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;
 - "appropriate nurse practitioner" means-
 - (a) a person who-
 - (i) is registered in Part 1 or 12 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of

^{(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).

- the Nurses, Midwives and Health Visitors Act 1979(3) (referred to below in this definition as "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(4); 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;

[F1"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;]

[FI":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(5);

"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;

"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;

"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;

I^{F1}"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;]

"health prescription" means a prescription issued by a doctor, dentist or nurse prescriber under or by virtue of—

- (a) in England and Wales, the National Health Service Act 1977(6),
- (b) in Scotland, the National Health Service (Scotland) Act 1978(7), and

^{(3) 1979} c. 36; the Parts of the professional register were determined by S.I. 1983/667, amended by S.I. 1989/104 and 1989/1455.

⁽⁴⁾ Approved by S.I. 1983/873, to which there are amendments not relevant to this Order.

^{(5) 1971} c 38

⁽**6**) 1977 c. 49.

^{(7) 1978} c. 29.

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) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(8);

[FI"homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;] "inhaler" does not include an aerosol;

[FI"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(9);

"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(10) and in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986(11);

[F1"NHS trust"—

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

⁽⁸⁾ S.I. 1972/1265 (N.I. 14).

^{(9) 1995} c. 21.

⁽¹⁰⁾ S.I. 1985/2066.

⁽¹¹⁾ SR 1986 No. 52.

"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(12) 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(13); "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;

[F1"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;

[FI"Primary Care Trust" has the same meaning as in the National Health Service Act 1977;] "prolonged release" in relation to a medicinal product means a formulation of that product which—

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

"registered midwife" means a person who is registered in Part 10 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

"registered nurse" means a person who is registered in the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

"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(14);

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

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

^{(12) 1971} c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).

^{(13) 1964} c. 29.

^{(14) 1989} c. 44.

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

[F1"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 the Register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960(15) by the Chiropodists Board;

[F1" state registered paramedic" means a person who is registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Paramedics Board;

"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.

[FI"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 Schedules 1 to 3–
 - (a) entries specified in columns 2 to 5 relate to the substances listed in column 1 against which they appear and where, in relation to a particular substance listed in column 1, an entry in columns 2 to 5 bears a number or letter it relates only to such entries in the other of those columns as bear the same number or letter;
 - (b) the following abbreviations are used:

"g" for gram,

- "iu" for international unit of activity,
- "mcg" for microgram,
- "mg" for milligram,
- "ml" for millilitre
- (6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.
- [F2(7)] In articles 12 to 12C, 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.]

- 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)
- 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)**

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, veterinary surgeons and veterinary practitioners;
 - (b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, appropriate nurse practitioners.

Medicinal products on prescription only

- **3.** Subject to article 6, the following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—
 - (a) medicinal products consisting of or containing a substance listed in column 1 of Schedule 1;
 - (b) medicinal products that are controlled drugs;
 - (c) medicinal products that are for parenteral administration^{F3}...;
 - (d) cyanogenetic substances, other than preparations for external use;
 - (e) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;
 - (f) medicinal products for human use which are classified as subject to medical prescription in marketing authorizations granted under Council Regulation 2309/93(16);

(16) OJ No. L214, 24.8.93, p. 1.

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- (g) medicinal products-
 - (i) which are not of a description and do not fall within a class specified in subparagraphs (a) to (f),
 - (ii) which are of a description in respect of which the conditions specified in section 59(1) are satisfied, and
 - (iii) in respect of which a product licence or marketing authorization has been granted which contains a provision to the effect that the method of sale or supply of the medicinal product is to be only in accordance with a prescription given by an appropriate practitioner.

Textual Amendments

Words in art. 3(c) omitted (13.8.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 2

Duration of special provisions in relation to new medicinal products

4. The duration specified for the purposes of section 59(2)(a) (duration of restrictions for certain new products) shall be a period of 5 years.

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.
- (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

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.

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

- **6.**—(1) A medicinal product shall not be a prescription only medicine by reason that it is a controlled drug listed in Schedule 2 to the Misuse of Drugs Act 1971 where, it—
 - (a) contains not more than one of the substances listed in column 1 of Schedule 2 to this Order and no other controlled drug;
 - (b) contains that substance at a strength that does not exceed the maximum strength specified in column 2 of that Schedule; and
 - (c) is sold or supplied-

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- (i) in such pharmaceutical form as may be specified in column 3 of that Schedule, and
- (ii) for use at a maximum dose which does not exceed that specified in column 4 of that Schedule.
- (2) A medicinal product for human use in respect of which a marketing authorization has been granted under Council Regulation 2309/93/EEC(17) shall not be a prescription only medicine where that authorization does not classify the medicinal product as subject to medical prescription.

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

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

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

Atropine Sulphate Injection

Chlorpheniramine Injection

Cobalt Edetate Injection

Dextrose Injection Strong B.P.C.

Diphenhydramine Injection

Glucagon Injection

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum

Sodium Nitrite Injection

Sodium Thiosulphate Injection

Sterile Pralidoxime

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

Exemptions for emergency sale or supply

- **8.**—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.
 - (2) The conditions referred to in paragraph (1) are-
 - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor who by reason of an emergency is unable to furnish a prescription immediately;
 - (b) that the doctor 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 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(18) 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 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 [F4a 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".

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(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

F4 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. 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).

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.

[F5 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).]

F5 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)

[F6 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 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).

- (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 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.

F6 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)

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—

- (a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or
- (b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;
- (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
- (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (3) In this article—
 - (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
 - (i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997;
 - (ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
 - (iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997;
 - (b) a reference to the provision of NHS primary medical services shall be construed as a reference to—
 - (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.

F6 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)

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—
 - (a) the medicine is supplied or, as the case may be, is administered by such a person 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 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);
 - (c) the Patient Group Direction is signed on behalf of the body with which an arrangement has been made as referred to in paragraph (1)(a); 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

F6 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)

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.

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) 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, an appropriate nurse practitioner, a veterinary surgeon or a veterinary practitioner,
 - (iv) where the appropriate practitioner giving it is a doctor, dentist or appropriate nurse practitioner, the name, address and the age, if under 12, of the person for whose treatment it is given, and
 - (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
 - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
 - (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.
- (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) 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.

Revocations

- **16.**—(1) The Orders specified in Schedule 6 are revoked.
- (2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(19) articles 2 to 6 and Schedules 1 and 2 are revoked.

Signed by authority of the Secretary of State for Health

Baroness Jay Minister of State, Department of Health

Win Griffiths
Parliamentary Under Secretary of State, Welsh
Office

Sam Galbraith
Parliamentary Under Secretary of State, The
Scottish Office

Jeff Rooker Minister of State, Ministry of Agriculture, Fisheries and Food Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 22nd July 1997.



D. C. Gowdy
Permanent Secretary

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



P. Small Permanent Secretary

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 EXEMP TIONS 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

[F7Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F7Aceclofenac]

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

infections of the lips and face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

19

Container or package containing not more than 2g of

than 2g of medicinal product

Status: Point in time view as at 09/08/2000.

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 administratiuse or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
Acrivastine			24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine		
Acrosoxacin						
Actinomycin C						
Actinomycin D						
[F8Adapalene]						
Adenosine						
Adrenaline		(1) By inhaler				
		(2) External				
Adrenaline Acid		(1) By inhaler				
Tartrate		(2) External				
Adrenaline Hydrochloride	e	(1) By inhaler				
		(2) External				
Adrenocortica Extract	ıl					
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

 I^{F7} Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F9Aloxiprin (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 Substance Column 2 Maximum strength

Column 3 Route of administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F8Altretamine]

Amantadine

Hydrochloride Ambenonium

Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine

Non-Gentisate ophthalmic

> use Non-

Amethocaine

Hydrochloride ophthalmic

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 Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Aminopterin

Sodium

Amiodarone

Hydrochloride

Amiphenazole

Hydrochloride

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

Amsacrine

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

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

3 Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic use

[F7Anastrozole]

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

Antimony

Sulphate

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Status: Point in time view as at 09/08/2000.

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

Trichloride

Antimony

Trioxide

Antimony Trisulphide

Apiol

Apomorphine

Apomorphine Hydrochloride

[F8Apraclonidine Hydrochloride]

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

Arsenic

Trioxide

Status: Point in time view as at 09/08/2000.

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 Substance	prescription Column 2 Maximum strength	only medicines Column 3 Route of administratio use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Arsphenami	ne				
[F10 Aspirin	[FII(1) 75mg]	[Fii(1) Non- effervescent tablets and capsules]		[FII(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]	
	[^{F12} [^{F13} (20)] mg]	[F13 (2N]on-effervescent tablets and capsules		[F13(2)]The quantity sold or supplied in one container or package shall not exceed 32	

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	prescription Column 2	ı onıy meaicine Column 3	s Column 4	Colu	mn 5	
Substance	Maximum strength	Route of administration use or pharmaceuti	Treatment limitations on,	Maxi quan	mum	
		form			The	
		[F13(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		F14	F14	F14		
		F14				
		F14				
Atenolol						
Atracurium Besylate						
Atropine		(1) Internal				
		(a) by inhaler				
		(b) otherwise	(b) 300mcg (MD)			
		than by inhaler				

		from the restri	ictions on the sale and supp	ly 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
		(2) External (except ophthalmic)		
Atropine	1	(1) Internal		
Methobromic	le	(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		(1) Internal		
Oxide Hydrochlorid	le	(a) by inhaler		
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD) 3	
		(2) External (except ophthalmic)		
Atropine		(1) Internal		
Sulphate		(a) by inhaler		

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)

			ictions on the sale and suppl	ly of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD)	
		(2) External (except ophthalmic)		
Auranofin				
Azapropazone	•			
Azathioprine				
Azathioprine Sodium				
Azelaic Acid				
Azelastine Hydrochloride	e	For nasal administration	140mcg per nostril (MD)	Container or package
		For the treatment of seasonal allergic rhinitis	280mcg per nostril (MDD)	containing not more than 5,040mcg of Azelastine Hydrochloride
		For use in adults and children not less than 12 years		Trydrocinoride
		As a non- aerosol, aqueous form		
Azidocillin Potassium				
Azithromycin				
Azlocillin Sodium				
Aztreonam				

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

Bacampicillin Hydrochloride

Bacitracin

Bacitracin Methylene Disalicylate

Bacitracin

Zinc

Baclofen

Bambuterol Hydrochloride

Barium Carbonate

Barium Chloride

Barium Sulphide

Beclamide

Beclomethasone

Beclomethasone Dipropionate For nasal 100mcg per nostril (MD) administration

(non-aerosol)

or package containing not more than [F1520,000 mcg] of Beclomethasone

Dipropionate

Container

For the prevention and treatment of allergic rhinitis

in persons aged 18 years and over] 200 mcg per nostril (MDD)[^{F16}For a maximum period of 3 months]

30

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 I Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
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 Hydrochloride	e				
Bendrofluazid	le				
Benethamine Penicillin					
Benoxaprofen					
Benperidol					
Benserazide Hydrochloride	2				
Bentiromide					
Benzathine Penicillin					
Benzbromaro	ne				
Benzhexol Hydrochloride	e				
Benzilonium Bromide					
Benzocaine		Any use except ophthalmic use			
Benzoctamine Hydrochloride					
·-	10.0 per cent	External			

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

N-Benzoyl

Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine

Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin

Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine

Hydrochloride

Betamethasone

Betamethasone

Adamantoate

Betamethasone

Benzoate

Betamethasone

Dipropionate

Betamethasone

Sodium

Phosphate

Betamethasone

Valerate

Betaxolol

Hydrochloride

Bethanechol

Chloride

Bethanidine

Sulphate

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

Bezafibrate

[F8Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

Fumarate

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

Bromvaletone

Brotizolam

Budesonide

For nasal 200mcg per nostril (MD) administration

For the [F16For a maximum period prevention of 3 months]

or treatment of seasonal allergic rhinitis 200 mcg

per nostril (MDD)

[F17For use in persons aged 18

or package containing not more than 10mg of Budesonide

Container

Status: Point in time view as at 09/08/2000.

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)

			ictions on the sale and sup	ply of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati	Column 4 Treatment limitations	Column 5 Maximum quantity
		use or pharmaceut form	ical	
		years and over]		
		As a non- aerosol, aqueous form		
Bufexamac				
Bumetanide				
Buphenine			6mg (MD)	
Hydrochlorid	e		18mg (MDD)	
Bupivacaine		Any use except ophthalmic use		
Bupivacaine Hydrochlorid	e	Any use except ophthalmic use		
Buserelin Acetate				
Buspirone Hydrochlorid	e			
Busulphan				
Butacaine Sulphate		Any use except ophthalmic use		
Butorphanol Tartrate				
Butriptyline Hydrochlorid	e			
Calcipotriol				
[^{F8} Calcipotrio Hydrate]	1			
Calcitonin				
Calcitriol				

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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

Calcium

Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

[F18Candesartan

Cilexetil]

Candicidin

Canrenoic

Acid

Cantharidin 0.01 per External

cent

Capreomycin

Sulphate

Captopril

Carbachol

Carbamazepine

Carbaryl

Carbenicillin

Sodium

Carbenoxolone (1) Pellet Sodium

(1) 5mg (MD)

25mg (MDD)

Status: Point in time view as at 09/08/2000.

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 administration use or pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
	(2) 2.0 per cent	(2) Gel				
	(3) 1.0 per cent	(3) Granules for mouthwash in adults and children not less than 12 years	(3) 20mg (MD) 80mg (MDD)	(3) Container or package containing not more than [F19560mg] of Carbenoxolone Sodium		
Carbidopa						
Carbimazole						
Carbocisteine	;					
Carbon Tetrachloride						
Carboplatin						
Carboprost Trometamol						
Carbuterol Hydrochlorid	e					
Carfecillin Sodium						
Carindacillin Sodium						
Carisoprodol						
Carmustine						
Carperidine						
Carteolol Hydrochlorid	e					
Cefaclor						
Cefadroxil						
Cefazedone						

Sodium

Status: Point in time view as at 09/08/2000.

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

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

Ceftriaxone

Sodium

Cefuroxime

Axetil

Cefuroxime

Sodium

Celiprolol

Hydrochloride

Cephalexin

Cephalexin

Sodium

Cephaloridine

Cephalothin

Sodium

Cephamandole

Nafate

Cephazolin

Sodium

Cephradine

Cerium

Oxalate

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

Cerivastatin

Ceruletide Diethylamine

Cetirizine 10mg (MDD) Container

Hydrochloride or package containing not more than 100mg of Cetirizine Hydrochloride

Chenodeoxycholic

Acid

Chloral External

Hydrate

Chlorambucil

Chloramphenicol

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium

Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(**20**)) 5.0 per (1) Internal cent

(2) External

⁽²⁰⁾ SeeS.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)

		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 pharmaceutiform	,	Column 5 Maximum quantity
Chloroquine Phosphate		Prophylaxis of malaria		
Chloroquine Sulphate		Prophylaxis of malaria		
Chlorothiazid	le			
Chlorotrianis	ene			
Chlorphenoxa Hydrochlorid				
Chlorpromaz	ine			
Chlorpromaz Embonate	ine			
Chlorpromaz Hydrochlorid				
Chlorpropam	ide			
Chlorprothixe	ene			
Chlorprothixe Hydrochlorid				
Chlortetracyc	line			
Chlortetracyc Calcium	line			
Chlortetracyc Hydrochlorid				
Chlorthalidor	ie			
Chlorzoxazor	ne			
Cholestyrami	ne			
Ciclacillin				
Ciclobendazo	le			
Cilastatin Sodium				
Cilazapril				
Cimetidine		(a) For the short-term symptomatic	(a) 200mg (MD) 800mg (MDD)	

relief of

			ctions on the sale and supply	v of	
Column 1	Column 2	only medicine Column 3	s Column 4	Column 5	
Substance	Maximum strength	Route of administration use or pharmaceutiform	Treatment limitations on,	Maximum quantity	
		heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity and for the prophylaxis of meal- induced	For a maximum period of 14 days		
		heartburn (b) For the prophylactic management of nocturnal heartburn by a single dose taken at night	(b) 100mg (MD) to be taken as a single dose at night For a maximum period of 14 days		
Cimetidine Hydrochlorid	e				
Cinchocaine	3.0 per cent	Non- ophthalmic use			
Cinchocaine Hydrochlorid		Non- ophthalmic use			
Cinchophen					
Cinoxacin					
Ciprofibrate					
Ciprofloxacin	1				
Ciprofloxacin Hydrochlorid					
Cisapride					
Cisplatin					

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

[F8Citalopram Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin Hydrochloride

Clindamycin Palmitate

Hydrochloride

Clindamycin Phosphate

Clioquinol (1) External

(other than treatment of mouth ulcers)

(2) 35mg

(2) 350mg (MDD)

Treatment of mouth ulcers

(2)

Clobetasol Propionate

Clobetasone Butyrate

Clofazimine

Clofibrate

Clomiphene Citrate

Clomipramine

Clomipramine 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 Substance Maximum

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Clomocycline

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

Status: Point in time view as at 09/08/2000.

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

Column 1 Column 2 Colum Substance Maximum Route strength admi.

Route of Treatment limitations administration,

use or

form

pharmaceutical

Maximum quantity

Colfosceril

Palmitate

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

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

Cyproterone

Acetate

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

44

26mg (MDD)

Status: Point in time view as at 09/08/2000.

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 Maximum strength

Column 3 Column 4 Route of

Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Deptropine

Substance

Citrate

Dequalinium (1) 0.25mg

Chloride

(1) Internal: throat lozenges or throat pastilles

(2) 1.0 per cent

(2) External:

paint

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

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 administration,

Column 4 Treatment limitations

Column 5

Maximum

quantity

use or

pharmaceutical

form

Dexamethasone

Sodium

Phosphate

Dexamethasone

Troxundate

Dexfenfluramine Hydrochloride

Dextromethorphan Hydrobromide

Internal

(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 maximum period of 7 days

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

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

Dihydrostreptomycin

Status: Point in time view as at 09/08/2000.

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 pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		joints and in localised forms of soft tissue rheumatism		
		For use in adults and children not less than 12 years		
Diclofenac Potassium				
Diclofenac Sodium				
Dicyclomine Hydrochloride	e		10mg (MD) 60mg (MDD)	
[F7Didanosine]			
Dienoestrol				
Diethanolami Fusidate	ne			
Diflucortolone Valerate	e			
Diflunisal				
Digitalin				
Digitalis Leaf				
Digitalis Prepared				
Digitoxin				
Digoxin				
Dihydralazine Sulphate	;			
Dihydroergota Mesylate	amine			

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

Dihydrostreptomycin

Sulphate

Diloxanide

Furoate

Diltiazem

Hydrochloride

Dimercaprol

Dimethisoquin Hydrochloride Non-

ophthalmic

use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost

Trometamol

Dinoprostone

[F9Diphenhydramine Hydrochloridepreparations

except liquid-filled capsules]

Dipivefrin

Hydrochloride

Dipyridamole

Disodium

Etidronate

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

Disodium

Pamidronate

Disopyramide

Disopyramide Phosphate

Distigmine Bromide

Disulfiram

Dithranol 1.0 per cent

Dobutamine Hydrochloride Domperidone

Domperidone

Maleate

[F20For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching

epigastric bloating and belching, occasionally accompanied by

by epigastric discomfort and heartburn,] [F21] 10 mg of Domperidone [F20] Container as Domperidone Maleate or package (MD)] containing

[F2140 mg of Domperidone as Domperidone Maleate (MDD)]

[F20]Container or package containing not more than 100mg of Domperidone as

Domperidone Maleate;]

Dopamine Hydrochloride

Dopexamine Hydrochloride

[F8Dorzolamide Hydrochloride]

Dothiepin

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

Dothiepin

Hydrochloride

Doxapram

Hydrochloride

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

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

Ecothiopate

Iodide

Edrophonium

Chloride

Eflornithine

Hydrochloride

[F7Eformoterol

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, Tick-

borne, Cent

Eur

Enoxacin

Enoxaparin

Sodium

Enoximone

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

(other than nasal sprays or nasal drops)

60mg (MDD)

		from the restri	ictions on the sale and supply	of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceut	•	Maximum quantity
	(2) 2.0 per cent	(2) Nasal sprays or nasal drops		
		(3) External		
Ephedrine Hydrochlori	de	(1) Internal (other than	(1) Equivalent of 30mg of Ephedrine (MD)	
		nasal sprays or nasal drops)	Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Ephedrine Sulphate		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD)	
			Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Epicillin				
Epirubicin				
Epirubicin Hydrochlori	de			
Epithiazide				
Epoetin Alfa				
Epoetin Beta				

Status: Point in time view as at 09/08/2000.

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

Epoprostenol

Sodium

Ergometrine

Maleate

Ergometrine

Tartrate

Ergot,

Prepared

Ergotamine

Tartrate

Erythromycin

Erythromycin

Estolate

Erythromycin

Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin

Lactobionate

Erythromycin

Phosphate

i nospiiate

Erythromycin

Stearate

Erythromycin

Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

[F22]Estramustine

Sodium

Phosphate]

Etafedrine

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 2 Column 3 Column 4 Column 5

Maximum Route of Treatment limitations Maximum strength administration, quantity

use or

pharmaceutical

form

Ethacrynic

Column 1

Substance

Acid

Ethambutol

Hydrochloride

Ethamivan

Ethamsylate

Ethiazide

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine

Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol

Diacetate

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

[F8 Exemestane]

Famciclovir

Famotidine For the 10mg (MD)

short-term

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 administration use or pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Fazadinium		symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms	20mg (MDD) For maximum period of 14 days	
Bromide Felbinac	3.17 per cent	External [F24For the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions] For use in adults and	For maximum period of 7 days	Container or package containing not more than [F2350g] 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 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Felodipine

Felypressin

Fenbufen

Fenclofenac

Fenfluramine

Hydrochloride

Fenofibrate Fenoprofen

Fenoprofen

Calcium

Fenoterol

Hydrobromide

Fenticonazole

Nitrate

Feprazone

Ferrous

Arsenate

[F8Ferumoxsil]

Filgrastim

Finasteride

Flavoxate

Hydrochloride

Flecainide

Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone

Acetonide

Flucloxa cill in

Magnesium

Flucloxacillin

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 rescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceute form	•	Column 5 Maximum quantity			
Fluconazole		For oral administration for the treatment of vaginal candidiasis in persons aged not less than 16 but less than 60 years	150mg (MD) n	Container or package containing not more than 150mg of Fluconazole			
Flucytosine							
Fludrocortiso Acetate	one						
Flufenamic Acid							
Flumazenil							
Flumethason	e						
Flumethason Pivalate	e						
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			
		[F25For use in persons aged 18 years and over]	[F26For a maximum period of 3 months]				
		In the form of a non- pressurised nasal spray					
		F27	F27	F27			

	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			
				•••			
			F27				
		F27	•••				
		F27					
Fluocinolone Acetonide							
Fluocinonide							
Fluocortin Butyl							
Fluocortolone							
Fluocortolone Hexanoate							
Fluocortolone Pivalate							
Fluorescein Dilaurate							
Fluorometholo	one						
Fluorouracil							
Fluorouracil Trometamol							
Fluoxetine Hydrochloride							
Flupenthixol Decanoate							
Flupenthixol Hydrochloride							
Fluperolone Acetate							
Fluphenazine Decanoate							

Status: Point in time view as at 09/08/2000.

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

Fluphenazine

Enanthate

Fluphenazine

Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen

Flurbiprofen

Sodium

Fluspirilene

Flutamide

Fluticasone

Propionate

Fluvastatin

Sodium

Fluvoxamine

Maleate

Folic Acic

500mcg (MDD)

Formestane

Formocortal

Foscarnet

Sodium

Fosfestrol

Sodium

Fosfomycin

Trometamol

Fosinopril

Sodium

Framycetin

Sulphate

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

Frusemide

Furazolidone

Fusafungine

Fusidic

Acid

Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

Ganciclovir

Gelsemine

Sodium

0.1 per cent

Gelsemium 25mg (MD)

75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin

Sulphate

Gestodene

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Status: Point in time view as at 09/08/2000.

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

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

Halofantrine

Hydrochloride

Haloperidol

Haloperidol

Decanoate

External Heparin

Heparin External

Calcium

Heparin Sodium

Hexachlorophane

External

			from the restrictions on the sale and supply of 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		
	(a) 2.0 per cent	(a) Soaps				
	(b) 0.1 per cent	(b) Aerosols				
	(c) 0.75 per cent	(c) preparations other than soaps and aerosols				
Hexamine Phenylcinch	oninate					
Hexobarbito	ne					
Hexobarbito Sodium	one					
Hexoestrol						
Hexoestrol Dipropionate	e					
L-Histidine Hydrochlori	de	Dietary supplementat	tion			
Homatropin	e	(1) Internal	(1) 0.15mg (MD)			
			0.45mg (MDD)			
		(2) External (except ophthalmic)				
Homatropin			0.2mg (MD)			
Hydrobromi	de		0.6mg (MDD)			
Homatropin			2mg (MD)			
Methylbrom	iide		6mg (MDD)			
Hydralazine Hydrochlori						
Hydrargapho	en	Local application to skin				
Hydrobromi Acid	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)

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity			
Hydrochloro	thiazide						
Hydrocortiso	one [F28(1) 0.5 per cent]	(a) For use in combin with Nystation of maxim strengt 3.0 per cent for intertri (b) For use in adults and childre not less than 10 years]	nation in um h	Containing not more than 15g of medicinal product			
	[F29(2)]1.0 per cent	[F29(2)] E (a) For use either alone or in conjun with Crotam in irritant dermat contact allergic dermat insect bite reaction mild	ction niton itis, t c itis,	reaction or package containing not more than 15g of medicinal product (cream or ointment) or 30ml (spray)			

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 Maximum Substance Route of Treatment limitations strength administration, quantity use or pharmaceutical form moderate eczema, and

either in combination

with Clotrimazole

[F30 or

Miconazole

Nitrate]

for

athlete's

foot

and

candidal

intertrigo

or in

combination

with

lignocaine

for

anal

and

perianal

itch

associated

with

haemorrhoids

(b) For

use in

adults

and

children

not

less

than

10

years

(c) Cream ointment

or

spray

Hydrocortisone Caprylate Status: Point in time view as at 09/08/2000.

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)

		rom the restriction only medicines	as on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Co.	lumn 4 catment limitations	Column 5 Maximum quantity
Hydrocortiso Acetate	to 1.0 per cent Hydrocortison	External For use in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination with one or more of the following: Benzyl Benzoate, Bismuth Oxide, Bismuth Subgallate, Peru Balsam, Pramoxine Hydrochloride, Zinc Oxide, for haemorrhoids For use in adults and children not less than 10 years Cream, ointment or suppositories		Container or package containing not more than 15g of medicinal product In the case of suppositories, container or package containing no more than 12
Hydrocortiso Butyrate	ne			

		from the restrictions on the sale and supply of a nonly 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	
Hydrocortiso Hydrogen Succinate	one				
Hydrocortiso Sodium Phosphate	one				
Hydrocortiso Sodium Succinate	onEquivalent to 2.5mg Hydrocortiso	ulceration of the mouth for adults and children not less than 12 years		Container or package containing not more than equivalent to 50mg of Hydrocortisone	
		In the form of pellets			
[^{F9} Hydrocyar Acid]	nic				
Hydroflumet	hiazide				
Hydroxychlo Sulphate	oroquine	Prophylaxis of malaria			
Hydroxyprog	gesterone				
Hydroxyprog Enanthate	gesterone				
Hydroxyprog Hexanoate	gesterone				
Hydroxyurea	ι				
Hydroxyzine Embonate	;				
Hydroxyzine Hydrochlorid		managamant	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg of	

Column 1 Substance Substan		-	from the restri nonly medicine	ictions on the sale and sup	ply of
dermatitis or contact dermatitis, in adults and in children not less than 12 years (b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis, in children not less than for a spice dermatitis, in children not less than for each acute or contact dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis, in children not less than for each acute dermatitis dermatiti		Column 2 Maximum	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Maximum
management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in children not less than 6 years but less than 12 years Hyoscine (1) 0.15 per cent (2) External (except ophthalmic) Hyoscine (1) Internal (a) by inhaler (b) (b) 20mg (MD) (b) Container or package containing not more than by inhaler (container or package containing not more than 240mg of Hyoscine Butylbromide			dermatitis or contact dermatitis, in adults and in children not less than 12		
(2) External (except ophthalmic) Hyoscine Butylbromide (a) by inhaler (b) (b) 20mg (MD) (b) Container or package containing not more than 240mg of Hyoscine Butylbromide			management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in children not less than 6 years but less than 12		Container or package containing not more than 750mg of Hydroxyzine
Hyoscine Butylbromide (a) by inhaler (b) (b) 20mg (MD) (b) otherwise than by inhaler 80mg (MDD) or package containing not more than 240mg of Hyoscine Butylbromide	Hyoscine		(2) External (except		
Butylbromide (a) by inhaler (b) (b) 20mg (MD) (b) Container or package containing not more than 240mg of Hyoscine Butylbromide	Hyoscine		-		
otherwise than by inhaler 80mg (MDD) Container or package containing not more than 240mg of Hyoscine Butylbromide	Butylbromide	le			
than by inhaler or package containing not more than 240mg of Hyoscine Butylbromide				(b) 20mg (MD)	
			than by	80mg (MDD)	or package containing not more than 240mg of Hyoscine
(2) External			(2) External		

	ply of			
Column 1 Substance	Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Hydrobromide		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine	1	(1) Internal		
Methobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
Hyoscine		(1) Internal		
Methonitrate		(a) by inhaler		
		(b)	(b) 2.5mg (MD)	
		otherwise than by inhaler	7.5mg (MDD)	
		(2) External		
Hyoscyamin	e	(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD)	
			1mg (MDD)	
		(2) External		
Hyoscyamin Hydrobromio		(1) Internal		

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, use or pharmaceutical form		Column 5 Maximum quantity		
		(a) by inhaler				
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)			
		(2) External	Tryoseyamme (MDD)			
Hyoscyamine		(1) Internal				
Sulphate		(a) by inhaler				
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)			
		(2) External				
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)			

	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 pharmaceute form		Column 5 Maximum quantity		
			1,200mg (MDD)			
	(2) 5.0 per cent	(2) External				
	[F31(3) 10.0 per cent]	[F31(3) External]	[F31(3) 125 mg (MD) 500 mg (MDD)]	[F31(3) Container or package containing not more than 100 g of medicinal product]		
[^{F9} Ibuprofen Lysine		Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrho feverishness, symptoms of colds and influenza				
		Internal	(b) in any other case 400 mg (MD) 1,200 mg (MDD)]			
Idarubicin Hydrochlorid	le					
Idoxuridine						
Ifosfamide						
Ignatius Bean						
[^{F7} Imidapril Hydrochloric	le]					

Status: Point in time view as at 09/08/2000.

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

Imipenem

Hydrochloride

Imipramine

Imipramine

Hydrochloride

Imipramine

Ion

Exchange

Resin

Bound Salt

or Complex

Indapamide

Hemihydrate

Indomethacin

Indomethacin

Sodium

Indoprofen

Indoramin

Hydrochloride

Inosine

Pranobex

[F32Insulin]

Iodamide

Iodamide

Meglumine

Iodamide

Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

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

Ioxaglic Acid

Ipratropium Bromide

Iprindole Hydrochloride

Iproniazid Phosphate Isoaminile

Isoaminile Citrate

Isocarboxazid

Isoconazole Nitrate External but in the case of vaginal use only external use for the treatment of vaginal candidiasis

Isoetharine

Isoetharine Hydrochloride

Isoetharine Mesylate

Isoniazid

Isoprenaline Hydrochloride

Isoprenaline Sulphate

Isopropamide Iodide

Equivalent of 2.5mg of Isopropamide ion (MD)

Equivalent of 5.0mg of Isopropamide ion (MDD)

Isotretinoin

	prescription	from the restri only medicine	ctions on the sale and suppl s	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	,	Column 5 Maximum quantity
Isradipine				
Itraconazole				
Jaborandi		External		
Kanamycin Acid Sulphate				
Kanamycin Sulphate				
Ketamine Hydrochlorid	e			
Ketoconazole	2.0 per cent	$[^{F33}(a)][^{F34}Ext$	tdrna(4)] Maximum	[F33(a)]
		For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a	frequency of application of once every 3 days	Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole
		shampoo [F35(b) For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo]		
Ketoprofen	2.5 per cent	External For rheumatic and	For maximum period of 7 days	Container or package containing not more

Status: Point in time view as at 09/08/2000.

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 su	pply 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
		muscular pain in adults and children not less than 12		than 30g of medicinal product
Ketorolac Trometamol				
Ketotifen Fumarate				
Labetalol Hydrocholorio	le			
Lachesine Chloride				
Lacidipine				
Lamotrigine				
Lanatoside C				
Lanatoside Complex A, B and C				
Latamoxef Disodium				
Levallorphan Tartrate				
Levobunolol Hydrochloride	e			
[^{F9} Levocabast Hydrochloride	of 0.05	(1) Nasal sprays For the symptomatic treatment of seasonal allergic rhinitis		(1) Container or package containing not more than 10 ml of medicinal product
		(2) Aqueous eye drops		(2) Container or package containing

		from the restru nonly medicine.	ctions on the sale and sup	pıy oj
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		For the symptomatic treatment of seasonal allergic conjunctivitis		not more than 4 ml of medicinal product]
[^{F36} Levocarni	tine]	[^{F36} For dietary supplementat	ion]	
Levodopa				
Levonorgestr	el			
Lidoflazine				
Lignocaine		Non- ophthalmic use		
Lignocaine Hydrochlorid	e	Non- ophthalmic use		
Lincomycin				
Lincomycin Hydrochlorid	e			
Liothyronine Sodium				
Lisinopril				
Lithium Carbonate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lithium Citrate				
Lithium Succinate				
Lithium Sulphate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	

Status: Point in time view as at 09/08/2000.

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	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Lobeline		(1) Internal	(1) 3mg (MD)	
			9mg (MDD)	
		(2) External		
Lobeline Hydrochlorid	e	(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				
Lofepramine				
Lofepramine Hydrochlorid	e			
Lofexidine Hydrochlorid	e			
Lomefloxacii Hydrochlorid				
Lomustine				
Loperamide Hydrochlorid	e	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	Container or package containing not more than 100mg of Loratidine
[F18Lornoxica	m]			

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

[F18Losartan

Potassium]

Loxapine

Succinate

Lung

Surfactant

Porcine

Luteinising

Hormone

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Maleate

Mafenide

Mafenide

Acetate

Mafenide

Hydrochloride

Mafenide 5

5.0 per cent Eye drops

Propionate

Magnesium

Fluoride

Magnesium

Metrizoate

Mandragora

Autumnalis

Mannomustine

Hydrochloride

Maprotiline

Hydrochloride

Mebanazine

Mebendazole For oral 100mg (MD) Container use in the or package

treatment of containing

Status: Point in time view as at 09/08/2000.

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 medicines	ctions on the sale and supp	ply of
Column 1 C Substance M	rescription Column 2 Aaximum trength	Column 3 Route of administratio use or pharmaceutic	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Mebeverine Hydrochloride		enterobiasis in adults and in children not less than 2 years [F37(a) For the symptomatic relief of irritable bowel syndrome (b) For uses other than the	[F37(a) 135 mg (MD) 405 mg (MDD)] [F37(b) 100 mg (MD) 300 mg (MDD)]	not more than 800mg of Mebendazole
Mebeverine Pamoate		symptomatic relief of irritable bowel syndrome]		
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride				
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyproges Acetate	terone			
Mefenamic Acid				

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

Mefloquine Hydrochloride

Mefruside

Megestrol

Megestrol Acetate

Meglumine Gadopentetate

Meglumine Iodoxamate

Meglumine loglycamate

Meglumine Iothalamate

Meglumine Iotroxate

Meglumine Ioxaglate

Melphalan

Melphalan Hydrochloride

Menotrophin

Mepenzolate Bromide 25mg (MD)

75mg (MDD)

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic

use

Meptazinol Hydrochloride

Mequitazine

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

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

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

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 administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine Hydrochloride

Methotrimeprazine

Maleate

Methoxamine 0.25 per Hydrochlorideent

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

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

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

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

External but

Miconazole Nitrate

in the case of vaginal use only external use for the treatment of vaginal candidiasis

Mifepristone

Miglitol

Milrinone

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

Milrinone

Lactate

Minocycline

Minocycline Hydrochloride

Minoxidil

[F38(1) 2.0 per cent]

[F38(1) External

[F38(2) 5.0 per cent

(2) External use for the treatment of alopecia androgenetica, in men aged 18 to 65 (but not in women);]

[F7Mirtazapine]

Misoprostol

Mitobronitol

Mitomycin

Mitozantrone

Hydrochloride

Mivacurium

Chloride

[F22Mizolastine]

Moclobemide

[F8Moexipril

Hydrochloride]

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

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

Morazone

Hydrochloride

[F7Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

Naphazoline (1) 0.05 per

Hydrochlorideent

(1) Nasal sprays

or nasal drops not containing liquid paraffin as a vehicle

		from the restric nonly medicines	ctions on the sale and sup	ply of
Column 1	prescription Column 2	i oniy meaicines Column 3	s Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceution form	Treatment limitations on,	Maximum quantity
	(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				
Natamycin				
[^{F18} Nebivolol Hydrochlorid				
Nedocromil Sodium	[^{F39} 2.0 per cent]	[F39]For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis]	[F39]Container or package containing not more than 3 ml of medicinal product]
Nefazodone Hydrochlorid	e			
Nefopam Hydrochlorid	e			
Neomycin				
Neomycin Oleate				
Neomycin Palmitate				
Neomycin Sulphate				
Neomycin Undecanoate				

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 Co Substance Ma

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Neostigmine

Bromide

Neostigmine Methylsulphate

Netilmicin Sulphate

Nicardipine Hydrochloride

Nicergoline

[F22Niceritrol]

Nicotinic Acid Any use, 600mg (MDD)

except for the treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F9Nilutamide]

Nimodipine

Niridazole

[F18Nisoldipine]

Nitrendipine

Nitrofurantoin

Nitrofurazone

Nizatidine

For the prevention [F40] and

75mg (MD)

[F41150mg (MDD)]

treatment] of the symptoms

symptoms of foodrelated heartburn [F42For a maximum period

of 14 days]

Novobiocin Sodium

Nux Vomica Seed Status: Point in time view as at 09/08/2000.

		from the restri	ctions on the sale and supp s	ply of	
Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form [F40]and		Column 5 Maximum quantity	
		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					
Noscapine Hydrochloride					
Novobiocin Calcium					

Status: Point in time view as at 09/08/2000.

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	ply of
Column 1 Substance	Column 2 Maximum strength	only medicines Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
Nystatin	[F433.0 per cent]	[F43External] For use in combination with Hydrocortisone of maximum strength 0.5 per cent for intertrigo	[F43Container or package containing not more than 15g of medicinal product]
		For use in adults and children not less than 10 years]	
Octacosactri	n		
Octreotide			
Oestradiol			
Oestradiol Benzoate			
Oestradiol Cypionate			
Oestradiol Dipropionat	e		
Oestradiol Diundecano	ate		
Oestradiol Enanthate			
Oestradiol Phenylpropi	onate		
Oestradiol Undecanoate	e		
Oestradiol Valerate			
0			

Oestriol

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

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

[F7Omeprazole

Magnesium]

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

Oxatomide

Oxedrine

Tartrate

Oxethazaine

10mg (MD)

30mg (MDD)

Container or package containing not more than

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

400mg of Oxethazaine

Oxitropium Bromide

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Oxybuprocaine Hydrochloride Nonophthalmic

use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

Oxyphenonium Bromide

5mg (MD)

15mg (MDD)

Oxytetracycline

Oxytetracycline

Calcium

Oxytetracycline

Dihydrate

Oxytetracycline Hydrochloride

Oxytocin, natural

Oxytocin, synthetic

Pancreatin (1

(1) 21,000 (1) capsules

European

		from the restri only medicine	ctions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
	Pharmacopoo units of lipase per capsule	<u> </u>		
	(2) 25,000 European Pharmacopoo units of lipase per gram	(2) powder eia		
Pancuronium Bromide				
Papaverine		(1) By inhaler		
		(2) Otherwise than by inhaler	(2) 50mg (MD) 150mg (MDD)	
Papaverine Hydrochlorid	le	(1) By inhaler		
		(2) Otherwise than by	(2) Equivalent of 50mg of Papaverine (MD) Equivalent of 150mg of	
		inhaler	Papaverine (MDD)	
[F10Paracetam	mg	effervescent tablets and capsules for use in children aged less than 12 years		(1) The quantity sold or supplied in one container or package shall not exceed 32 The
	(2) 500 mg	(2) Non- effervescent tablets and capsules for use in adults and children		quantity of non- effervescent tablets, capsules or a

Status: Point in time view as at 09/08/2000.

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 pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity		
		form				
		not less than 12 years		combination of both sold or supplied to a person at any one time shall not exceed		
				100		
		(3) All preparations other than non-effervescent tablets and capsules		(2) The quantity sold or supplied in one container or package shall not exceed 32 The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall		

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Status: Point in time view as at 09/08/2000.

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

exceed 100]

Paraldehyde

Paramethadione

Paramethasone

Acetate

Parathyroid

Gland

Pargyline

Hydrochloride

Paroxetine

Hydrochloride

Pecilocin

Penamecillin

Penbutolol

Sulphate

Penicillamine

Penicillamine

Hydrochloride

Pentamidine

Isethionate

Penthienate

5mg (MD)

Bromide

15mg (MDD)

Pentolinium

Tartrate

Perfluamine

Pergolide

Mesylate

Perhexiline

Maleate

Pericyazine

Perindopril

Perindopril

Erbumine

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

Perphenazine

Phenacetin

0.1 per cent

Phenazone

External

Phenazone Salicylate

Phenbutrazate Hydrochloride

Phenelzine Sulphate

Phenethicillin Potassium

Phenformin Hydrochloride

Phenglutarimide Hydrochloride

Phenindione

[F44Phenolphthalein.]

Phenoxybenzamine Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine

Hydrochloride

Phentolamine

Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Pilocarpine

Status: Point in time view as at 09/08/2000.

			ctions on the sale and supp	oly of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Maximum quantity
Phenylpropar		Internal		
Hydrochlorid	e	(1) all	(1) 25mg (MD)	
		preparations except prolonged release capsules, nasal sprays and nasal drops	100mg (MDD)	
		(2)	(2) 50mg (MD)	
		prolonged release capsules	100mg (MDD)	
	(3) 2.0 per cent	(3) nasal sprays and nasal drops		
Phenytoin				
Phenytoin Sodium				
Phthalylsulph	athiazole			
Physostigmin	e			
Physostigmin Aminoxide Salicylate	e			
Physostigmin Salicylate	e			
Physostigmin Sulphate	e			
[^{F9} Phytomena	dione	Any use except the prevention or treatment of haemorrhagic disorders	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)

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 Pilocarpine Hydrochloride Pilocarpine Nitrate Pimozide Pindolol Pipenzolate 5mg (MD) **Bromide** 15mg (MDD) Piperacillin Sodium Piperazine Oestrone Sulphate Piperidolate 50mg (MD) Hydrochloride 150mg (MDD) Pipothiazine **Palmitate** Piracetam Pirbuterol Acetate Pirbuterol Hydrochloride [F45Pirenzepine Dihydrochloride Monohydrate] Pirenzepine Hydrochloride Piretanide Piroxicam 0.5 per cent External For maximum period of 7 Container days or package

containing

than 30g of

not more

medicinal

product

For the

relief of

arthritic

rheumatic

pain, pain of

non-serious

			ctions on the sale and sup	ply of
	prescription Column 2	only medicine Column 3	s Column 4	Column 5
Substance	Column 2 Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Column 5 Maximum quantity
		conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries		
		For use in adults and children not less than 12 years		
F ²² Piroxicam Beta- cyclodextrin]				
Pituitary Gland Whole Dried)		By inhaler		
Pituitary Powdered Posterior Lobe)		By inhaler		
Pivampicillin				
Pivampicillin Hydrochloride				
Pivmecillinam				
Pivmecillinam Hydrochloride				
Pizotifen				
Pizotifen Malate				
Plicamycin				
Podophyllotox	in			

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 Maximi

Column 2 Maximum I strength

Column 3 Column 4
Route of Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

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

Arsenite c
Potassium

Potassium Bromide

Potassium Canrenoate

Potassium Clavulanate

Potassium Perchlorate

Practolol

Pralidoxime Chloride

Pralidoxime Iodide

Pralidoxime Mesylate Document Generated: 2024-07-17

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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,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pravastatin

Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone

Butylacetate

Prednisolone

Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

Prednisolone

Steaglate

Prednisone

Prednisone

Acetate

Prenalterol

Hydrochloride

Prenylamine

Lactate

Prilocaine Hydrochloride Nonophthalmic

use

Primidone

Probenecid

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

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Probucol

Procainamide Hydrochloride

Procaine Hydrochloride Nonophthalmic use

Procaine Penicillin

Procarbazine Hydrochloride

Prochlorperazine

Prochlorperazine Edisylate

Prochlorperazine

Maleate

Prochlorperazine

Mesylate

Procyclidine Hydrochloride

Progesterone

Prolactin

Proligestone

Prolintane Hydrochloride

Promazine Embonate

Promazine Hydrochloride

Propafenone

Propafenone Hydrochloride

Propanidid

Propantheline Bromide 15mg (MD)

45mg (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 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form

[F18Propiverine Hydrochloride]

Propofol

Propranolol Hydrochloride

Propylthiouracil

Proquazone

Protamine Sulphate

Prothionamide

Protirelin

Protriptyline Hydrochloride

Proxymetacaine Hydrochloride

Nonophthalmic use

Pseudoephedrine Hydrochloride

Internal

(a) In the case of a prolonged release

preparation 120mg (MD) 240mg (MDD)

(b) in any other case 60mg

(MD)

240mg (MDD)

Pseudoephedrine Sulphate

60mg (MD) 180mg (MDD)

Pyrantel Embonate (a) For the treatment of single dose) enterobiosis, in adults

(a) 750mg MDD (as a

Container or package containing not more than 750mg of Pyrantel **Embonate**

(a)

and children not less than 12 years

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 pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		(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 years but not less than 2 years	(c) 250mg MDD (as a single dose)	(c) Container or package containing not more than 750mg of Pyrantel Embonate	
Pyrantel Tartrate					
Pyrazinamide					
Pyridostigmin Bromide	e				
Pyrimethamin	e				
[^{F18} Quetiapine Fumarate]					
[^{F8} Quinagolide Hydrochloride					
Quinapril					
^{F45} Quinapril Hydrochloride]				
Quinestradol					
Quinestrol					
Quinethazone					

Quinidine

Quinidine Bisulphate

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

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

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)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Dihydrochloride Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Ethyl Quinine (MD)

Carbonate Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Glycerophosphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Hydrobromide Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Hydrochloride Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Status: Point in time view as at 09/08/2000.

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 suppl	ly of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Maximum quantity
Quinine Iodobismuthate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Phosphate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Salicylate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Sulphate			Equivalent of 100mg of Quinine (MD)	
			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 Hydrochlorid	le			
Ramipril				
[^{F7} Ranitidine Bismuth Citrate]				
Ranitidine Hydrochlorid	le	For the short term	Equivalent to 75mg of Ranitidine (MD)	
		symptomatic relief of heartburn,	Equivalent to 300mg of Ranitidine (MDD)	
		dyspepsia, indigestion, acid indigestion	For a maximum period of 14 days	
		and		

Nitrate

Status: Point in time view as at 09/08/2000.

		from the restri	ictions on the sale and supp es	ply of
Column 1	Column 2 Maximum	Column 3	S Column 4 Treatment limitations	Column 5
	strength	Route of Treatment limitations administration, use or		Maximum quantity
		pharmaceut form	ical	
		hyperacidity [F46 or the		
		prevention of these		
		symptoms		
		when associated		
		with		
		consuming food and drink		
Rauwolfia Serpentina		•		
Rauwolfia Vomitoria				
Razoxane				
Remoxipride Hydrochloride)			
Reproterol Hydrochloride	e			
Rescinnamine				
Reserpine				
Rifabutin				
Rifampicin				
Rifampicin Sodium				
Rifamycin				
[F7Rimexolone	e]			
Rimiterol Hydrobromide	e			
Risperidone				
Ritodrine Hydrochloride)			
Rolitetracyclii	ne			

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

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F7Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F7Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium Ethacrynate Status: Point in time view as at 09/08/2000.

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 Sodium Antimonylgluconate Sodium Arsanilate Sodium Arsenate Sodium 0.013 per Arsenite cent Sodium Bromide Sodium Clodronate Sodium (a) For nasal Cromoglycate admistration (b) 2.0 per (b) For the (b) Container cent treatment of acute or package seasonal containing allergic not more conjunctivitis than 10ml [F47or of medicinal product perennial allergic conjunctivitis] In the form of aqueous eye drops (c) 4.0 per (c) For the (c) Container cent treatment of acute or package seasonal containing not more allergic conjunctivitis than 5g of medicinal In the form product of an eye ointment

Status: Point in time view as at 09/08/2000.

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 supp	ply of
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Route of administrationse or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices		
		(2) Other preparations for use in the prevention 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 phæspthate	Dentrifrice		
Sodium Oxidronate				
Sodium Stiboglucona	ate			
Sodium Valproate				
Somatorelin Acetate				
Sotalol Hydrochlorio	de			
[^{F8} Sparfloxae	cin]			

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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,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Spectinomycin

Spectinomycin

Hydrochloride

Spiramycin

Spiramycin Adipate

Spironolactone

Stannous 0.62 per

Fluoride cent

Dentifrice

Stilboestrol

Stilboestrol

Dipropionate

Streptodornase External Streptokinase External

Streptomycin

Streptomycin Sulphate

Strychnine

Strychnine

Arsenate

Strychnine Hydrochloride

[F9Strychnine

Nitrate]

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

Sulbenicillin

Sulbenicillin

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 External Sulconazole Nitrate (except vaginal) [F9Sulfabenzamide] Sulfacytine Sulfadoxine Sulfamerazine Sulfamerazine Sodium Sulfametopyrazine Sulfamonomethoxine Sulindac Sulphacetamide Sulphacetamide Sodium Sulphadiazine Sulphadiazine Sodium Sulphadimethoxine Sulphadimidine Sulphadimidine Sodium Sulphafurazole Sulphafurazole Diethanolamine

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Sulphaguanidine

Sulphamethizole
Sulphamethoxazole
Sulphamethoxydiazine
Sulphamethoxypyridazine

Sulphaloxic Acid Document Generated: 2024-07-17

Status: Point in time view as at 09/08/2000.

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

Sulphamethoxy pyridazine

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

[F18Tacalcitol

Monohydrate]

Tacrine

Hydrochloride

Talampicillin

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 Talampicillin Hydrochloride Talampicillin Napsylate Tamoxifen Tamoxifen Citrate [F7Tazarotene] Tazobactam Sodium Teicoplanin Temocillin Sodium Tenoxicam Terazosin Hydrochloride Terbinafine [F48Terbinafine]F481.0 per [F48 External [F48Container use for the Hydrochloridedent] or package treatment of containing tinea pedis not more and tinea than 15 g of medicinal cruris] product.] Terbutaline Terbutaline Sulphate Terfenadine F49 F49 Terlipressin Terodiline Hydrochloride Tetrabenazine Tetracosactrin

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Status: Point in time view as at 09/08/2000.

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

Tetracosactrin

Acetate

Tetracycline

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

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,

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Thymoxamine Hydrochloride

Thyroid

Thyrotrophin

Thyroxine Sodium

Tiamulin Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin Sodium

Sourani

Tigloidine Hydrobromide

Timolol Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except

vaginal)
(2) Vaginal for

treatment of vaginal candidiasis

[F8Tizanidine 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 1 Column 2 Substance Maximum

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Tofenacin

Hydrochloride

Tolazamide

Tolazoline

External

Hydrochloride

Tolbutamide

Tolbutamide Sodium

Tolfenamic

Acid

Tolmetin

Sodium

[F7Topiramate]

[F22Torasemide]

Tramadol

Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone

Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolon@.1 per cent

Acetonide

For the treatment of common mouth ulcers

Container or package containing not more than 5g of medicinal product

Triamcinolone Diacetate

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

Triamcinolone

Hexacetonide

Triamterene

Tribavirin

Triclofos

Sodium

Trientine

Dihydrochloride

Trifluoperazine

Trifluoperazine

Hydrochloride

Trifluperidol

Trifluperidol

Hydrochloride

Trilostane

Trimeprazine

Trimeprazine

Tartrate

Trimetaphan

Camsylate

Trimetazidine

Trimetazidine

Hydrochloride

Trimethoprim

Trimipramine

Maleate

Trimipramine

Mesylate

Tropicamide

Tropisetron

Hydrochloride

Troxidone

L- (1) Oral

Tryptophan

Hydrochloride

Status: Point in time view as at 09/08/2000.

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 Dietary supplementation (2) External Tubocurarine Chloride Tulobuterol Tulobuterol Hydrochloride Tyrothricin Throat lozenges or throat pastilles Uramustine Urea Stibamine Urethane Uridine 5'triphosphate Urofollitrophin Urokinase Ursodeoxychoic Acid Vaccine: Bacillus Salmonella Typhi Vaccine: Poliomyelitis (Oral) [F8 Valaciclovir Hydrochloride] Valproic Acid Vancomycin

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 Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

[F8Venlafaxine

Hydrochloride]

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

Veratrum,

White

Vidarabine

Vigabatrin

Viloxazine

Hydrochloride

Vinblastine

Sulphate

Vincristine

Sulphate

Vindesine

Sulphate

Viomycin

Pantothenate

Viomycin

Sulphate

Vitamin A

(1) Internal (1) 7,500iu (2,250mcg

Retinol equivalent)

(MDD)

(2) External

Vitamin A

Acetate

(1) Internal (1) Equivalent to 7,500iu

Vitamin A (2,250mcg

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 restr	ictions on the sale and suppl	v of
	•	n only medicine	11.	, 9
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum	Route of	Treatment limitations	Maximum
	strength	administrati	ion,	quantity
		use or	:1	
		pharmaceut form	icai	
		jorni	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 Hydrochlorid	le			
[F8Zalcitabine				
Zidovudine	,			
Zimeldine				
Hydrochloric	le			
Zolpidem				
Tartrate				
Zomepirac				
Sodium				
Zopiclone				
Zuclopenthix	ol			
Acetate				
Zuclopenthix	col			
Decanoate				
Zuclopenthix Hydrochloric				

Textual Amendments

- F7 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)
- F8 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)
- F9 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.
- **F10** 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**
- F11 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)
- F12 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)
- F13 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)
- F14 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)
- F15 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)
- F16 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)
- F17 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)
- F18 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)
- F19 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)
- **F20** 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)**
- **F21** 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)**
- F22 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)
- F23 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)
- F24 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)
- F25 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)
- F26 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)
- F27 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)
- F28 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)
- F29 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)
- **F30** 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)**
- **F31** 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)**

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)

- F32 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)
- F33 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)
- F34 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)
- F35 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)
- **F36** 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)**
- F37 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)
- **F38** 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)**
- **F39** 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)**
- **F40** 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)
- **F41** 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)
- **F42** 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)**
- F43 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)
- **F44** 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)**
- F45 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)
- F46 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)
- F47 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)
- **F48** 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)**
- **F49** 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)**

SCHEDULE 2

Articles 6(1) and 10

Circumstances excluding medicinal products from the class of prescription only medicines			
Column 1	Column 2	Column 3	Column 4
Substance	Maximum strength	Pharmaceutical Form	Maximum Dose
Codeine and its salts	Equivalent of 1.5 per cent of codeine monohydrate		Equivalent of 20 mg of codeine monohydrate
Dihydrocodeine and its salts	Equivalent of 1.5 per cent of dihydrocodeine		Equivalent of 10 mg of dihydrocodeine

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

SCHEDULE 3

Article 2(b)

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

[F50Co-danthramer Capsules NPF]

[F50Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F50Co-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

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)

Textual Amendments

F50 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

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	Column 2	Col	umn 3	
Persons exempted	Prescription only medicines to which the exemption applies	Conditions		
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines	1.	The be— (a)	sale or supply shall subject to the presentation of an order signed by the principal of the institution concerned with education or research or the appropriate head of department in charge of a specified course of research stating— (i) the name of the institution for which the prescription only medicine is required, (ii) the purpose for which the prescription only medicine is required, and (iii) the total quantity required, and for the purposes of the education or research with which the institution is concerned.
0 D W	2 411 : 4: 1	2 T		1 1 11 1

- 2. Persons selling or supplying prescription
- 2. All prescription only medicines.
- 2. The sale or supply shall be subject to the presentation of an order signed by or on behalf

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	Conditions		
	to which the exemption			
	applies			
only medicines to any o	f	of any person listed in column		
the following–		1 of this paragraph stating the		
(1) a public analyst		status of the person signing it		
appointed under		and the amount of prescription		
section 27 of the		only medicine required, and		
Food Safety Act 1990(21) or article		shall be only in connection		
36 of the Food		with the exercise by those persons of their statutory		
(Northern Ireland)		functions.		
Order 1989(22),		functions.		
(2) an authorized				
officer within				
the meaning of				
section 5(6) of the				
Food Safety Act				
1990,				
(3) a sampling officer				
within the meanin	g			
of article 38(1) of				
the Food (Norther	n			
Ireland) Order				
1989,				
(4) a person duly				
authorized by				
an enforcement				
authority under				
sections 111 and				
112,				
(5) a sampling officer within the meanin				
of Schedule 3 to the	C			
Act.				
3. Persons selling or supplyin	g 3. All prescription only	3. The sale or supply shall		

- 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(23), the National Health Service (Scotland) Act 1978(24) and the Health and Personal Social
- medicines.
- 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

^{(21) 1990} c. 16.

⁽²²⁾ S.I. 1989/846 (N.I. 6).

^{(23) 1977} c. 49.

^{(24) 1978} c. 29.

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	
Services (Northern Ireland) Order 1972(25), or under any subordinate legislation made under those Acts or that Order.			(b)	medicine required, and for the purposes of a scheme referred to in column 1 in this paragraph.
4. Registered midwives.	4.	Prescription only medicines containing any of the following substances— Chloral hydrate Ergometrine maleate Pentazocine hydrochloride [F51Phytomenadione] Triclofos sodium.	be only in profession case of Erg only when medicinal for parente	e or supply shall the course of their all practice and in the gometrine maleate a contained in a product which is not eral administration.
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	5.	Prescription only medicines which are not for parenteral administration and which— (a) are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or (b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any	subject to	e or supply shall be the presentation of igned by a registered c optician.

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)

	<u> </u>	- C 1	2
Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column Conditio	
	of the following substances: Atropine sulphate Bethanecol chloride Carbachol Cyclopentolate hydrochloride Homatropine hydrobromide Naphazoline hydrochloride Naphazoline nitrate Physostigmine salicylate Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.		
6. Registered ophthalmic opticians.	6. Prescription only medicines listed in column 2 of paragraph 5.		e sale or supply shall only— in the course of their professional practice and in an emergency.
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.		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

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

Status: Point in time view as at 09/08/2000.

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
	77	or determining the standards for such containers.
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	8. The sale or supply shall be only— (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(26) 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(27).	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.
[F5210. State registered chiropodists who hold a	10. The following prescription only medicines—	10. The sale or supply shall be only in the course of their professional practice and (a)

Board.

certificate of competence in the

use of the medicines specified

in Column 2 issued by or with

the approval of the Chiropodists

(a) Co-dydramol 10/500

hydrochloride

cream where the

tablets;

(b) Amorolfine

⁽**26**) 1972 c. 66.

⁽²⁷⁾ 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		tion only medicines the exemption	Conditions
		maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;	amount sufficient for 3 days' treatment to a maximum of 24 tablets.]
	(c)	Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume; and	
	(d)	Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	

Textual Amendments

- **F51** 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)
- F52 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.

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
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 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.	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 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.

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
6. The operator or commander of an aircraft.	6. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons employed as qualified first-aid personnel on offshore installations.	7. All prescription only medicines.	7. The supply shall be only so far as is necessary for the treatment of persons on the installation.

Article 11(2)

PART III
EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1 Persons exempted	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— [F53] 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 131	1. The administration shall be only in the course of their professional practice.

Status: Point in time view as at 09/08/2000.

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
	Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride [F54Mepivacaine hydrochloride] 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.

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
5. Persons operating an occupational health scheme.	5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	5. — (1) The administration shall be in the course of an occupational health scheme. (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or 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,	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.

Status: Point in time view as at 09/08/2000.

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 I Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
acupuncture or other similar field except chiropody.		
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— (a) Diazepam 5 mg per ml emulsion for injection; (b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion; (c) prescription only medicines containing one or more of the following substances, but no active ingredient— Adrenaline Acid Tartrate Anhydrous Glucose [F55 Bretylium Tosylate] Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution) Ergometrine Maleate Glucose Heparin Sodium Lignocaine Hydrochloride Nalbuphine 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 applies	Conditions
	Naloxone Hydrochloride Polygeline Sodium Bicarbonate Sodium Chloride	e

Textual Amendments

- F53 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)
- **F54** 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)**
- F55 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
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

Status: Point in time view as at 09/08/2000.

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

[F56SCHEDULE 7

Articles 12A to 12C

Textual Amendments

F56 Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(e)

PART I

PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

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

Status: Point in time view as at 09/08/2000.

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

Column 1 Class of person by whom a prescription only medicine is supplied or administered	Column 2 Person on whose behalf the Direction must be signed
Common Services Agency	The Agency
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

PART III

CLASSES OF INDIVIDUAL BY WHOM SUPPLIES MAY BE MADE

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.

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Orthoptists Board (state registered orthoptists).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Physiotherapists Board (state registered physiotherapists).

Individuals who are registered in the register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960 by the Radiographers Board (state registered radiographers).]

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)

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;
- (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 09/08/2000.

Changes to legislation:

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