adrenaline Hydrochloride	e	(1) By inhaler				
		(2) External				
Adrenocortica Extract	1					
Albendazole						
Alclofenac						
Alclometason Dipropionate	e					
Alcuronium Chloride						
Aldesleukin						

Aldosterone

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

 $[^{F72}$ Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F75Aloxiprin (1) 620 mg

(1) Noneffervescent 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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colors
Substance Max

Column 2 Maximum strength Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F73Altretamine]

Amantadine Hydrochloride

Ambenonium

Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine Gentisate Nonophthalmic

use

Amethocaine

Hydrochloride

Nonophthalmic

use

Amikacin Sulphate

Amiloride Hydrochloride

Aminocaproic

Acid

Aminoglutethimide

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Aminopterin

Sodium

Amiodarone

Hydrochloride

Amiphenazole

Hydrochloride

[F76Amisulpride]

Amitriptyline

Amitriptyline

Embonate

Amitriptyline Hydrochloride

Amlodipine Besylate

Ammonium

Bromide

Amodiaquine Hydrochloride

Amorolfine

Hydrochloride

Amoxapine

Amoxycillin

Amoxycillin

Sodium

Amoxycillin

Trihydrate

Amphomycin

Calcium

Amphotericin

Ampicillin

Ampicillin

Sodium

Ampicillin

Trihydrate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Amsacrine

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic use

[F72Anastrozole]

Ancrod

Androsterone

Angiotensin Amide

Anistreplase

Anterior

Pituitary Extract

Antimony

Barium

Tartrate

Antimony

Dimercaptosuccinate

Antimony

Lithium

Thiomalate

Antimony

Pentasulphide

Antimony

Potassium

Tartrate

Antimony

Sodium

Tartrate

Antimony

Sodium

Thioglycollate

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or

pharmaceutical

form

Antimony

Sulphate

Antimony

Trichloride

Antimony

Trioxide

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F73Apraclonidine

Hydrochloride]

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form		Column 5 Maximum quantity			
Arsenic Trioxide							
Arsphenami	ne						
[^{F77} Aspirin	[F78(1) 75mg]	[F78(1) Non- effervescent tablets and capsules]		[F78(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]			
	[^{F79} [^{F80} 50]] mg]	[F80(2)]on-effervescent tablets and capsules		[F80(2)]The quantity sold or supplied in one container or package			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	prescription	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrationse or pharmaceutiform		Column 5 Maximum quantity			
		jorm		shall not exceed 32			
		[F80(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		F81 F81 F81	F81 	F81			
Atenolol							
Atracurium Besylate							
Atropine		(1) Internal(a) by inhaler					
		(b) otherwise	(b) 300mcg (MD)				

	•	from the restri	ictions on the sale and supp	oly 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	
		than by			
		inhaler	1mg (MDD)		
		(2) External (except ophthalmic)	Ting (WDD)		
Atropine	1	(1) Internal			
Methobromic	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	de	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restra	ictions on the sale and suppl es	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	,	Column 5 Maximum quantity
Atropine Sulphate		(1) Internal(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	le	For nasal administration	140mcg per nostril (MD)	Container or package
		For the treatment of seasonal allergic rhinitis [F82 or perennial allergic rhinitis]	280mcg per nostril (MDD)	containing not more than 5,040mcg of Azelastine Hydrochloride
		For use in adults and children not less than [F835 years]		
		As a non-aerosol,		

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1	Column 2	onty meatcines Column 3 Column 4	!	Column 5			
Substance	Maximum strength	Route of Treatment administration, use or pharmaceutical form	t limitations	Maximum quantity			
		aqueous form					
Azidocillin Potassium							
Azithromycin							
Azlocillin Sodium							
Aztreonam							
Bacampicillin Hydrochloride							
Bacitracin							
Bacitracin Methylene Disalicylate							
Bacitracin Zinc							
Baclofen							
[^{F76} Balsalazide Sodium]	e						
Bambuterol Hydrochloride	e						
Barium Carbonate							
Barium Chloride							
Barium Sulphide							
Beclamide							
Beclomethaso	ne						
Beclomethaso Dipropionate	ne	For nasal 100mcg po administration (non- aerosol)	er nostril (MD)	Container or package containing not more than [F8420,000 mcg] of			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	•	from the restra	ictions on the sale and suppl	y 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
		For the prevention and treatment of allergic rhinitis	200 mcg per nostril (MDD) [F85For a maximum period of 3 months]	Beclomethasone Dipropionate
		[F86For 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 Hydrochlorid	le			
Bendrofluazi	de			
Benethamine Penicillin				
Benoxaprofe	n			
Benperidol				
^{F76} Benserazi	de]			
Benserazide Hydrochlorid	le			
Bentiromide				
Benzathine Penicillin				
Benzbromaro	one			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 C Substance M

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Benzhexol Hydrochloride

Benzilonium Bromide

Benzocaine

Any use except ophthalmic use

Benzoctamine Hydrochloride

Benzoyl 10.0 per

External

Peroxide cent

N-Benzoyl Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine Hydrochloride

Betamethasone

Betamethasone Adamantoate

Betamethasone Benzoate Document Generated: 2024-05-24

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Betamethasone

Dipropionate

Betamethasone

Sodium

Phosphate

Betamethasone

Valerate

Betaxolol

Hydrochloride

Bethanechol

Chloride

Bethanidine

Sulphate

Bezafibrate

[F73Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

Fumarate

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

[F76Brimonidine

Tartrate]

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

			ictions on the sale and supply	y of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administrati use or pharmaceuti form	Treatment limitations on,	Maximum quantity
Bromvaleton	e			
Brotizolam				
Budesonide		For nasal administration	200mcg per nostril (MD)	Container or package
		For the prevention or treatment of seasonal allergic rhinitis	[F85For a maximum period of 3 months]	containing not more than 10mg of Budesonide
		200 mcg per nostril (MDD)		
		[F86For use in persons aged 18 years and over]		
		As a non- aerosol, aqueous form		
Bufexamac				
Bumetanide				
Buphenine	la.		6mg (MD)	
Hydrochlorid	le		18mg (MDD)	
Bupivacaine		Any use except ophthalmic use		
Bupivacaine Hydrochlorid	le	Any use except ophthalmic use		
Buserelin Acetate				

Document Generated: 2024-05-24

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Buspirone Hydrochloride

Busulphan

Butacaine Sulphate Any use except ophthalmic use

Butorphanol

Tartrate

Butriptyline Hydrochloride

[F87Cabergoline]

Calcipotriol

[F73Calcipotriol

Hydrate]

Calcitonin

Calcitriol

Calcium

Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium

Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

 ${\sf I}^{F88}$ Candesartan

Cilexetil]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form Candicidin Canrenoic Acid Cantharidin 0.01 per External cent Capreomycin Sulphate Captopril Carbachol Carbamazepine Carbaryl [F76Carbasalate Calcium] Carbenicillin Sodium Carbenoxolone (1) Pellet (1) 5mg (MD) Sodium 25mg (MDD) (2) 2.0 per(2) Gel cent (3) 20mg (MD) (3) (3) 1.0 per (3) Granules for Container cent 80mg (MDD) mouthwash or package in adults containing and children not more not less than than 12 years [F89560mg] Carbenoxolone Sodium Carbidopa Carbimazole Carbocisteine Carbon Tetrachloride

Carboplatin

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

[F76Cefdinir]

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

[F87Cefprozil]

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form Ceftriaxone Sodium Cefuroxime Axetil Cefuroxime Sodium Celiprolol Hydrochloride Cephalexin Cephalexin Sodium Cephaloridine Cephalothin Sodium Cephamandole Nafate Cephazolin Sodium Cephradine Cerium Oxalate Cerivastatin [F76Cerivastatin Sodium] Ceruletide Diethylamine

Chenodeoxycholic

Acid

Chloral External

Hydrate

Cetirizine

Hydrochloride

Chlorambucil

Chloramphenicol

10mg (MDD)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colum Substance Maxin

Column 2 Maximum strength Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium

Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(15)) 5.0 per

cent

(1) Internal

(2) External

Chloroquine Prophylaxis
Phosphate of malaria
Chloroquine Prophylaxis
Sulphate of malaria

Chlorothiazide

Chlorotrianisene

Chlorphenoxamine Hydrochloride

Chlorpromazine

Chlorpromazine

Embonate

Chlorpromazine Hydrochloride

Chlorpropamide

 $[\]textbf{(15)} \;\; \textit{See} S.I. \; 1979/382 \; amended \; by \; S.I. \; 1980/263 \; and \; S.I. \; 1989/1124.$

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

(a) For the (a) 200mg (MD) short-term 800mg (MDD) symptomatic

relief of

For a maximum period of

heartburn, 14 days dyspepsia,

indigestion, acid indigestion and hyperacidity and for the prophylaxis of mealinduced heartburn

(b) For the management night of nocturnal

heartburn by a single

(b) 100mg (MD) to be prophylactic taken as a single dose at

For a maximum period of

14 days

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

dose taken at night

Cimetidine Hydrochloride

Cinchocaine 3.0 per cent Non-

ophthalmic

use

Cinchocaine Equivalent Hydrochloride f 3.0 per

ent Noner ophthalmic use

cent of

Cinchocaine

Cinchophen

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[F73Citalopram

Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin

Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin

Phosphate

		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 pharmaceutiform	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	[F910.05 per cent]	[F91]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)]		[F91]Container or package containing not more than 15g of medicinal product]
Clofibrate				
Clofibrate Clomiphene				
Citrate				
Clomipramin Clomipramin	ie			
Hydrochlorid				
Clomocyclin	e			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Clomocycline

Sodium

Clonidine

Clonidine

Hydrochloride

Clopamide

Clopenthixol

Decanoate

Clopenthixol

Hydrochloride

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 Hydrochloride

Colfosceril Palmitate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Colistin

Sulphate

Colistin

Sulphomethate

Colistin

Sulphomethate

Sodium

Coniine

Conium

7.0 per cent External

Leaf

Corticotrophin

Cortisone

Cortisone

Acetate

Co-

tetroxazine

Co-

trimoxazole

Cropropamide

Crotethamide

Croton Oil

Croton Seed

Curare

Cyclofenil

Cyclopenthiazide

Cyclopentolate

Hydrochloride

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cyproterone

Acetate

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Column 3 C Route of T administration,

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Cytarabine

Cytarabine Hydrochloride

Dacarbazine

Dalteparin Sodium

Danazol

Danthron

Dantrolene Sodium

Dapsone

Dapsone

Ethane

Ortho

Sulphonate

Daunorubicin Hydrochloride

Deanol

Bitartrate

Debrisoquine Sulphate

Demecarium Bromide

Demeclocycline

Demeclocycline

Calcium

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone

Pivalate

Deptropine

Citrate

26mg (MDD)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form Dequalinium (1) 0.25mg (1) Internal: Chloride throat lozenges or throat

pastilles

(2) 1.0 per (2) External: paint cent

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Dexamethasone

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

Dexamethasone

Sodium

Phosphate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines

Column 1 Column 2

Substance Maximum

strength

Column 3 Column 4 Route of

Treatment limitations

administration,

Column 5 Maximum quantity

Dexamethasone

Troxundate

Dexfenfluramine Hydrochloride

Dextromethorphan Hydrobromide

Internal

use or

form

pharmaceutical

(a) In the case of a prolonged release preparation: equivalent of 30mg of Dextromethorphan (MD)

equivalent of 75mg of Dextromethorphan (MDD)

(b) in any other case: equivalent of 15mg of Dextromethorphan (MD)

equivalent of 75mg of Dextromethorphan (MDD)

Dextrothyroxine Sodium

Diazoxide

Dibenzepin Hydrochloride

Dichloralphenazone

Dichlorphenamide

Diclofenac 1.16 per Diethylammorciantn

External

For local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and ioints and in localised forms of

For maximum period of 7 days

Container or package containing not more than 30g of medicinal product

	prescription	only medicines		ply of
Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutifform soft tissue		Column 5 Maximum quantity
		rheumatism		
		For use in adults and children not less than 12 years		
Diclofenac Potassium				
Diclofenac Sodium				
Dicyclomine			10mg (MD)	
Hydrochloride			60mg (MDD)	
[F72Didanosine]				
Dienoestrol				
Diethanolamin Fusidate	e			
Diflucortolone Valerate				
Diflunisal				
Digitalin				
Digitalis Leaf				
Digitalis Prepared				
Digitoxin				
Digoxin				
Dihydralazine Sulphate				
Dihydroergotai Mesylate	nine			
Dihydrostrepto	mycin			
Dihydrostrepto Sulphate	mycin			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Diloxanide

Furoate

Diltiazem Hydrochloride

Dimercaprol

Dimethisoquin Hydrochloride Nonophthalmic use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost Trometamol

Dinoprostone

[F75DiphenhydAllnine Hydrochloridepreparations

except liquid-filled capsules]

[F92Diphenoxy[at2.5 mg] Hydrochloride]

com with Atro Sulp

combination with Atropine Sulphate for short term use as an adjunctive therapy to

[F92In

[^{F92}25 mg (MDD)]

[F92Container or package containing not more than 20 tablets]

	•	•	ctions on the sale and suppl	y of
Column 1	Column 2	only medicine Column 3	S Column 4	Column 5
Substance	Maximum	Route of	Treatment limitations	Maximum
	strength	administrati	on,	quantity
		use or	:1	
		pharmaceuti form	ecai	
		appropriate		
		rehydration in acute		
		diarrhoea		
		For use in		
		persons		
		aged 16 years and		
		over		
		Tablets]		
Dipivefrin Hydrochlorid	e			
Dipyridamole	2			
Disodium Etidronate				
Disodium Pamidronate				
Disopyramide	e			
Disopyramide Phosphate	e			
Distigmine Bromide				
Disulfiram				
Dithranol	1.0 per cent			
Dobutamine Hydrochlorid	e			
[^{F92} Dolasetron Mesilate]	1			
Domperidone	,	[F93For the relief of post- prandial symptoms of excessive fullness, nausea, epigastric	[F9310mg of Domperidone (MD)] [F9340mg of Domperidone (MDD)]	[F93Container or package containing not more than 200mg of Domperidone]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

			ctions on the sale and supply	y of
G 1 -		only medicine		a 1 -
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceuti	,	Column 5 Maximum quantity
		form	Cui	
		bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]		
Domperidone Maleate		[F94For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,]	[F9510 mg of Domperidone as Domperidone Maleate (MD)] [F9540 mg of Domperidone as Domperidone Maleate (MDD)]	[F94Container or package containing not more than [F96200mg] of Domperidone as Domperidone Maleate;]
[^{F76} Donepezil Hydrochlorid				
Dopamine Hydrochlorid	e			
Dopexamine Hydrochlorid	e			
[^{F73} Dorzolam Hydrochlorid				
Dothiepin				
Dothiepin Hydrochlorid	e			
Doxapram Hydrochlorid	e			

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 C Substance M

Column 2 Maximum strength Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Doxazosin

Mesylate

Doxepin

Hydrochloride

Doxorubicin

Doxorubicin

Hydrochloride

Doxycycline

Doxycycline Calcium

Chelate

Doxycycline Hydrochloride

Droperidol

Dydrogesterone

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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Eflornithine Hydrochloride

[^{F72}Eformoterol Fumarate]

Embutramide

Emepronium Bromide

Emetine 1.0 per cent

Emetine Bismuth Iodide

Emetine Equivalent Hydrochloride 1.0 per

cent of Emetine

Enalapril Maleate

Encephalitis Virus, Tickborne, Cent

Eur

Enoxacin

Enoxaparin Sodium

Enoximone

Ephedrine (1) Internal (1) 30mg (MD)

(other than nasal sprays or nasal drops)

60mg (MDD)

(2) 2.0 per cent

(2) Nasal sprays or nasal drops

(3) External

Substance Maximum strength administration, administration, use or pharmaceutical form Sphedrine Hydrochloride (1) Internal (other than nasal sprays or nasal drops cent of Ephedrine (2) Per cent of Ephedrine (3) External (1) Internal (other than nasal sprays or nasal drops or nasal drops or nasal drops or nasal drops or nasal drops) (2) Equivalent of 2.0 per cent of Ephedrine (1) Internal (other than nasal sprays or nasal drops) (2) Equivalent of 30mg of Ephedrine (MD) (3) External (1) Internal (other than nasal sprays or nasal drops) Equivalent of 60mg of Ephedrine (MDD) (2) Equivalent of 60mg of Ephedrine (MDD) (2) Equivalent of 60mg of Ephedrine (MDD) (3) External (3) External (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (3) External (5) Equivalent of 60mg of Ephedrine (MDD) (4) Equivalent of 60mg of Ephedrine (MDD) (5) Equivalent of 60mg of Ephedrine (MDD) (6) Equivalent of 60mg of Ephedrine (MDD) (6) Equivalent of 60mg of Ephedrine (MDD) (7) Equivalent of 60mg of Ephedrine (MDD) (8) Equivalent of 60mg of Ephedrine (MDD) (9) Equivalent of 60mg of Ephedrine (MDD) (1) Equivalent of 60mg of Ephedrine (MDD) (2) Equivalent of 60mg of Ephedrine (MDD)				ictions on the sale and supply	y of
And the properties of the prop	Column 1 Substance	Column 2 Maximum	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Maximum
Equivalent of 2.0 per cent of Ephedrine (3) External (1) Internal (other than nasal sprays or nasal drops) (2) Equivalent of 2.0 per cent of Ephedrine (3) External (1) Equivalent of 30mg of Ephedrine (MD) (2) Equivalent of 2.0 per cent of Ephedrine (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (2) Nasal Equivalent of 2.0 per cent of Ephedrine (3) External (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (5) Equivalent of 2.0 per cent of Ephedrine (6) External (7) Equivalent of 60mg of Ephedrine (MDD) (8) External (9) Equivalent of 60mg of Ephedrine (MDD) (1) Equivalent of 60mg of Ephedrine (MDD) (2) Nasal Equivalent of 3.0 mg of Ephedrine (MDD) (3) External (4) Equivalent of 60mg of Ephedrine (MDD) (5) Equivalent of 60mg of Ephedrine (MDD) (6) External (7) Equivalent of 60mg of Ephedrine (MDD)	Ephedrine Hydrochlorid	le	(other than nasal sprays or nasal	Ephedrine (MD) Equivalent of 60mg of	
Ephedrine dulphate (1) Internal (other than nasal sprays or nasal drops) (2) (2) Nasal Equivalent of 2.0 per cent of Ephedrine (3) External Epicillin Epirubicin		Equivalent of 2.0 per cent of	sprays or		
Sulphate (other than nasal sprays or nasal drops) Equivalent of 60mg of Ephedrine (MDD) (2) (2) Nasal sprays or nasal drops cent of Ephedrine (3) External Epicillin Epirubicin Epirub			(3) External		
Ephedrine (MDD) (2) (2) Nasal Equivalent sprays or of 2.0 per nasal drops cent of Ephedrine (3) External Epicillin Epirubicin Epirubicin Hydrochloride Epithiazide Epoetin Mfa Epoetin Beta Epoprostenol Godium	Ephedrine Sulphate		(other than nasal sprays or nasal		
Equivalent of 2.0 per nasal drops cent of Ephedrine (3) External Epicillin Epirubicin Epirubicin Hydrochloride Epithiazide Epoetin Alfa Epoetin Beta Epoprostenol Godium					
Epirubicin		Equivalent of 2.0 per cent of	sprays or		
Epirubicin Epirubicin Hydrochloride Epithiazide Epoetin Alfa Epoetin Beta Epoprostenol Godium			(3) External		
Epirubicin Hydrochloride Epithiazide Epoetin Alfa Epoetin Beta Epoprostenol Godium	Epicillin				
Aydrochloride Epithiazide Epoetin Alfa Epoetin Beta Epoprostenol Bodium	Epirubicin				
Epoetin Alfa Epoetin Beta Epoprostenol Bodium	Epirubicin Hydrochlorid	le			
Alfa Epoetin Beta Epoprostenol Godium	Epithiazide				
Beta Epoprostenol Godium	Epoetin Alfa				
odium	Epoetin Beta				
rgometrine	Epoprostenol Sodium				
	Ergometrine Maleate				

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Ergometrine

Tartrate

Ergot,

Prepared

Ergotamine

Tartrate

Erythromycin

Erythromycin

Estolate

Erythromycin

Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin

Lactobionate

Erythromycin

Phosphate

Erythromycin

Stearate

Erythromycin

Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

[F97Estramustine

Sodium

Phosphate]

Etafedrine

Hydrochloride

Ethacrynic

Acid

Ethambutol

Hydrochloride

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column .
Substance Maximus

Column 2
Maximum
strength

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Ethamivan

Ethamsylate

Ethiazide

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol Diacetate

Diacetate

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

[F73Exemestane]

Famciclovir

Famotidine

For the short-term symptomatic

10mg (MD)

20mg (MDD)

68

relief of For maximum period of heartburn, 14 days

dyspepsia, indigestion,

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	Exemptions from the restrictions on the sale and supply of						
Column 1	prescription only medicines Column 2 Column 3 Column 4 Column 5						
Substance	Maximum strength	Route of administration use or pharmaceutic form	Maximum quantity				
		acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms					
Fazadinium Bromide							
Felbinac	3.17 per cent	External [F99] For the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions]	For maximum period of 7 days	Container or package containing not more than [F9850g] of medicinal product			
		For use in adults and children not less than 12 years					
Felodipine							
Felypressin							
Fenbufen							

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or pharmaceutical

form

Fenfluramine Hydrochloride

Fenofibrate

Fenoprofen

Fenoprofen Calcium

Fenoterol Hydrobromide

Fenticonazole Nitrate [F91 External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)]

Feprazone

Ferrous Arsenate

[F73Ferumoxsil]

[^{F76}Fexofenadine Hydrochloride]

Filgrastim

Finasteride

Flavoxate Hydrochloride

Flecainide Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone Acetonide

Flucloxacillin Magnesium

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
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			
Flucloxacilli Sodium	n						
Fluconazole		For oral administration for the treatment of vaginal candidiasis [F100] or associated candidal balanitis] in persons aged not less than 16 but less than 60 years	150mg (MD) on	Container or package containing not more than 150mg of Fluconazole			
Flucytosine							
Fludrocortise Acetate	one						
Flufenamic Acid							
Flumazenil							
Flumethasor	ne						
Flumethasor Pivalate	ne						
Flunisolide	0.025 per cent	(a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever	(a) 50mcg per nostril (MD) 100mcg per nostril (MDD)	(a) Container or package containing not more than 6,000mcg of Flunisolide			
		[F101] For use in persons aged 18	[F102For a maximum period of 3 months]				

	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		
		years and over]				
		In the form of a non- pressurised nasal spray		_		
		F103	F103	F103		
				•••		
			F103			
			• • •			
		F103				
		F103				
Fluocinolone Acetonide						
Fluocinonide						
Fluocortin Butyl						
Fluocortolone						
Fluocortolone Hexanoate						
Fluocortolone Pivalate						
Fluorescein Dilaurate						
Fluorometholo	ne					
Fluorouracil						
Fluorouracil Trometamol						
Fluoxetine Hydrochloride						
Flupenthixol Decanoate						

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

Flupenthixol Hydrochloride

Fluperolone

Acetate

Fluphenazine

Decanoate

Fluphenazine

Enanthate

Fluphenazine

Hydrochloride Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen [F1048.75 | F105Throat | F10643.75 mg (MDD)] | F107Container or package containing not more than 140 mg of

Flurbiprofen]

Flurbiprofen Sodium

Fluspirilene

Flutamide

Fluticasone

Propionate

[F76Flutrimazole]

Fluvastatin

Sodium

Fluvoxamine

Maleate

Folic Acic 500mcg (MDD)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form 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

0.1 per cent

Gelsemium 25mg (MD)

75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin

Sulphate

Gestodene

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Glucagon

Glycopyrronium 1mg (MD) Bromide 2mg (MDD)

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride

Griseofulvin

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Halofantrine Hydrochloride

Haloperidol

Haloperidol Decanoate

External Heparin Heparin External

Calcium

Heparin Sodium

Hexachlorophane External

> (a) 2.0 per cent

(a) Soaps

(b) 0.1 per

(b) Aerosols

cent

(c) 0.75 per

(c) cent preparations

> other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

Hexobarbitone

Sodium

Hexoestrol

Hexoestrol Dipropionate

L-Histidine Dietary

Hydrochloride supplementation

Homatropine (1) Internal (1) 0.15mg (MD)

0.45mg (MDD)

(2) External (except ophthalmic)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restrictions on the sale and sup only medicines	pply 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
Homatropine		0.2mg (MD)	
Hydrobromic	de	0.6mg (MDD)	
Homatropine		2mg (MD)	
Methylbrom	iue	6mg (MDD)	
Hydralazine Hydrochlorio	de		
Hydrargaphe	en	Local application to skin	
Hydrobromio Acid	С		
Hydrochloro	thiazide		
Hydrocortisc	one [F108(1)0.5 per cent]	[F108(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]	(Folk(a))ner or package containing not more than 15g of medicinal product]
	[^{F109} (2)].0 per cent	[F109(2)] External (a) For use either alone	(Eln(2))her or package containing not more than 15g

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restr	ictions on the sale and sup es	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance Maximum strength		Route of Treatment limitations administration, use or pharmaceutical form		Maximum quantity
		or in conjun	ction	of medicinal product
		with		(araam ar

or in
conjunction
with
Crotamiton
in
irritant
dermatitis,
contact
allergic
dermatitis,
insect
bite
reactions,
mild

of medicinal product (cream or ointment) or 30ml (spray)

reactions, mild moderate eczema, and either in combination with Clotrimazole [F110 or Miconazole Nitrate] for athlete's foot and candidal intertrigo or in combination with lignocaine for anal

or in combination with lignocaine for anal and perianal itch associated with haemorrhoids

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restrictions on the sale and so only medicines	supply 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
Hydrocortiso	onEquivalent to 1.0 per cent Hydrocortiso	(b) For use in adults and children not less than 10 years (c) Cream ointment or spray External For use	Container or package containing not more than 15g of medicinal product In the case of suppositories, container or package containing no more than 12

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restr	ictions on the sale and sup	oply of
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 [FIII 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 suppositorie	s	
Hydrocortise Butyrate Hydrocortise				
Caprylate Hydrocortiso Hydrogen Succinate	one			
Hydrocortiso Sodium Phosphate	one			
Hydrocortisc Sodium Succinate	onEquivalent to 2.5mg Hydrocortiso	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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	prescription	n only medicine	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	,	Column 5 Maximum quantity
[F75Hydrocya	nnic			
Hydroflumet	hiazide			
Hydroxychlo Sulphate	oroquine	Prophylaxis of malaria		
Hydroxyprog	gesterone			
Hydroxyprog Enanthate	gesterone			
Hydroxyprog Hexanoate	gesterone			
Hydroxyurea	ı			
Hydroxyzine Embonate)			
Hydroxyzine Hydrochlorio		(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

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

			ctions on the sale and supp	ply of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceute form	Treatment limitations on,	Maximum quantity
		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		
Butylbromide		(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		
Hydrobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine	_	(1) Internal		
Methobromi	de	(a) by inhaler		
		(b) otherwise	(b) 2.5mg (MD) 7.5mg (MDD)	

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restri	ictions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form than by	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		inhaler		
Uvoqoina		(2) External(1) Internal		
Hyoscine 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		
Hydrobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine Sulphate	2	(1) Internal		
Sulphace		(a) by inhaler		
		(b) otherwise	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
		than by inhaler	Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restri	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 4 Treatment limitations on,	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		
	[F112(3) 10.0 per cent]	[FII2(3) External]	[F112(3) 125 mg (MD) 500 mg (MDD)]	[F112(3) Container or package containing not more than [F11350g] of medicinal product]
[^{F75} 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)	

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	•	from the restri nonly medicine	ctions on the sale and supp	ly of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceuti form	,	Maximum quantity
		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)]	
darubicin Hydrochloric	le			

Idoxuridine

Ifosfamide

Ignatius Bean

[F72Imidapril Hydrochloride]

Imipenem Hydrochloride

Imipramine

Imipramine Hydrochloride

Imipramine

Ion

Exchange

Resin

Bound Salt

or Complex

[F87Indapamide]

Indapamide

Hemihydrate

Indomethacin

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical

form

Indomethacin

Sodium

Indoprofen

Indoramin

Hydrochloride

Inosine

Pranobex

[F114Insulin]

Iodamide

Iodamide

Meglumine

Iodamide

Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic

Acid

Ipratropium

Bromide

Iprindole

Hydrochloride

Iproniazid

Phosphate

[F76Irbesartan]

Isoaminile

Isoaminile

Citrate

Isocarboxazid

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	•	from the restri	ictions on the sale and suppl es	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti	Column 4 Treatment limitations ion,	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 Hydrochlorid	e			
Isoetharine Mesylate				
Isoniazid				
Isoprenaline Hydrochlorid	e			
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 Hydrochlorid	e			

Column 1 Column 2 Column 3 Substance Maximum Strength Administration. Use or pharmaceutical form Ketoconazole 2.0 per cent For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of the form of a shampoo For the treatment of the form of a shampoo For the treatment of the scalp In the form of a shampoo For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigol Ketoprofen 2.5 per cent External For maximum period of 7 days Ocntainer or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole Ketoprofen 2.5 per cent External For maximum period of 7 days Ocntainer or package containing not more than 120ml of medicinal product days Ocntainer or package containing not more than 2,400mg of Container or package containing not more than 30g of medicinal product	Column 1 Column 2 Substance Maximum strength	Column 3 Route of administration use or pharmaceutiform [F115(a)][F116E2 For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	Column 4 Treatment limitations on, ical xtehn(a) Maximum frequency of application	Maximum quantity [FII5(a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of
For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo I **Fir* (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 maximum period of 7 container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole **External For maximum period of 7 days or package containing not more than 30g of medicinal product and containing not more than 30g of medicinal product and containing not more than 30g of medicinal product and product and containing not more than 30g of medicinal product and containing not more than 30g of medicina	Ketoconazole 2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	frequency of application	Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of
tinea cruris and candidal intertrigo] Ketoprofen 2.5 per cent External For maximum period of 7 Container or package containing not more than 30g of muscular pain in medicinal product		For the treatment of the following mycotic infections of the skin:		
	Ketoprofen 2.5 per cent	tinea cruris and candidal intertrigo] External For rheumatic and muscular pain in	_	or package containing not more than 30g of medicinal

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Lachesine Chloride Lacidipine Lamotrigine Lanatoside C Lanatoside Complex A, B and C [F87Lansoprazole] Latamoxef Disodium [F87]Lercanidipine Hydrochloride] Levallorphan Tartrate Levobunolol Hydrochloride [F75Levocabast Figurivalent (1) Nasal (1) Container Hydrochloride of 0.05 sprays per cent or package Levocabastine symptomatic containing not more treatment than 10 ml of seasonal of medicinal allergic product rhinitis (2) Aqueous (2) eye drops Container or package For the containing symptomatic not more treatment than 4 ml of of seasonal medicinal allergic product] conjunctivitis [F118 Levocarnitine] [F118For dietary

supplementation]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Levodopa

[F76Levofloxacin]

Levonorgestre $[F^{119}0.75mg]$ $[F^{119}for]$

use as an emergency contraceptive in women aged 16 years and over]

Lidoflazine

Lignocaine Non-

ophthalmic

use

Lignocaine Hydrochloride Nonophthalmic

use

Lincomycin

Lincomycin Hydrochloride

Liothyronine Sodium

Lisinopril

Lithium Equivalent of 5mg of Carbonate Lithium (MD)

Equivalent of 15mg of

Lithium (MDD)

Lithium Citrate

Lithium Succinate

Lithium Equivalent of 5mg of

Sulphate Lithium (MD)

Equivalent of 15mg of

Lithium (MDD)

Lobeline (1) Internal (1) 3mg (MD)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restri	ctions on the sale and supplys	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
		jorni	9mg (MDD)	
		(2) External		
Lobeline Hydrochlorid	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	[F120] equivaler of 0.1 per cent Lodoxamide	treatment of ocular	3,	
Lofepramine				
Lofepramine Hydrochloric	le			
Lofexidine Hydrochlorid	le			
Lomefloxacii Hydrochloric				
Lomustine				
Loperamide Hydrochlorid	le	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	F122

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

[F88Lornoxicam]

[F88]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

Exemptions from the restrictions on the sale and supply of prescription only medicines				ly of
Column 1 Substance	orescription Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	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		[F123(a)For the symptomatic relief of irritable bowel syndrome	[F123(a) 135 mg (MD) 405 mg (MDD)]	
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[F123(b) 100 mg (MD) 300 mg (MDD)]	
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride				
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyproge: Acetate	sterone			

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 1 Substance

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Mefenamic

Acid

Mefloquine Hydrochloride

Mefruside

Megestrol

Megestrol Acetate

Meglumine Gadopentetate

Meglumine Iodoxamate

Meglumine Ioglycamate

Meglumine Iothalamate

Meglumine Iotroxate

Meglumine Ioxaglate

[F87Meloxicam]

Melphalan

Melphalan Hydrochloride

Menotrophin

Mepenzolate 25mg (MD) Bromide 75mg (MDD)

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride

Any use except ophthalmic use

Document Generated: 2024-05-24

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Meptazinol

Hydrochloride

Mequitazine

[F76Mercaptamine

Bitartrate]

Mercaptopurine

Mersalyl

Mersalyl

Acid

Mesalazine

Mesna

Mestranol

Metaraminol

Tartrate

Metergoline

Metformin

Hydrochloride

Methacycline

Methacycline

Calcium

Methacycline

Hydrochloride

Methallenoestril

Methicillin

Sodium

Methixene

Methixene

Hydrochloride

Methocarbamol

Methocidin

Throat lozenges and throat pastilles

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine Hydrochloride

Methotrimeprazine

Maleate

Methoxamine 0.25 per Hydrochloridæent Nasal sprays or nasal drops not containing liquid paraffin as a vehicle

Methsuximide

Methyclothiazide

Methyldopa

Methyldopate Hydrochloride

Methylephedrine Hydrochloride 30mg (MD) 60mg (MDD)

Methylprednisolone

Methylprednisolone

Acetate

Methylprednisolone

Sodium Succinate

Methylthiouracil

Methysergide

Maleate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines

prescription only mealcin mn 1 Column 2 Column 3

Column 1 Column 2 Substance Maximum

Maximum Route of Tastrength administration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

Metoprolol

Fumarate

Metoprolol

Succinate

Metoprolol

Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

Mezlocillin

Sodium

Mianserin

Hydrochloride

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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form of vaginal candidiasis Mifepristone Miglitol Milrinone Milrinone Lactate Minocycline Minocycline Hydrochloride $[^{F124}(1) \ 2.0]$ [F124(1)]Minoxidil per cent] External [F124(2) 5.0 (2) External use for the per cent treatment of alopecia androgenetica, in men aged 18 to 65 (but not in women);] [F72Mirtazapine] Misoprostol Mitobronitol Mitomycin Mitozantrone Hydrochloride Mivacurium Chloride

[F97Mizolastine]
Moclobemide
[F76Modafinil]
[F73Moexipril
Hydrochloride]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

Hydrochloride

Morazone

Hydrochloride

[F72Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		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 pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
Naphazoline Hydrochlorid		(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						
[^{F76} Naratripta Hydrochlorid						
Natamycin						
[^{F88} Nebivolol Hydrochlorid						
Nedocromil Sodium	[F1252.0 per cent]	[F125] For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis]	I	[F125] Container or package containing not more than 3 ml of medicinal product]		
Nefazodone Hydrochlorid	le					
Nefopam Hydrochlorid	e					
Neomycin						

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or

pharmaceutical

form

Neomycin

Oleate

Neomycin

Palmitate

Neomycin

Sulphate

Neomycin

Undecanoate

Neostigmine

Bromide

Neostigmine

Methylsulphate

Netilmicin

Sulphate

Nicardipine

Hydrochloride

Nicergoline

[F97Niceritrol]

Nicotinic 600mg (MDD) Any use,

Acid except

for the treatment of

hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F75Nilutamide]

Nimodipine

Niridazole

[F88Nisoldipine]

Nitrendipine

Nitrofurantoin

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restres only medicing	ictions on the sale and supp es	ply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administrat use or pharmaceut form		Maximum quantity	

75mg (MD)

[F127150mg (MDD)]

[F128For a maximum

period of 14 days]

Nitrofurazone

Nizatidine

For the prevention [F126 and treatment] of the symptoms of food-related heartburn [F126 and meal-induced indigestion]

For use in adults and children not less than 16 years

Nomifensine Maleate

Noradrenaline

Noradrenaline

Acid

Tartrate

Norethisterone

Norethisterone

Acetate

Norethisterone

Enanthate

Norethynodrel

Norfloxacin

Norgestimate

Norgestrel

Nortriptyline Hydrochloride

Noscapine

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Noscapine

Hydrochloride

Novobiocin

Calcium

Novobiocin

Sodium

Nux Vomica

Seed

Nystatin

[F1293.0 per cent]

[F129 External

For use in combination

with

Hydrocortisone

of

maximum strength 0.5 per cent for intertrigo

For use in adults and children not less than 10 years]

Octacosactrin

Octreotide

Oestradiol

Oestradiol

Benzoate

Oestradiol

Cypionate

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

[F129]Container or package containing not more than 15g of medicinal product]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength

Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Oestradiol

Phenylpropionate

Oestradiol

Undecanoate

Oestradiol

Valerate

Oestriol

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

[F72Omeprazole

Magnesium]

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Oxatomide

Oxedrine Tartrate

Oxethazaine 10mg (MD) Container or package 30mg (MDD)

containing not more than 400mg of

Oxethazaine

Oxitropium Bromide

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Oxybuprocaine Non-Hydrochloride ophthalmic use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

Oxyphenonium 5mg (MD) Bromide 15mg (MDD)

Oxytetracycline Oxytetracycline Calcium

Oxytetracycline Dihydrate

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		s from the restrictions on the sale and supply of n 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 Hydrochlorio					
Oxytocin, natural					
Oxytocin, synthetic					
Pancreatin	(1) 21,000 European Pharmacopo units of lipase per capsule	(1) capsules			
	(2) 25,000 European Pharmacopo units of lipase per gram	(2) powder eia			
Pancuroniun Bromide	1				
[^{F87} Pantopraz Sodium]	zole				
Papaverine		(1) By inhaler			
		(2)	(2) 50mg (MD)		
		Otherwise than by inhaler	150mg (MDD)		
Papaverine Hydrochloride		(1) By inhaler			
		(2) Otherwise than by inhaler	(2) Equivalent of 50mg of Papaverine (MD)		
			Equivalent of 150mg of Papaverine (MDD)		
[^{F77} Paracetar	nol (1) [^{F130} 2.	50mg]) Non- effervescent tablets and capsules		(1) The quantity sold or supplied in	

Exemptions from the restrictions on the sale and supply of				
		only medicines		
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum	Route of	Treatment limitations	Maximum
	strength	administratio	on,	quantity
		use or		
		pharmaceuti	cal	
		form		
		[F131wholly		one
		or mainly]		container or
		for use		package
		in children		shall not
		aged less		exceed 32
		than 12		The
		years		quantity
	(2) 500	-		of —
	(2) 500	· /		non-
	mg	effervescent		effervescent
		tablets and		tablets,
		capsules		capsules
		[F132wholly		or a
		or mainly]		combination
		for use in		of
		adults and		both
		children not		sold or
		less than 12		supplied
		years		to a
				person
				at any
				one
				time
				shall
				not
				exceed
				100
		(2) 4.11		
		(3) All		(2) The
		preparations		quantity
		other than		sold or
		non-		supplied in
		effervescent		one
		tablets and		container or
		capsules		package
				shall not
				exceed 32
				The .
				quantity
				of
				non-
				effervescent
				tablets,
				capsules
				oup sures

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

> both sold or supplied to a person at any one time

of

combination

not exceed 100]

shall

Paraldehyde

Paramethadione

Paramethasone

Acetate

Parathyroid

Gland

Pargyline Hydrochloride

Paroxetine

Hydrochloride

Pecilocin

Penamecillin

Penbutolol Sulphate

[F87Penciclovir]

Penicillamine

Penicillamine

Hydrochloride

Pentamidine Isethionate

Penthienate Bromide 5mg (MD)

15mg (MDD)

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

olumn 1 Column 2 Column 3

Column 1 Column 2 Substance Maximum

Maximum Route of T strength administration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

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

Phenglutarimide

Hydrochloride

Phenindione

 $[^{F133}$ Phenolphthalein.]

Phenoxybenzamine

Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine Hydrochloride

Phentolamine Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine Hydrochloride Internal

(1) all (1) 25mg (MD) preparations except 100mg (MDD)

except prolonged release capsules, nasal sprays and nasal drops

(2) (2) 50mg (MD) prolonged release capsules (2) 50mg (MDD)

(3) 2.0 per cent

(3) nasal sprays and nasal drops

Phenytoin

Phenytoin Sodium

Phthalylsulphathiazole

Physostigmine

Physostigmine Aminoxide Salicylate Document Generated: 2024-05-24

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Physostigmine Salicylate

Physostigmine Sulphate

[F75Phytomenadione

Any use except the prevention

treatment of haemorrhagic disorders

Picrotoxin

Pilocarpine

Pilocarpine Hydrochloride

Pilocarpine Nitrate

Pimozide

Pindolol

Pipenzolate Bromide 5mg (MD)

15mg (MDD)

Piperacillin Sodium

Piperazine Oestrone Sulphate

Piperidolate Hydrochloride 50mg (MD)

150mg (MDD)

Pipothiazine Palmitate

Piracetam

Pirbuterol Acetate

Pirbuterol Hydrochloride

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	prescription	from the restri	ctions on the sale and suppl	ly 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
[^{F134} Pirenzep Dihydrochlo Monohydrat	ride			
Pirenzepine Hydrochlori	de			
Piretanide				
Piroxicam	0.5 per cent	External	For maximum period of 7	Container
		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	days	or package containing not more than 30g of medicinal product
		adults and children not less than 12 years		
[^{F97} Piroxicar Beta- cyclodextrin				
Pituitary Gland (Whole Dried)		By inhaler		
Pituitary Powdered (Posterior Lobe)		By inhaler		

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pivampicillin

Pivampicillin Hydrochloride

Pivmecillinam

Pivmecillinam Hydrochloride

Pizotifen

Pizotifen Malate

Plicamycin

Podophyllotoxin

Podophyllum

Podophyllum

Indian

Podophyllum 20.0 per

Resin cent

External

Ointment or impregnated plaster

Poldine Methylsulphate 2mg (MD)

6mg (MDD)

Polidexide

Polyestradiol Phosphate

Polymyxin B Sulphate

Polythiazide

Poppy Capsule

Potassium 0.0127 per Arsenite cent

Potassium Bromide

Potassium Canrenoate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

strength

Column 1 Column 2 Substance Maximum Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Potassium

Clavulanate

Potassium

Perchlorate

Practolol

Pralidoxime

Chloride

Pralidoxime

Iodide

Pralidoxime

Mesylate

[F76Pramipexole

Hydrochloride]

Pravastatin

Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone

Butylacetate

Prednisolone

Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Prednisolone Steaglate Prednisone Prednisone Acetate Prenalterol Hydrochloride Prenylamine Lactate Prilocaine Non-Hydrochloride ophthalmic use Primidone Probenecid Probucol Procainamide Hydrochloride Procaine Non-Hydrochloride ophthalmic use Procaine Penicillin Procarbazine Hydrochloride Prochlorperazine Prochlorperazine Edisylate Prochlorperazine 3mg [F91Buccal [F91Container [F9112mg (MDD)] Maleate tablets or package for the containing treatment of not more nausea and than 8 vomiting tablets] in cases of previously diagnosed

migraine

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

			ctions on the sale and supp	ply of
C = 1		only medicine		C = 1
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceution form		Column 5 Maximum quantity
		only. For use in persons aged 18 years and over.]		
Prochlorperaz Mesylate	zine			
Procyclidine Hydrochlorid	le			
Progesterone				
Prolactin				
Proligestone				
Prolintane Hydrochlorid	le			
Promazine Embonate				
Promazine Hydrochlorid	le			
Propafenone				
Propafenone Hydrochlorid	le			
Propanidid				
Propantheline Bromide	e		15mg (MD) 45mg (MDD)	
[^{F88} Propiverir Hydrochlorid				
Propofol				
Propranolol Hydrochlorid	e			
Propylthioura	ncil			
Proquazone				
Protamine Sulphate				
uipnate				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	-	from the restri	ctions on the sale and supply	vof
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Prothionami	de			
Protirelin				
Protriptyline Hydrochloric				
Proxymetaca Hydrochlorio		Non- ophthalmic use		
Pseudoepheo Hydrochlorio		Internal	(a) In the case of a prolonged release preparation	
			120mg (MD)	
			240mg (MDD)	
			(b) in any other case 60mg (MD)	
			240mg (MDD)	
Pseudoepheo	drine		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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administrat use or pharmaceut form	,	Maximum quantity	
		years but not less than 2 years		than 750mg of Pyrantel Embonate	

Pyrantel Tartrate

Pyrazinamide

Pyridostigmine

Bromide

Pyrimethamine

[F88Quetiapine Fumarate]

[^{F73}Quinagolide Hydrochloride]

Quinapril

[F134Quinapril Hydrochloride]

Quinestradol

Quinestrol

Quinethazone

Quinidine

Quinidine Bisulphate

Quinidine

Polygalacturonate

Quinidine Sulphate

Quinine 100mg (MD)

300mg (MDD)

Quinine Equivalent of 100mg of

Bisulphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Cinchophen Quinine (MD)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		pply of
Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
	Equivalent of 300mg of Quinine (MDD)	·
ide	Equivalent of 100mg of Quinine (MD)	
	Equivalent of 300mg of Quinine (MDD)	
	Equivalent of 100mg of Quinine (MD)	
	Equivalent of 300mg of Quinine (MDD)	
ohate	Equivalent of 100mg of Quinine (MD)	?
	Equivalent of 300mg of Quinine (MDD)	
e	Equivalent of 100mg of Quinine (MD)	?
	Equivalent of 300mg of Quinine (MDD)	?
e	Equivalent of 100mg of Quinine (MD)	
	Equivalent of 300mg of Quinine (MDD)	
ıte	Equivalent of 100mg of Quinine (MD)	?
	Equivalent of 300mg of Quinine (MDD)	?
	Equivalent of 100mg of Quinine (MD)	?
	Equivalent of 300mg of Quinine (MDD)	
	Equivalent of 100mg of Quinine (MD)	?
	Equivalent of 300mg of Quinine (MDD)	
	Equivalent of 100mg of Quinine (MD)	?
	prescription Column 2 Maximum strength ide	Maximum strength administration, use or pharmaceutical form Equivalent of 300mg of Quinine (MDD)

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restri only medicine	ctions on the sale and supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	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 [F72Ranitidine Bismuth				
Citrate]				
Ranitidine Hydrochloride	e	For the short term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity [F135] or the prevention of these symptoms when associated with consuming food and drink]	Equivalent to 75mg of Ranitidine (MD) Equivalent to 300mg of Ranitidine (MDD) For a maximum period of 14 days	
Rauwolfia Serpentina				
Rauwolfia Vomitoria				

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Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription 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

Razoxane

[F76Reboxetine

Mesilate]

Remoxipride

Hydrochloride

Reproterol

Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

 $[^{F72}$ Rimexolone]

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

[F92Ropinirole

Hydrochloride]

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F76Sertindole]

[F72Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F72Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	-	from the restri	ictions on the sale and supes	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti 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 conjunctivities [F136 or perennial allergic conjunctivities] In the form of aqueous		(b) Container or package containing not more than 10ml of medicinal product
	(c) 4.0 per cent	eye drops (c) For the treatment of acute seasonal allergic conjunctivitis	s	(c) Container or package containing not more than 5g of
		In the form of an eye ointment		medicinal product
Sodium Ethacrynate				
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices		
		(2) Other preparations for use in the prevention		

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

			ctions on the sale and supp	ply of	
Column 1 Substance	prescription Column 2 Maximum strength	only medicine. Column 3 Route of administration use or pharmaceuti	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		of dental 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 Monofluoroj	1.14 per phæmphate	Dentrifrice			
Sodium Oxidronate					
Sodium Stiboglucona	ate				
Sodium Valproate					
Somatorelin Acetate					
Sotalol Hydrochlori	de				
[^{F73} Sparfloxa	ncin]				
Spectinomy	ein				
Spectinomyo Hydrochlori					
Spiramycin					
Spiramycin Adipate					

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administrat use or pharmaceur form		Maximum quantity	

Stannous Fluoride

 $([^{F137}1])$ 0.62 per cent

 $([^{F137}1])$ Dentifrice

[F137(2) 0.4 per]

 $I^{F137}(2)$ Dental gels for use in the prevention and treatment of dental caries and decalcification of the teeth]

Stilboestrol

Stilboestrol Dipropionate

Streptodornase

External

Streptokinase

External

Streptomycin

Streptomycin Sulphate

Strychnine

Strychnine Arsenate

Strychnine

Hydrochloride

[F75Strychnine

Nitrate]

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1
Substance

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Sulbenicillin

Sulbenicillin

Sodium

Sulconazole Nitrate

External (except vaginal)

[F75Sulfabenzamide]

Sulfacytine

Sulfadoxine

Sulfamerazine

Sulfamerazine

Sodium

Sulfametopyrazine

Sulfamonomethoxine

Sulindac

Sulphacetamide

Sulphacetamide

Sodium

Sulphadiazine

Sulphadiazine

Sodium

Sulphadimethoxine

Sulphadimidine

Sulphadimidine

Sodium

Sulphafurazole

Sulphafurazole

Diethanolamine

Sulphaguanidine

Sulphaloxic

Acid

Sulphamethizole

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

Suxethonium

Bromide

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

[F88Tacalcitol Monohydrate]

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin Napsylate

Tamoxifen

Tamoxifen

Citrate

[^{F87}Tamsulosin Hydrochloride]

[F72Tazarotene]

Tazobactam Sodium

Teicoplanin

[F76Temocapril Hydrochloride]

Temocillin Sodium

Tenoxicam

Terazosin Hydrochloride

[F138] 1.0 per [F139 External Terbinafine [F140 Container cent] use for the or package treatment of containing not more tinea pedis, tinea cruris than 30 and tinea grams of corporis. In medicinal the form of product] a gell

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		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 administration use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
[^{F141} Terbinaf Hydrochlorid	in e 141 1.0 per dæjentj	([F142]]) [F143] Preparation other than spray solutions, for [F141] externuse for the treatment of tinea pedis and tinea cruris]		([F1421]) [F141Container or package containing not more than 15 g of medicinal product.]
		[F144(2) Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis]		[F144(2) Container containing not more than 30ml of medicinal product]
Terbutaline				
Terbutaline Sulphate				
Terfenadine			F145	F145
Torlinrossin				
Terlipressin Terodiline				
Hydrochlorid				
[F76Testostero	one]			
Tetrabenazin	e			
Tetracosactri	n			
Tetracosactri Acetate	n			
Tetracycline				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Tetracycline

Hydrochloride

Tetracycline

Phosphate

Complex

Tetroxoprim

Thallium

Acetate

Thallous

Chloride

Thiabendazole

Thiambutosine

Thiethylperazine

Malate

Thiethylperazine

Maleate

Thiocarlide

Thioguanine

Thiopentone

Sodium

Thiopropazate

Hydrochloride

Thioproperazine

Mesylate

Thioridazine

Thioridazine

Hydrochloride

Thiosinamine

Thiotepa

Thiothixene

Thiouracil

Thymoxamine

Hydrochloride

Thyroid

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Thyrotrophin

Thyroxine

Sodium

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

Sodium

[F87Ticlopidine Hydrochloride]

Tigloidine

Hydrobromide

[F87Tiludronate

Disodium]

Timolol

Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except vaginal)

(2) Vaginal

for treatment of vaginal candidiasis

[^{F73}Tizanidine Hydrochloride]

Tobramycin

Tobramycin Sulphate

Tocainide

Hydrochloride

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

Tofenacin Hydrochloride

Tolazamide

Tolazoline

External

Hydrochloride

Tolbutamide

Tolbutamide Sodium

Tolfenamic

Acid

Tolmetin

Sodium

[F72Topiramate]

[F97Torasemide]

[F87Toremifene]

Tramadol

Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone

Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolonq^{F146}(1)] 0.1 Acetonide per cent

[F146(1)] For the treatment of common mouth ulcers

[F146(1)] Container or package containing not more than 5g of

Tartrate

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

		from the restri nonly medicine	ictions on the sale and suppl	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
				medicinal product
		[F147(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]	[F147(2) 110mcg per nostril (MD) 110mcg per nostril (MDD) For a maximum period of 3 months]	[F147 Container or package containing not more than 3.575mg of Triamcinolone Acetonide]
Triamcinolono Diacetate	e			
Triamcinolone Hexacetonide				
Triamterene				
Tribavirin				
Triclofos Sodium				
Trientine Dihydrochlori	ide			
Trifluoperazir	ne			
Trifluoperazir Hydrochloride				
Trifluperidol				
Trifluperidol Hydrochloride	e			
Trilostane				
Trimeprazine				
Trimeprazine				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Trimetaphan Camsylate

Trimetazidine

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

(1) Oral Tryptophan

Dietary supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

Tulobuterol Hydrochloride

Tyrothricin Throat

> lozenges or throat pastilles

Uramustine

Urea Stibamine Urethane

Uridine 5'triphosphate

Urofollitrophin

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Urokinase

Ursodeoxychoic

Acid

Vaccine:

Bacillus

Salmonella

Typhi

Vaccine:

Poliomyelitis

(Oral)

[^{F73}Valaciclovir Hydrochloride]

Valproic

Acid

[F76Valsartan]

Vancomycin

Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

[F73Venlafaxine Hydrochloride]

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

Veratrum,

White

Vidarabine

Vigabatrin

Viloxazine

Hydrochloride

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form 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 (1) Equivalent to 7,500iu (1) Internal Vitamin A (2,250mcg Acetate Retinol equivalent) (MDD) (2) External Vitamin A (1) Internal (1) Equivalent to 7,500iu Palmitate Vitamin A (2,250mcg Retinol equivalent) (MDD) (2) External Warfarin Warfarin Sodium Xamoterol Fumarate Xipamide Yohimbine Hydrochloride [F73Zalcitabine] Zidovudine

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Exemptions from the restrictions on the sale and supply of prescription only medicines

Column 2 Column 3 Column 4 Column 5

Maximum Route of Treatment limitations Maximum

Substance Maximum Route of Touristration,

dministration,

Maximum quantity

pharmaceutical form

use or

Zimeldine

Column 1

Hydrochloride

Zolpidem

Tartrate

Zomepirac

Sodium

Zopiclone

Zuclopenthixol

Acetate

Zuclopenthixol

Decanoate

Zuclopenthixol

Hydrochloride]

Textual Amendments

- F72 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)
- **F73** 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(c)
- F74 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(a)
- F75 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.
- F76 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)
- F77 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
- F78 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)
- F79 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)
- F80 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)
- **F81** 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)**
- **F82** 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(a)
- F83 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)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- 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)**
- F85 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)
- F86 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)
- **F87** 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)
- F88 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)
- F89 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)
- **F90** 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)**
- 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(f)
- F92 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)
- F93 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)
- F94 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)
- F95 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)
- **F96** 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)
- F97 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)
- F98 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)
- F99 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)
- **F100** 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)
- **F101** 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)**
- F102 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)
- F103 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)
- **F104** 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)**
- **F105** 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)**
- **F106** 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)**
- **F107** 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)**
- F108 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)
- F109 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)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- F110 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)
- F111 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)
- F112 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)
- **F113** 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)
- F114 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)
- F115 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)
- **F116** 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)
- 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(g)(iii)
- **F118** 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)**
- F119 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
- **F120** 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)
- **F121** 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)
- **F122** 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)
- **F123** 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)**
- F124 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)
- **F125** 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)**
- **F126** 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)**
- F127 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)
- F128 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)
- F129 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)
- **F130** 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)
- **F131** 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)
- **F132** 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)
- **F133** 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)**
- **F134** 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)**
- F135 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)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- F136 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)
- F137 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)
- **F138** 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)**
- F139 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)
- F140 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)
- **F141** 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)**
- F142 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)
- **F143** 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)
- F144 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)
- F145 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)
- F146 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)
- F147 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)

SCHEDULE 2

Articles 6(1) and 10

Circumstances excluding medicinal products from the class of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical Form	Column 4 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 of 3 mg of anhydrous morphine		
	(2) Equivalent of 0.04 per cent of anhydrous morphine; equivalent of 300	(2) Solid	(2) Equivalent of 3 mg of anhydrous morphine		

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

	Circumstances excluding medicinal products from the class of prescription only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical	Column 4 Maximum Dose	
	mcg of anhydrous morphine	Form		
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 pholoodine monohydrate		Equivalent of 20 mg of pholoodine monohydrate	

SCHEDULE 3

Article 2(b)

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

[F148Co-danthramer Capsules NPF]

[F148Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F148Co-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

[F149Water for Injections]

Textual Amendments

F148 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

F149 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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

[F150SCHEDULE 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

F150 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 I	Column 2
Substance	Requiremen

Substance 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

Amorolfine hydrochloride External use

Amoxycillin trihydrate Oral Aspirin Oral

Azelaic acid External use

Azelastine hydrochloride Ophthalmic use or nasal

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

Carbaryl External use
Carbenoxolone sodium Mouthwash

Cetirizine hydrochloride Oral

Chloramphenicol Ophthalmic use

Cimetidine Oral

Cinchocaine hydrochloride External use
Clindamycin phosphate External use
Clobetasone butyrate External use
Clotrimazole External use

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1

Substance Requirements as to use, route of

administration, or pharmaceutical form

Cyclizine Parenteral administration in palliative care

Dantrolene sodium Oral administration in palliative care

Dantron Oral
Desogestrel Oral

Desoximetasone (Desoxymethasone) External use

Dexamethasone Aural
Dexamethasone isonicotinate Nasal

Diclofenac diethylammonium External use

Domperidone Oral or rectal administration in palliative care

Domperidone maleate Oral administration in palliative care

Doxycycline [F151 hyclate] Oral

[F152 Doxycycline monohydrate Oral]

Econazole nitrate External use

[F152 Emedastine Ophthalmic use]

Erythromycin External use

Ethinylestradiol Oral
Etynodiol diacetate (ethynodiol diacetate) Oral
Famotidine Oral

Felbinac External use
Fenticonazole nitrate External use

Fexofenadine hydrochloride Oral

[F152]Flucloxacillin magnesium Oral]

Flucloxacillin sodium Oral

Fluconazole Oral

Fludroxycortide (Flurandrenolone) External use

Flumetasone pivalate Aural Flunisolide Nasal

Fluocinolone acetonide External use
Fluocinonide External use
Fluocortolone hexanoate External use
Fluocortolone pivalate External use
Flurbiprofen Lozenges

Fluticasone propionate External use or nasal

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1

Substance Requirements as to use, route of

administration, or pharmaceutical form

Fusidic acid Ophthalmic use

Gentamicin sulphate Aural Gestodene Oral

Hydrocortisone External use
Hydrocortisone acetate External use
Hydrocortisone butyrate External use
Hydrocortisone sodium succinate Lozenges

Hyoscine butylbromide Parenteral administration in palliative care

Hyoscine hydrobromide Oral, parenteral or transdermal administration

in palliative care

Ibuprofen External use or oral

Ibuprofen lysineOralIpratropium bromideNasal

IsotretinoinExternal useKetoconazoleExternal useKetoprofenExternal 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

Lithium succinate External use

Lodoxamide trometamol Ophthalmic use

Loperamide hydrochloride Oral
Loratadine Oral
Mebendazole Oral

Medroxyprogesterone acetate Parenteral

Mestranol Oral

Metoclopramide hydrochloride Oral or parenteral administration in palliative

care

Metronidazole External use or oral

Metronidazole benzoate Oral

Miconazole Dental lacquer

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
Miconazole nitrate	External use
Minocycline	Oral
[F152Minocycline hydrochloride	Oral]
[F152Mizolastine	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
Nystatin	External use
Oxytetracycline dihydrate	Oral
Paracetamol	Oral
Penciclovir	External use
Piroxicam	External use
Prednisolone hexanoate	External use
Prednisolone sodium phosphate	Aural

Ranitidine hydrochloride Oral
Silver sulphadiazine External use

Sodium cromoglycate Ophthalmic use
Streptodornase External use
Streptokinase External use
Sulconazole nitrate External use
Terbinafine hydrochloride External use

Tetracycline hydrochloride External use or oral

Tretinoin External use

Triamcinolone acetonide External use, aural, nasal or oral paste

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1 Substance	Column 2 Requirements as to use, route of
Trimethoprim	administration, or pharmaceutical form 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
Vaccine, Pneumococcal	Parenteral
F153	F153
Vaccine, Poliomyelitis, Live (Oral)	Oral
Vaccine, Rubella, Live	Parenteral
Vaccine, Tetanus, Adsorbed	Parenteral

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2
Substance	Requirements as to use, route of administration, or pharmaceutical form
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Parenteral
[F152Water for Injections	Parenteral]]

Textual Amendments

- F151 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)
- F152 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)
- F153 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)

I^{F154}SCHEDULE 3B

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

PARTICULARS FOR CLINICAL MANAGEMENT PLANS

Textual Amendments

F154 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		lumn 3 nditions
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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions

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 is required, and
- (iii) the total quantity required, and
- (b) for the purposes of the education or research with which the institution is concerned.

- Persons selling or supplying prescription only medicines to any of the 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),
 - (2) an authorized officer within the meaning of section 5(6) of the

- 2. All prescription only medicines.
- 2. The sale or supply shall be subject to the presentation of an order signed by or on behalf of any person listed in column 1 of this paragraph stating the status of the person signing it and the amount of prescription only medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.

^{(16) 1990} c. 16.

⁽¹⁷⁾ S.I. 1989/846 (N.I. 6).

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1		Column 2	Column 3
Persons e.	xempted	Prescription only medicines to which the exemption applies	Conditions
(3)	Food Safety Act 1990, 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.		

- 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.
- - 4. Prescription only medicines containing any of the following substances-

Chloral hydrate Ergometrine maleate

- 3. The sale or supply shall be-
 - (a) subject to the presentation of an order signed by or on behalf of the person so employed 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. 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 not for parenteral administration.

4. Registered midwives.

^{(18) 1977} c. 49.

^{(19) 1978} c. 29.

⁽²⁰⁾ S.I. 1972/1265 (N.I. 14).

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Col	lumn 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies		Conditions
		Pentazocine hydrochloride [^{F155} Phytomenadion Triclofos sodium.	e]
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	5. The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.

- whichare eyes drops and (a) are prescription only medicines by reason only that they contain not more than 0.5 per cent
- Chloramphenicol, (b) are eye ointments and are prescription
 - by reason only that they contain not more than 1.0 per cent Chloramphenicol,

only medicines

- (c) are prescription only medicines by reason only that they contain any of the following substances:

Atropine Cyclopentolate hydrochloride hydrobromide hydrochloride Physostigmine salicylate

sulphate Bethanecol chloride Carbachol Homatropine Naphazoline Naphazoline nitrate

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
	Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.	
6. Registered ophthalmic opticians.	6. Prescription only medicines listed in column 2 of paragraph 5.	 6. The sale or supply shall be only— (a) in the course of their professional practice and (b) in an emergency.
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 an order signed 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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2	Column 3	
Persons exempted	Prescription only medicines to which the exemption applies	Conditions	
		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) or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(22).	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.	

[F15610. State 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.

- nte registered 10. The following who hold a 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
- 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.]

^{(21) 1972} c. 66.

⁽²²⁾ S.I. 1976/1214 (N.I. 23).

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption	Conditions
	applies	
	(d) Topical	
	hydrocortisone	
	where the maximum	
	strength of the	
	hydrocortisone in the	
	medicinal product	
	does not exceed 1	
	per cent by weight in	
	weight.	

Textual Amendments

F155 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)

F156 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.

Article 11(1)(b)

PART II EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines.	1. The supply shall be only so far as is necessary for the the treatment of sick or injured persons in the exercise of the functions of the Institution.
2. The owner or the master of a ship which does not carry a doctor on board as part of her complement.	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the treatment of persons on the ship.
3. Persons authorized by licences granted under regulation 5 of the Misuse of Drugs Regulations to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any	4. Such prescription only medicines as may be specified in the relevant enactment.	4. The supply shall be— (a) for the purpose of enabling them to comply with
	154	

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

C-1 1	C-1 2	C-1 2	
Column I Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions	
business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.		any requirements made by or in pursuance of any such enactment, and (b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.	
5. Persons operating an occupational health scheme.	5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	 (1) The supply shall be in the course of an occupational health scheme. (2) The individual supplying the prescription only 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.	

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
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	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
1. State registered chiropodists who hold a certificate of competence in the use of analgesics issued by or with the approval of the Chiropodists Board.	1. Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than one of the following substances— [F157] 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 Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride [F158] Mepivacaine hydrochloride [F158]	1. The administration shall be only in the course of their professional practice.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1 Column 2		Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
	Prilocaine hydrochloride.]	
2. Registered midwives.	2. 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— Ergometrine maleate Lignocaine Lignocaine Lignocaine hydrochloride Oxytocins, natural and synthetic Pentazocine lactate Pethidine hydrochloride Phytomenadione Promazine hydrochloride.	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.
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
	157	a doctor nor acting

Column 3

Status: Point in time view as at 04/04/2003.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 2

Column 1

Persons exempted	Prescription only medicines to which the exemption applies	Conditions
		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 supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The administration 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 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 products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).	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 prescription only medicines that are for parenteral administration.	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	9. The following prescription only medicines for parenteral administration—	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

Column 1	Column 2		Column 3
Persons exempted		on only medicines	Conditions
		he exemption	
	applies		
[F159] or persons who are state	(a)	Diazepam 5 mg per	shall be only for the purpose of
registered paramedics].		ml emulsion for	cannula flushing.
	(1.)	injection;	
	(b)	Succinylated	
		Modified Fluid	
		Gelatin 4 per cent intravenous	
		infusion;	
	(bb)	[^{F160} medicines	
	(00)		
		containing the substances	
		Ergometrine	
		Maleate 500mcg	
		per ml with	
		Oxytocin 5 iu per	
		ml, but no other	
		active ingredient]	
	(d)	prescription	
	. ,	only medicines	
		containing one	
		or more of	
		the following	
		substances, but no	
		active ingredient-	
		Adrenaline	
		Acid Tartrate	
		Anhydrous	
		Glucose	
		[F161Benzylpen	icillinj
		[F162Bretylium	
		Tosylate]	
		Compound	
		Sodium	
		Lactate Intravenous	
		Infusion	
		(Hartmann's	
		Solution)	
		Ergometrine	
		Maleate	
		[F161Frusemide	1
		Glucose	ı
		Heparin	
		Sodium	
		Soutuin	
		Lignocaine Hydrochloride	

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2	Column 3
Persons exempted Prescription only medicines to which the exemption		Conditions
	applies	
	[F161]Morphine	
	Sulphate]	
	Nalbuphine	
	Hydrochloride	9
	Naloxone	
	Hydrochloride	9
	Polygeline	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride	
	[F161Streptokir	nase]

Textual Amendments

- F157 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)
- **F158** 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)**
- **F159** 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)**
- **F160** 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)**
- **F161** 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)
- **F162** 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

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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2
Column 1 Orders	Column 2 References
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
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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary	S.I. 1996/3193
Drugs) (Prescription Only) Amendment (No. 2)	
Order 1996	

I^{F163}SCHEDULE 7

Articles 12A to 12C

Textual Amendments

F163 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;
- (1) 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.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

PART II

PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED

<u> </u>	C 1 2
Column 1	Column 2
Class of person by whom a prescription only	Person on whose behalf the Direction must be
medicine is supplied or administered	signed
Common Services Agency	The Agency
[F164Strategic Health Authority]	[F164The Strategic Health Authority]
Health Authority	The Health Authority
Special Health Authority	The Special Health Authority
NHS 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 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 or Primary Care Trust with which the arrangement has been made

Textual Amendments

F164 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)**

[F165PART 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 Amendments

F165 Sch. 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
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 England or Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996)
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 [$^{\rm F166}$ BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

Textual Amendments

F166 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)**

Individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, or individuals who are state registered paramedics.

Pharmacists.

Registered health visitors.

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

State registered chiropodists.

[F167] Individuals who are registered in the register of orthoptists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered orthoptists).]

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

[F167] Individuals who are registered in the register of physiotherapists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered physiotherapists).]

[F167] Individuals who are registered in the register of radiographers maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered radiographers).]]

Textual Amendments

F167 Words in Sch. 7 Pt. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 10

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 (seeSchedule 1) but others are included because of other criteria, such as their method of administration (seearticle 3). In many cases the provisions of the Act apply subject to exemptions (seearticles 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;

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Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

- (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 04/04/2003.

Changes to legislation:

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