### 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

<sup>(1) 1968</sup> 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.

<sup>(2)</sup> 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;

[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

 $<sup>\</sup>textbf{(3)} \quad 1979 \text{ c. } 36; \text{the Parts of the professional register were determined by S.I. } 1983/667, \text{amended by S.I. } 1989/104 \text{ and } 1989/1455.$ 

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

<sup>(5) 1971</sup> c 38

<sup>(</sup>**6**) 1977 c. 49.

<sup>(7) 1978</sup> 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;]

<sup>(8)</sup> S.I. 1972/1265 (N.I. 14).

<sup>(9) 1995</sup> c. 21.

<sup>(10)</sup> S.I. 1985/2066.

<sup>(11)</sup> 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;

[F1": 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;

<sup>(12) 1971</sup> c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).

<sup>(13) 1964</sup> c. 29.

<sup>(14) 1989</sup> 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,

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

### **Textual Amendments**

- 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<sup>F3</sup>...;
  - (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.

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)

- (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**

F3 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  $I^{F4}$ ,

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

- (5) Where a pharmaceutical form is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied in that pharmaceutical form.
- (6) Where a maximum dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum dose which does not exceed that specified maximum dose.
- (7) Subject to paragraph (8), where a maximum daily dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum daily dose which does not exceed that specified maximum daily dose.
  - (8) A medicinal product which contains more than one of the substances—

Atropine

Atropine Methobromide

Atropine Methonitrate

Atropine Oxide Hydrochloride

Atropine Sulphate

Hyoscine

Hyoscine Butylbromide

Hyoscine Hydrobromide

Hyoscine Methobromide

Hyoscine Methonitrate

Hyoscyamine

Hyoscyamine Hydrobromide

Hyoscyamine Sulphate,

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

- (9) Where a maximum period of use or a maximum frequency of use is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use for a maximum period or frequency, as the case may be, which does not exceed the maximum period of use or the maximum frequency of use which is so specified.
- (10) Where a maximum quantity is specified in column 5 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it, or where so specified in that column, the medicinal product which contains that substance is sold or supplied in a quantity which does not exceed that specified maximum quantity.
- (11) In paragraphs (2) to (7) and (9) and (10) a reference to a numbered column is a reference to the column bearing that number in Schedule 1.

### **Textual Amendments**

F4 Words in art. 5(4) added (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 2

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

## Circumstances 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-
    - (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.

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

- (2) The 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 [F5a 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-

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)

- (i) the date on which the prescription only medicine is sold or supplied,
- (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,
- (iii) the name of the person requesting the prescription only medicine,
- (iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and
- (v) the words "Emergency Supply".
- (5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.

### **Textual Amendments**

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.

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)

### [F6Exemption for sale or supply in hospitals

12. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine in the course of the business of a hospital where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) to a particular person in accordance with the written directions of a doctor or dentist relating to that person notwithstanding that those directions do not satisfy the conditions specified in article 15(2).]

### **Textual Amendments**

F6 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)

### [F7 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;

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

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

### **Textual Amendments**

F7 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

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performance of personal medical services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997.

### **Textual Amendments**

F7 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
  - [ where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business within the meaning of section 69, the individual who administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing, on behalf of the body with which an arrangement has been made as referred to in paragraph (1)(a), for the purpose of the administration of prescription only medicines under the Patient Group Direction; and]
    - (d) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

### **Textual Amendments**

F7 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)

F8 Art. 12C(2)(cc) inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 3(1)

### 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

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)

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—
    - (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 EXEMPTIONS FROM RESTRICTIONS ON THE SALE AND SUPPLY OF PRESCRIPTION ONLY MEDICINES

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

[F9Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F9Aceclofenac]

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 the lips and

infections of face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

19

Container or package containing not more than 2g of

medicinal product

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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 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							
[F10Adapalene	]						
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

[F9Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F11Aloxiprin (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 Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F10 Altretamine]

Amantadine Hydrochloride

Ambenonium

Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine Gentisate Nonophthalmic

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 Route of Tadministration,

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 Column 3

Substance Maximum strength

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic

use

[F9Anastrozole]

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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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

Antimony

Trichloride

Antimony

Trioxide

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F10 Apraclonidine

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 01/01/2001.

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 pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Arsphenami	ne				
[F12Aspirin	[ F13(1) 75mg]	effervescent tablets and capsules]		Fi3(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]	
	[ <sup>F14</sup> [ <sup>F15</sup> (20)] mg]	[F15(2)]on-effervescent tablets and capsules		[F15(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)

Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, use or pharmaceutical form   [F15(3)]All preparations quantity  The quantity	
form  [F15(3)]All  preparations  The quanti	
[F15(3)]All The preparations quanti	
other than of non- effervescent efferve tablets or tablets capsules capsulor of ecombination of the tablets of tablets or a combination of the tablets capsulor of the tablets of tablets or a combination of the tablets of tablets or a combination of the tablets of tablets or a combination of the tablets or a capsulor of tablets or a combination of the tablets or a capsulor of tablets or a capsu	escent s, les ination r ed
Astemizole F16 F16 F16	
F16	
F16	
•••	
Atenolol	
Atracurium Besylate	
Atropine (1) Internal	
(a) by inhaler	
(b) (b) 300mcg (MD) otherwise	
than by inhaler	

Status: Point in time view as at 01/01/2001.

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		
		(2) External (except ophthalmic)				
Atropine	1	(1) Internal				
Methobromic	de	(a) by inhaler				
		(b) otherwise than by inhaler	(b) 400mcg (MD)			
			1.3mg (MDD)			
		(2) External (except ophthalmic)				
Atropine		Internal				
Methonitrate		(a) by inhaler				
		(b) otherwise than by inhaler	(b) 400mcg (MD)			
			1.3mg (MDD)			
Atropine		(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)

	Exemptions from the restrictions on the sale and supply of					
Column 1	prescription Column 2	n only medicine Column 3		Column 5		
Substance	Maximum strength	Route of administratiuse or pharmaceut form	,	Column 5 Maximum quantity		
		(b) otherwise than by inhaler	(b) 360mcg (MD)			
			1.2mg (MDD)			
		(2) External (except ophthalmic)				
Auranofin						
Azapropazone	e					
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 [F17 or perennial allergic rhinitis]	280mcg per nostril (MDD)	containing not more than 5,040mcg of Azelastine Hydrochloride		
		For use in adults and children not less than [F185 years]				
		As a non- aerosol, aqueous form				
Azidocillin Potassium						

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

Azithromycin

Azlocillin

Sodium

Aztreonam

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 [F1920,000 mcgl of

Container

[F1920,000 mcg] of Beclomethasone

Dipropionate

For the prevention and treatment

[F20For a maximum period

200 mcg per nostril

of 3 months]

(MDD)

of allergic rhinitis

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 4 Treatment limitations ion,	Column 5 Maximum quantity		
		[F21For use in persons aged 18 years and over]				
Belladonna Herb		(1) Internal	(1) 1mg of the alkaloids (MDD)			
		(2) External				
Belladonna Root		(1) Internal	(1) 1mg of the alkaloids (MDD)			
		(2) External				
Bemegride						
Bemegride Sodium						
Benapryzine Hydrochloride	;					
Bendrofluazid	e					
Benethamine Penicillin						
Benoxaprofen						
Benperidol						
Benserazide Hydrochloride	÷					
Bentiromide						
Benzathine Penicillin						
Benzbromaroi	ne					
Benzhexol Hydrochloride	÷					
Benzilonium Bromide						
Benzocaine		Any use except ophthalmic use				

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

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

Benzoctamine Hydrochloride

Benzoyl

10.0 per

External

Peroxide cent

N-Benzoyl Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin

Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine

Hydrochloride

Betamethasone

Betamethasone

Adamantoate

Betamethasone

Benzoate

Betamethasone

Dipropionate

Betamethasone

Sodium

Phosphate

Betamethasone

Valerate

Betaxolol

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

Column 3 Route of administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Bethanechol

Chloride

Bethanidine Sulphate

Bezafibrate

[F10Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

**Fumarate** 

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

Bromvaletone

Brotizolam

Budesonide

For nasal administration

200mcg per nostril (MD)

For the prevention or treatment of seasonal allergic rhinitis

[F20For a maximum period of 3 months]

containing not more than 10mg of Budesonide

Container

or package

33

Status: Point in time view as at 01/01/2001.

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	i only medicine Column 3	es Column 4		Column 5	
Substance	Maximum strength	Route of administratiuse or pharmaceut	Treatment lir ion,	nitations	Maximum quantity	
		200 mcg per nostril (MDD)				
		[F21For use in persons aged 18 years and over]			_	
		As a non- aerosol, aqueous form				
Bufexamac						
Bumetanide						
Buphenine			6mg (MD)			
Hydrochlorid	e		18mg (MDD)	)		
Bupivacaine		Any use except ophthalmic use				
Bupivacaine Hydrochlorid	e	Any use except ophthalmic use				
Buserelin Acetate						
Buspirone Hydrochlorid	e					
Busulphan						
Butacaine Sulphate		Any use except ophthalmic use				
Butorphanol Tartrate						
Butriptyline Hydrochlorid	e					

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

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

[F22Cabergoline]

Calcipotriol

 $\[ \[ \]^{F10}$ Calcipotriol

Hydrate]

Calcitonin

Calcitriol

Calcium

Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium

Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

[F23Candesartan

Cilexetil

Candicidin

Canrenoic

Acid

Cantharidin 0.01 per External

cent

Capreomycin

Sulphate

Captopril

Carbachol

Carbamazepine

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

		s from the restrictions on the sale and supply of n only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	•	Column 5 Maximum quantity		
Carbaryl						
Carbenicillin Sodium						
Carbenoxolone		(1) Pellet	(1) 5mg (MD)			
Sodium			25mg (MDD)			
	(2) 2.0 per cent	(2) Gel				
	(3) 1.0 per (	(3)	(3) 20mg (MD)	(3)		
	cent	Granules for mouthwash in adults and children not less than 12 years	80mg (MDD)	Container or package containing not more than [F <sup>24</sup> 560mg] of Carbenoxolone Sodium		
Carbidopa						
Carbimazole						

Carbocisteine

Carbon

Tetrachloride

Carboplatin

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

[F22Cefprozil]

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

Ceftriaxone

Sodium

Cefuroxime

Axetil

Cefuroxime

Sodium

Celiprolol

Hydrochloride

Cephalexin

Cephalexin

Sodium

Cephaloridine

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

Cephalothin

Sodium

Cephamandole

Nafate

Cephazolin Sodium

Cephradine

Cerium Oxalate

Cerivastatin

Ceruletide Diethylamine

Cetirizine Hydrochloride 10mg (MDD)

Container 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

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

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(20) 5.0 per

cent

(1) Internal

(2) External

Chloroquine Prophylaxis
Phosphate of malaria
Chloroquine Prophylaxis
Sulphate of malaria

Chlorothiazide

Chlorotrianisene

Chlorphenoxamine Hydrochloride

Chlorpromazine

Chlorpromazine

Embonate

Chlorpromazine Hydrochloride

Chlorpropamide

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

<sup>(20)</sup> SeeS.I. 1979/382 amended by S.I. 1980/263 and S.I. 1989/1124.

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

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

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

symptomatic relief of For a maximum period of

14 days

heartburn, dyspepsia, indigestion,

acid indigestion

and

hyperacidity and for the prophylaxis of mealinduced heartburn

(b) For the

management night of nocturnal

heartburn

by a single dose taken at night

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

For a maximum period of

14 days

Cimetidine Hydrochloride

Cinchocaine 3.0 per cent Non-

ophthalmic

use Non-

Cinchocaine Equivalent Hydrochloride f 3.0 per

ophthalmic use

cent of Cinchocaine

Cinchophen

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[F10Citalopram Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin Phosphate

Clioquinol

(1) External (other than treatment of mouth ulcers)

(2)

of mouth ulcers

(2) 35mg

Treatment

(2) 350mg (MDD)

Clobetasol Propionate

Clobetasone Butyrate

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

Clofazimine

Clofibrate

Clomiphene

Citrate

Clomipramine

Clomipramine

Hydrochloride

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

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Co-

dergocrine

Mesylate

Colaspase

Colchicine

Colestipol

Hydrochloride

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

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 2 Column 3 Column 4 Maximum Maximum Route of Treatment limitations

administration, strength

quantity use or pharmaceutical

form

Cyclopentolate Hydrochloride

Column 1

Substance

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

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

44

26mg (MDD)

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone

Pivalate

Deptropine

Citrate

Dequalinium (1) 0.25mg

Chloride

(1) Internal: throat lozenges or throat pastilles

(2) 1.0 per

(2) External:

cent

paint

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine

Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

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

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

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

For local symptomatic relief of

External

For maximum period of 7 days

Container or package containing not more

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

			tions on the sale and sup	ply of	
Column 1	prescription Column 2	only medicines Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administratio use or pharmaceutic	Treatment limitations on,	Maximum quantity	
		pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism		than 30g of medicinal product	
		For use in adults and children not less than 12 years			
Diclofenac Potassium					
Diclofenac Sodium					
Dicyclomine Hydrochlorid	e		10mg (MD) 60mg (MDD)		
[ <sup>F9</sup> Didanosine	·]				
Dienoestrol					
Diethanolami Fusidate	ne				
Diflucortolon Valerate	e				
Diflunisal					
Digitalin					
Digitalis Leaf					
Digitalis Prepared					
Digitoxin					
Digoxin					

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

Dihydralazine Sulphate

Dihydroergotamine

Mesylate

Dihydrostreptomycin

Dihydrostreptomycin

Sulphate

Diloxanide

Furoate

Diltiazem

Hydrochloride

Dimercaprol

Dimethisoquin Hydrochloride Nonophthalmic

use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost

Trometamol

Dinoprostone

[FIIDiphenhyd Allnine Hydrochloride preparations

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

Dipivefrin Hydrochloride

Dipyridamole

Disodium

Etidronate

Disodium Pamidronate

Disopyramide

Disopyramide Phosphate

Distigmine Bromide

Disulfiram

Dithranol 1.0 per cent

Dobutamine Hydrochloride

I<sup>F25</sup>For I<sup>F25</sup>Container Domperidone [F2510mg of Domperidone the relief (MD)or package of postcontaining [F2540mg of Domperidone prandial not more (MDD)] symptoms than of excessive 200mg of fullness, Domperidone] nausea, epigastric bloating and belching, occasionally

> accompanied by epigastric discomfort and heartburn]

[F26For

of post-

prandial

symptoms

the relief

[F2710 mg of Domperidone F26Container as Domperidone Maleate (MD)

Domperidone Maleate

or package containing not more than

Status: Point in time view as at 01/01/2001.

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 supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceuti	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		form  of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,]	[F2740 mg of Domperidone as Domperidone Maleate (MDD)]	[F28200mg] of Domperidone as Domperidone Maleate;]
Oopamine Iydrochloride	e	,1		
Dopexamine Hydrochloride	2			
( <sup>F10</sup> Dorzolami Hydrochloride				
Dothiepin				
Dothiepin Hydrochloridd	e			
Doxapram Hydrochloridd	e			
Doxazosin Mesylate				
Doxepin Hydrochloride	e			
Doxorubicin				
Doxorubicin Hydrochloride	e			
Doxycycline				
Doxycycline Calcium Chelate				

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Doxycycline Hydrochloride

Droperidol

Dydrogesterone

Dyflos

Econazole

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

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

Ecothiopate Iodide

Edrophonium Chloride

Eflornithine Hydrochloride

[<sup>F9</sup>Eformoterol Fumarate]

Embutramide

Emepronium Bromide

Emetine 1.0 per cent

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 Emetine Bismuth Iodide Emetine Equivalent Hydrochloride 1.0 per cent of Emetine Enalapril Maleate Encephalitis Virus, Tickborne, Cent Eur Enoxacin Enoxaparin Sodium Enoximone **Ephedrine** (1) Internal (1) 30mg (MD) (other than nasal sprays or nasal drops) 60mg (MDD) (2) 2.0 per (2) Nasal cent sprays or nasal drops (3) External Ephedrine (1) Internal (1) Equivalent of 30mg of Hydrochloride (other than Ephedrine (MD) nasal sprays Equivalent of 60mg of or nasal Ephedrine (MDD) drops) (2) (2) Nasal Equivalent sprays or of 2.0 per nasal drops cent of Ephedrine

(3) 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)

		from the restri	ctions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
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 Hydrochloric	le			
Epithiazide				
Epoetin Alfa				
Epoetin Beta				
Epoprostenol Sodium	[			
Ergometrine Maleate				
Ergometrine Tartrate				
Ergot, Prepared				
Ergotamine Tartrate				
Erythromycii	1			
Erythromycii Estolate	1			

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

Erythromycin Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin

Lactobionate

Erythromycin

Phosphate

Erythromycin

Stearate

Erythromycin

Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

I<sup>F29</sup>Estramustine

Sodium

Phosphate]

Etafedrine

Hydrochloride

Ethacrynic

Acid

Ethambutol

Hydrochloride

Ethamivan

Ethamsylate

Ethiazide

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

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

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol

Diacetate

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

[F10 Exemestane]

Famciclovir

Famotidine

For the

10mg (MD)

short-term symptomatic

20mg (MDD)

relief of

For maximum period of

heartburn, 14 days

dyspepsia, indigestion,

acid

indigestion

and

hyperacidity,

and

prevention of these

symptoms when

associated

with food

Status: Point in time view as at 01/01/2001.

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 and drink, including nocturnal symptoms	Column 4 Treatment limitations on,	Column 5 Maximum quantity				
Fazadinium Bromide								
Felbinac	3.17 per cent	External  [F31] For 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 children not less than 12 years	For maximum period of 7 days	Container or package containing not more than [F3050g] of medicinal product				
Felodipine		J						
Felypressin								
Fenbufen								
Fenclofenac								
Fenfluramine Hydrochloric								
Fenofibrate								
Fenoprofen								
Fenoprofen Calcium								
Fenoterol Hydrobromio	de							

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

strength

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

Container

or package

containing

not more

150mg of

Fluconazole

than

use or

pharmaceutical

form

Fenticonazole

Nitrate

Feprazone

Ferrous

Arsenate

[F10Ferumoxsil]

Filgrastim

Finasteride

Flavoxate Hydrochloride

Flecainide

Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone

Acetonide

Flucloxacillin

Magnesium

Flucloxacillin

Sodium

Fluconazole

For oral 150mg (MD) administration

for the treatment of vaginal candidiasis in persons

aged not less than 16 but less than 60 years

Flucytosine

Fludrocortisone

Acetate

57

Status: Point in time view as at 01/01/2001.

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 administrat use or pharmaceur	Column 4 Treatment limitations ion,	Column 5 Maximum quantity				
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				
		[F32For use in persons aged 18 years and over]	[F33For a maximum period of 3 months]					
		In the form of a non- pressurised nasal spray						
		F34	F34	F34				
			F34					
		F34						
		F34						
Fluocinolone Acetonide		• • •						
Fluocinonide								
Fluocortin Butyl								

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

Fluocortolone

Fluocortolone

Hexanoate

Fluocortolone

Pivalate

Fluorescein

Dilaurate

Fluorometholone

Fluorouracil

Fluorouracil

Trometamol

Fluoxetine

Hydrochloride

Flupenthixol

Decanoate

Flupenthixol

Hydrochloride

Fluperolone

Acetate

Fluphenazine

Decanoate

Fluphenazine

Enanthate

Fluphenazine

Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen

Flurbiprofen

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

Fluspirilene

Flutamide

Fluticasone

Propionate

Fluvastatin Sodium

Fluvoxamine Maleate

Folic Acic 500mcg (MDD)

Formestane

Formocortal

Foscarnet Sodium

Fosfestrol Sodium

Fosfomycin Trometamol

Fosinopril Sodium

Framycetin Sulphate

Frusemide

Furazolidone

Fusafungine

Fusidic

Acid Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

Ganciclovir Sodium

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Status: Point in time view as at 01/01/2001.

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

Gelsemine 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

Glucagon

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

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride Griseofulvin

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

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

Halofantrine

Hydrochloride

Haloperidol

Haloperidol

Decanoate

Heparin External

Heparin Calcium

Heparin

Sodium

Hexachlorophane External

(a) 2.0 per

(a) Soaps

External

cent

(b) 0.1 per

(b) Aerosols

cent

(c) 0.75 per

cent preparations

(c)

other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

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 Hexobarbitone Sodium Hexoestrol Hexoestrol Dipropionate L-Histidine Dietary Hydrochloride supplementation Homatropine (1) 0.15 mg (MD)(1) Internal 0.45mg (MDD) (2) External (except ophthalmic) Homatropine 0.2mg (MD) Hydrobromide 0.6mg (MDD) Homatropine 2mg (MD) Methylbromide 6mg (MDD) Hydralazine Hydrochloride Local Hydrargaphen application to skin Hydrobromic Acid Hydrochlorothiazide [F35(1) External Hydrocortisone  $[^{F35}(1) 0.5]$ Container per cent] (a) For or package use in containing combination not more with than 15g of medicinal Nystatin of product] maximum strength 3.0 per cent for intertrigo

Status: Point in time view as at 01/01/2001.

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

		from the restr	ictions on the sale and sup	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati	Column 4 Treatment limitations	Column 5 Maximum quantity	
		pharmaceut form (b) For	ical		
		use in adults and childre not less than 10 years]	n		
	[ <sup>F36</sup> (2)]1.0 per cent	[F36(2)] E  (a) For use either alone or in conjuming with Crotam in irritant dermat contact allergic dermat insect bite reaction mild to moderate eczema and either in combing with Clotrin [F37 or Miconal Nitrate for athlete foot	ction niton itis, it chicking intis, ins, inte an, ination inazole inazole inazole	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)

Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum strength Route of Treatment limitations administration, use or pharmaceutical form  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 onintment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent HydrocortisonEquivalent Contact allergic containing container product reactions, mild to moderate eczema, and in combination with one or sprays  Lamber of Treatment limitations Maximum quantity  Maximu					ictions on the sale	and suppl	y of
Substance Maximum strength administration, administration, use or pharmaceutical form  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  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonGermatitis, contact not more allergic dematitis, insect bite reactions, mild to moderate eczema, and in or package containing container or package containing container or package complete the case of suppositories, container or package container			-				
strength administration, use or pharmaceutical form  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 ontment or spray  HydrocortisonEquivalent External  Acetate to 1.0 For use Container or package containing containing insect bite reactions, mild to moderate eczema, and in combining container or package container or package container or package and in combining container or package container or	Column 1	Column 2	Col	umn 3	Column 4		
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  HydrocortisonEquivalent External Acetate to 1.0 For use in irritant or package dermatitis, contact not more allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combinition containing containing containing containing containing or package containing containing containing containing containing or package dermatitis, mild to case of suppositories, container or package dermatitis, mild to case of suppositories, container or package dermatitis, mild to combination container or package containing container or package dermatities container or package containing container containe	Substance	Maximum	Rou	te of	Treatment limite	ations	Maximum
pharmaceutical form  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  HydrocortisonEquivalent External  Acetate to 1.0 For use containing containing insect bite product reactions, mild to moderate eczema, and in containing containi		strength	adn	inistrati	ion,		quantity
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  HydrocortisonEquivalent External Acetate to 1.0 per cent in irritant or package dematitis, contact not more allergic dematitis, insect bite product reactions, mild to moderate eczema, and in container or package combination or package containing or package combination or package container in co		_	use	or			
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  HydrocortisonEquivalent External Acetate to 1.0 per cent in irritant or package dematitis, contact not more allergic dematitis, insect bite product reactions, mild to moderate eczema, and in container or package combination or package containing or package combination or package container in co			pha	rmaceut	ical		
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  HydrocortisonEquivalent External  Acetate to 1.0 per cent in irritant or package dermatitis, containing contact allergic dematitis, insect bite product reactions, mild to moderate eczema, and in container or package container or package container or package and in container or package container or package container or product reactions, mild to case of moderate suppositories, container or package container or pa			•				
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  HydrocortisonEquivalent Acetate to 1.0 per cent Hydrocortison Grant	-		J				
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  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent Acetate In irritant or package of the moderate allergic than 15g of dermatitis, insect bite product reactions, mild to moderate suppositories, and in combination containing or package or packag					al		
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  HydrocortisonEquivalent External  Acetate to 1.0 For use in irritant or package or package dermatitis, containing containing containing insect bite product reactions, mild to moderate eczema, and in combination containing or package eczema, and in combination containing or package containing or package containing c							
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  HydrocortisonEquivalent Acetate to 1.0 per cent per cent HydrocortisonEquivalent HydrocortisonEquivalent HydrocortisonEquivalent Fexternal Acetate to 1.0 per cent in irritant HydrocortisonEquivalent HydrocortisonEquivalent Fexternal Acetate In the in irritant HydrocortisonEquivalent HydrocortisonEquivalent In irritant HydrocortisonEquivalent In irritant HydrocortisonEquivalent In the allergic dermatitis, contact allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combination containing					<i>5</i> -		
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  HydrocortisonEquivalent Acetate to 1.0 For use per cent in irritant Hydrocortison equivalent Acetate to 1.0 For use contact not more allergic than 15g of dermatitis, containing not more allergic than 15g of medicinal insect bite reactions, mild to moderate eczema, and in combination containing containing rocontaining rocontai					nation		
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  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent HydrocortisonEquivalent Cornatitis, containing dermatitis, insect bite reactions, mild to moderate eczema, and in combination or package containing not more lignocaine not less Container or package containing not more than 15g of medicinal in the moderate suppositories, container or package containing not more than 15g of medicinal in the container or package containing not more case of suppositories, container or package containing							
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anal and perianal itch associated with haemorrhoids (b) For use in adults and children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent Hydrocortison eq cent Hydrocortison eq containing contact allergic than 15g of dermatitis, medicinal insect bite reactions, mild to moderate eczema, and in combination eontaining container or package container or asse of suppositories, container or package containing				-			
and perianal itch associated with haemorrhoids  (b) For use in adults and children not less than 10 years  (c) Cream ointment or spray  HydrocortisonEquivalent HydrocortisonEquivalent HydrocortisonEquivalent contact allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combination container or package containing container or package container contain							
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associated with haemorrhoids (b) For use in adults and children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent External  Acetate to 1.0 For use Container per cent in irritant dermatitis, contact not more allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combination or package containing container or package container or package and in combination or package container or package container or package container or package and in combination or package containing container or package containing container or package containing container containing container containing conta							
with haemorrhoids (b) For use in adults and children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent External  Acetate to 1.0 For use per cent in irritant or package dermatitis, containing dermatitis, containing contact not more allergic than 15g of dermatitis, insect bite product reactions, mild to moderate eczema, and in combination  with haemorrhoids (b) For use in Container Octobaler  Container Octobaler Octobaler  Acetate to 1.0 For use per cent in irritant or package dermatitis, containing not more allergic than 15g of medicinal insect bite product reactions, mild to case of suppositories, container or package octobaler  in the case of suppositories, container or package octobaler  in the container or package octobaler  container or package				associa	ted		
(b) For use in adults and children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent Hydrocortison allergic dermatitis, contact allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combination containing or package container or package suppositories, container or package suppositories							
(b) For use in adults and children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent Hydrocortison allergic dermatitis, contact allergic dermatitis, insect bite product reactions, mild to moderate eczema, and in combination containing or package container or package suppositories, container or package suppositories					rrhoids		
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Acetate to 1.0 For use Container or package dermatitis, contact not more allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination interess in the containing or package containing container or package containing contact and in combination or package containing contact and in combination or package containing contact and in combination containing containing contact and in containing conta				use in			
Children not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent HydrocortisonEquivalent External  For use in irritant or package dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination  Children not not less  Container or package Container or package In the case of suppositories, container or package				adults			
not less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 For use in irritant per cent HydrocortisonCequitison dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination containing or package containing or package suppositories, container or package case of suppositories, container or package containing nedicinal product reactions, mild to case of suppositories, container or package containing not moderate suppositories, container or package containing nor package containing containing nor package containing n				and			
less than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent HydrocortisonEquivalent Germatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination  less than 10 years (c) Cream Ornatie Container Or package Container Or package Containing Or package In the case of suppositories, container Or package containing or package container Or package				childre	n		
than 10 years (c) Cream ointment or spray  HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonEquivalent HydrocortisonEquivalent Acetate to 1.0 per cent Hydrocortison ermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination  than 10 years  Cortainer Or package Container or package containing not more than 15g of medicinal product reactions, mild to case of suppositories, container or package containing				not			
HydrocortisonEquivalent				less			
HydrocortisonEquivalent				than			
HydrocortisonEquivalent Acetate to 1.0 For use per cent in irritant hydrocortison eduratitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination containing or package containing or package suppositories, containing not more suppositories, containing or package containing not more case of suppositories, containing or package containing not product reactions, mild to case of suppositories, container or package containing not package not p				10			
HydrocortisonEquivalent Acetate to 1.0 For use per cent in irritant hydrocortison eduratitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination containing or package containing or package suppositories, containing not more suppositories, containing or package containing not more case of suppositories, containing or package containing not product reactions, mild to case of suppositories, container or package containing not package not p				years			
HydrocortisonEquivalent			(c)	-			
HydrocortisonEquivalent Acetate to 1.0 per cent HydrocortisonE equivalent Acetate to 1.0 per cent HydrocortisonE erreactions, mild to moderate eczema, and in combination  External  Container or package Containing or package than 15g of than 15g of medicinal product In the case of suppositories, container or package			` /	ointme	nt		
HydrocortisonEquivalent Acetate to 1.0 per cent in irritant or package HydrocortisonEquivalent HydrocortisonEquivalent External  For use in irritant dermatitis, containing contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination  Container or package Container product reactioning medicinal in the case of suppositories, container or package containing				or			
HydrocortisonEquivalent Acetate to 1.0 per cent in irritant or package HydrocortisonEquivalent HydrocortisonEquivalent External  For use in irritant dermatitis, containing contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination  Container or package Container product reactioning medicinal in the case of suppositories, container or package containing				spray			
Acetate to 1.0 For use Container or package Hydrocortisone dermatitis, containing contact not more allergic than 15g of dermatitis, insect bite product reactions, mild to moderate eczema, and in combination Container or package containing container or package containing container containing container or package containing contai	TT 1 .:	Б 1 1	г.				
per cent in irritant or package dermatitis, containing contact not more allergic than 15g of dermatitis, insect bite product reactions, mild to moderate eczema, and in combination containing container or package containing container or package containing containin			Exte	rnai			
Hydrocortisone dermatitis, containing contact not more allergic than 15g of dermatitis, medicinal insect bite product reactions, mild to case of moderate eczema, and in combination or package containing contai	Acetate		For	use			Container
allergic than 15g of dermatitis, medicinal insect bite product reactions, mild to moderate eczema, and in combination not more than 15g of medicinal product reactions. In the case of suppositories, container or package containing containing		per cent					or package
allergic than 15g of dermatitis, medicinal insect bite product reactions, mild to moderate eczema, and in combination not more than 15g of medicinal product reactions. In the case of suppositories, container or package containing containing		пушосопиѕо	dern	natitis,			
dermatitis, medicinal insect bite product reactions, In the mild to case of moderate eczema, and in combination medicinal product reactions. In the case of suppositories, container or package containing containing			cont	act			_
dermatitis, medicinal insect bite product reactions, In the mild to case of moderate eczema, and in combination medicinal product reactions. In the case of suppositories, container or package containing containing			aller	gic			than 15g of
insect bite product reactions, In the mild to case of suppositories, container and in combination product  insect bite product case of case of suppositories, container or package containing containing							
reactions, mild to moderate eczema, and in combination  In the case of suppositories, container or package containing							product
mild to moderate eczema, and in combination  case of suppositories, container or package			reac	tions,			
eczema, suppositories, container and in or package combination							
and in container or package combination			mod	erate			
and in container or package combination			ecze	ma,			
Combination							
with one or			com	bination			
			with	one or			containing

Status: Point in time view as at 01/01/2001.

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	Column 4 Treatment limitations on,	Column 5 Maximum quantity				
		form	icai					
		more of the following: Benzyl Benzoate, Bismuth Oxide, Bismuth Subgallate, Peru Balsam, Pramoxine	lo.	no more than 12				
		Hydrochloric Zinc Oxide, for haemorrhoid						
		For use in adults and children not less than 10 years						
		Cream, ointment or suppositories	s					
Hydrocortiso Butyrate	one							
Hydrocortisc Caprylate	one							
Hydrocortisc Hydrogen Succinate	one							
Hydrocortisc Sodium Phosphate	one							
Hydrocortisc Sodium Succinate	onEquivalent to 2.5mg Hydrocortiso	External  For aphthous ulceration of the mouth for adults and children		Container or package containing not more than equivalent to 50mg of Hydrocortisone				

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

	prescription	n only medicine	from the restrictions on the sale and supply of a only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	,	Column 5 Maximum quantity		
		not less than 12 years				
		In the form of pellets				
[ <sup>F11</sup> Hydrocya Acid]	nic					
Hydroflumet	hiazide					
Hydroxychlo Sulphate	oroquine	Prophylaxis of malaria				
Hydroxyprog	gesterone					
Hydroxyprog Enanthate	gesterone					
Hydroxyprog Hexanoate	gesterone					
Hydroxyurea	ı					
Hydroxyzine Embonate	;					
Hydroxyzine Hydrochlorio		(a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride		
		(b) For the management of pruritis associated with acute or chronic	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than		

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	Column 4 Treatment limitations	Column 5 Maximum quantity	
		use or pharmaceut form	ical		
		urticaria or atopic dermatitis or contact dermatitis, in children not less than 6 years but less than 12 years		750mg of Hydroxyzine Hydrochloride	
Hyoscine	(1) 0.15 per cent	(1) Internal			
		(2) External (except ophthalmic)			
Hyoscine		(1) Internal			
Butylbromic	de	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 20mg (MD) 80mg (MDD)	(b) Container or package containing not more than 240mg of Hyoscine Butylbromide	
		(2) External			
Hyoscine	ida	(1) Internal			
Hydrobromide		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)		
		(2) External (except ophthalmic)			
Hyoscine Methobrom	ide	(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)

	_	from the restration only medicine	ictions on the sale and supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscine		(1) Internal		
Methonitrate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscyamine	;	(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 1mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Hydrobromid	e	(a) by inhaler		
		(b) otherwise	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
		than by inhaler	Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine	;	(1) Internal		
Sulphate		(a) by inhaler		

Status: Point in time view as at 01/01/2001.

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	y of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceut	Treatment limitations on,	Maximum quantity
		(b) otherwise than by	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
		inhaler	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, dysmenorrhofeverishness, symptoms of colds and influenza		
		(1) Internal	(1)(a) In the case of a prolonged release preparation 600mg (MD)	
			1,200mg (MDD)	
			(b) in any other case 400mg (MD)	
			1,200mg (MDD)	
	(2) 5.0 per cent	(2) External		
	[F38(3) 10.0 per cent]	[F38(3) External]	[F38(3) 125 mg (MD) 500 mg (MDD)]	[F38(3)] Container or package containing not more than [F3950g] of

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

		from the restres only medicin	rictions on the sale and suppers	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administratuse or pharmaceus form	,	Maximum quantity
				medicinal

medicina product

[F11]Ibuprofen Lysine Rheumatic and muscular

(a) in the case of a prolonged release preparation 600 mg (MD)

pain, pain of 1,200 mg (MDD)

non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza

Internal

(b) in any other case 400 mg (MD) 1,200 mg

(MDD)]

Idarubicin Hydrochloride

Idoxuridine

Ifosfamide

Ignatius Bean

[<sup>F9</sup>Imidapril Hydrochloride]

Imipenem Hydrochloride

Imipramine

Imipramine Hydrochloride

Imipramine

Ion

Exchange

Resin

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

Bound Salt or Complex

[F22Indapamide]

Indapamide Hemihydrate

Indomethacin

Indomethacin

Sodium

Indoprofen

Indoramin Hydrochloride

Inosine Pranobex

[F40 Insulin]

Iodamide

Iodamide Meglumine

Iodamide Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic Acid

Ipratropium Bromide

Iprindole

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

Column 3 Column 4 Route of administration,

Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

**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

Isradipine

Itraconazole

External Jaborandi

Kanamycin Acid Sulphate

Status: Point in time view as at 01/01/2001.

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 pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Kanamycin Sulphate		-			
Ketamine Hydrochlorid	de				
Ketoconazol	e 2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	te[ff[4]] Maximum frequency of application of once every 3 days	[F41(a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole	
		[F43(b)] For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo]			
Ketoprofen	2.5 per cent	External  For rheumatic and muscular pain in adults and children not less than 12	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product	

Trometamol

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 Ketotifen **Fumarate** Labetalol Hydrocholoride Lachesine Chloride Lacidipine Lamotrigine Lanatoside Lanatoside Complex A, B and C [F22Lansoprazole] Latamoxef Disodium [F22]Lercanidipine Hydrochloride] Levallorphan Tartrate Levobunolol Hydrochloride [F11LevocabastEquivalent (1) Nasal (1) Hydrochloride of 0.05 Container sprays or package per cent Levocabastine Symptomatic containing not more treatment than 10 ml of seasonal of medicinal allergic product rhinitis (2) Aqueous (2) eye drops Container or package For the containing symptomatic not more treatment than 4 ml of of seasonal

Status: Point in time view as at 01/01/2001.

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	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administrati use or pharmaceut form	Treatment limitations on,	Maximum quantity
		allergic conjunctiviti	S	medicinal product
[F44Levocarnitine]		[ <sup>F44</sup> For dietary supplementar		
Levodopa				
Levonorgest	re <mark> <sup>F45</sup>0.75mg]</mark>	[F45] for use as an emergency contraceptive in women aged 16 years and over]	e	
Lidoflazine				
Lignocaine		Non- ophthalmic use		
Lignocaine Hydrochlorio	de	Non- ophthalmic use		
Lincomycin				
Lincomycin Hydrochlorid	de			
Liothyronine Sodium	;			
Lisinopril				
Lithium Carbonate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lithium Citrate				
Lithium Succinate				

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

		Exemptions from the restrictions on the sale and supply of prescription only medicines			
Column 1 Substance	prescription of Column 2 Maximum strength	only medicine. Column 3 Route of administratio use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Lithium Sulphate		•	Equivalent of 5mg of Lithium (MD) Equivalent of 15mg of		
Lobeline		(1) Internal	Lithium (MDD) (1) 3mg (MD)		
Looeniic		(1) Internar	9mg (MDD)		
		(2) External	- 8( )		
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		treatment of ocular	,		
Lofepramine					
Lofepramine Hydrochlorid	e				
Lofexidine Hydrochlorid	e				
Lomefloxacir Hydrochlorid					

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 Lomustine

Loperamide Hydrochloride Treatment of acute diarrhoea

Loratidine 10mg (MDD)

> or package containing not more than 100mg of Loratidine

Container

[F23Lornoxicam]

[F23Losartan Potassium]

Loxapine

Succinate

Lung Surfactant Porcine

Luteinising Hormone

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Maleate

Mafenide

Mafenide Acetate

Mafenide Hydrochloride

Mafenide

5.0 per cent Eye drops

Propionate

Magnesium Fluoride

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Route of administrationse or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Magnesium Metrizoate					
Mandragora Autumnalis					
Mannomustin Hydrochlorid					
Maprotiline Hydrochlorid	e				
Mebanazine					
Mebendazole		For oral use in the treatment of enterobiasis in adults and in children not less than 2 years	100mg (MD)	Container or package containing not more than 800mg of Mebendazole	
Mebeverine Hydrochlorid	e	[F48(a) For the symptomatic relief of irritable bowel syndrome	405 mg (MDD)]		
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[F48(b) 100 mg (MD) 300 mg (MDD)]		
Mebeverine Pamoate					
Mebhydrolin					
Mebhydrolin					

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

Mecamylamine

Hydrochloride

Mecillinam

Meclofenoxate

Hydrochloride

Medigoxin

Medrogestone

Medroxyprogesterone

Acetate

Mefenamic

Acid

Mefloquine

Hydrochloride

Mefruside

Megestrol

Megestrol

Acetate

Meglumine

Gadopentetate

Meglumine

Iodoxamate

Meglumine

Ioglycamate

Meglumine

Iothalamate

Meglumine

Iotroxate

Meglumine

Ioxaglate

[F22Meloxicam]

Melphalan

Melphalan

Hydrochloride

Menotrophin

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic use

Meptazinol Hydrochloride

Mequitazine

Mercaptopurine

Mersalyl

Mersalyl Acid

Mesalazine

Mesna

Mestranol

Metaraminol

Tartrate

Metergoline

Metformin

Hydrochloride

Methacycline

Methacycline

Calcium

Methacycline Hydrochloride

Methallenoestril

Methicillin Sodium

Methixene

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance

Maximum strength

Column 3 Column 4 Route of

Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Methixene Hydrochloride

Methocarbamol

Methocidin

Throat lozenges and throat pastilles

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

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 30mg (MD) Hydrochloride 60mg (MDD)

Methylprednisolone

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

Methylprednisolone

Acetate

Methylprednisolone

Sodium

Succinate

Methylthiouracil

Methysergide

Maleate

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

Metoprolol

Fumarate

Metoprolol

Succinate

Metoprolol

Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

Mezlocillin

Sodium

Mianserin

Hydrochloride

Miconazole

External but in the case of vaginal use only external use for the treatment Status: Point in time view as at 01/01/2001.

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 sup	ply of
Column 1	prescription Column 2	only medicine Column 3	s Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceuting form	Treatment limitations on,	Maximum quantity
		candidiasis		
Miconazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Mifepristone	e			
Miglitol				
Milrinone				
Milrinone Lactate				
Minocycline	•			
Minocycline Hydrochlori				
Minoxidil	[ <sup>F49</sup> (1) 2.0 per cent]	[ <sup>F49</sup> (1) External		
	[ <sup>F49</sup> (2) 5.0 per cent	(2) External use for the treatment of alopecia androgenetics in men aged 18 to 65 (but not in women);]	<b>a</b> ,	
[ <sup>F9</sup> Mirtazapi	ne]			
Misoprostol				
Mitobronito	1			
Mitomycin				
Mitozantron Hydrochlori				

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

Mivacurium

Chloride

[F29Mizolastine]

Moclobemide

[F10 Moexipril Hydrochloride]

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

Hydrochloride

Morazone

Hydrochloride

[F9Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

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

Nalorphine Hydrobromide

Naloxone Hydrochloride

Naltrexone Hydrochloride

Naphazoline (1) 0.05 per Hydrochloridæent

sprays or nasal drops not containing liquid paraffin as a vehicle

(1) Nasal

(2) 0.015 (2) Eye per cent drops

Naphazoline 0.05 per Nitrate cent Nasal sprays or nasal drops not containing liquid paraffin as a vehicle

Naproxen

Naproxen Sodium

Natamycin

[F23Nebivolol Hydrochloride]

Nedocromil [F502.0 per Sodium cent]

[F50For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis]

[F50]Container or package containing not more than 3 ml of medicinal product]

Document Generated: 2024-05-23

Status: Point in time view as at 01/01/2001.

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

Nefazodone

Hydrochloride

Nefopam

Hydrochloride

Neomycin

Neomycin

Oleate

Neomycin

Palmitate

Neomycin Sulphate

Neomycin

Undecanoate

Neostigmine

Bromide

Neostigmine

Methylsulphate

Netilmicin

Sulphate

Nicardipine Hydrochloride

Nicergoline

[F29Niceritrol]

Nicotinic

Any use,

600mg (MDD)

Acid

except for the

treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F11Nilutamide]

Nimodipine

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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

Niridazole

[F23Nisoldipine]

Nitrendipine

Nitrofurantoin

Nitrofurazone

Nizatidine

For the 75mg (MD) prevention

 $\begin{bmatrix} F_{51} \\ \end{bmatrix}$  and  $\begin{bmatrix} F_{52} \\ \end{bmatrix}$ 

[F52150mg (MDD)]
[F53For a maximum period

treatment] of the symptoms

the of 14 days] nptoms

of foodrelated heartburn [F51] and mealinduced 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

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

Norgestimate

Norgestrel

Nortriptyline Hydrochloride

Noscapine

Noscapine Hydrochloride

Novobiocin Calcium

Novobiocin Sodium

Nux Vomica Seed

Nystatin

[F543.0 per cent]

 $[^{F54} \hbox{External}$ 

For use in combination with

Hydrocortisone

of maximum strength 0.5 per cent for intertrigo

For use in adults and children not less than 10 years] [F54Container or package containing not more than 15g of medicinal product]

Octacosactrin

Octreotide

Oestradiol

Oestradiol Benzoate

Oestradiol

Cypionate

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

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

Oestradiol

Phenylpropionate

Oestradiol

Undecanoate

Oestradiol

Valerate

Oestriol

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

[F9Omeprazole Magnesium]

Ondansetron

Hydrochloride

Orciprenaline Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

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

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

Oxatomide

Oxedrine Tartrate

Oxethazaine

10mg (MD) 30mg (MDD) Container or package containing not more than

than 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)

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 15mg (MDD)

Oxytetracycline

Oxytetracycline

Calcium

Oxytetracycline Dihydrate

Oxytetracycline Hydrochloride

Oxytocin, natural

Oxytocin, synthetic

Pancreatin

(1) 21,000 (1) capsules

European Pharmacopoeia units of lipase per capsule

(2) 25,000 (2) powder

European Pharmacopoeia units of lipase per gram

Pancuronium Bromide

[F22Pantoprazole Sodium]

Papaverine

(1) By inhaler

(2) (2) 50mg (MD) Otherwise than by 150mg (MDD)

inhaler

Papaverine Hydrochloride (1) 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)

	-	from the restri only medicine	ctions on the sale and supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		(2) Otherwise than by inhaler	(2) Equivalent of 50mg of Papaverine (MD) Equivalent of 150mg of Papaverine (MDD)	
F12Paracetan	(2) 500 mg	Omg[1) Non- effervescent tablets and capsules  [F56] wholly or mainly] for use in children aged less than 12 years  (2) Non- effervescent tablets and capsules  [F57] wholly or mainly] for use in adults and children not less than 12 years		(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
		(3) All preparations other than non-effervescent tablets and capsules		(2) The quantity sold or supplied in one container or package

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

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

shall not exceed 32 The quantity of noneffervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100]

Paraldehyde

Paramethadione

Paramethasone

Acetate

Parathyroid

Gland

Pargyline

Hydrochloride

Paroxetine

Hydrochloride

Pecilocin

Penamecillin

Penbutolol

Sulphate

[F22Penciclovir]

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Status: Point in time view as at 01/01/2001.

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

Penicillamine

Penicillamine Hydrochloride

Pentamidine Isethionate

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

Pentolinium Tartrate

Perfluamine

Pergolide Mesylate

Perhexiline Maleate

Pericyazine

Perindopril

Perindopril Erbumine

Perphenazine

Phenacetin 0.1 per cent

Phenazone External

Phenazone Salicylate

Phenbutrazate Hydrochloride

Phenelzine Sulphate

Phenethicillin Potassium

Phenformin Hydrochloride

Phenglutarimide Hydrochloride

Phenindione

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

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

[F58Phenolphthalein.]

Phenoxybenzamine Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine

Hydrochloride

Phentolamine

Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine Hydrochloride Internal

(1) all preparations except

(1) 25mg (MD) 100mg (MDD)

prolonged release capsules, nasal sprays and nasal drops

(2) prolonged release

(2) 50mg (MD)

100mg (MDD)

(3) 2.0 per cent

(3) nasal sprays and

capsules

nasal drops

Phenytoin

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 Colu Substance Maxi

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Phenytoin Sodium

Phthalylsulphathiazole

Physostigmine

Physostigmine Aminoxide Salicylate

Physostigmine Salicylate

Physostigmine Sulphate

[F11Phytomenadione

Any use except the prevention or

treatment of haemorrhagic disorders]

Picrotoxin

Pilocarpine

Pilocarpine Hydrochloride

Pilocarpine Nitrate

Pimozide

Pindolol

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

Piperacillin Sodium Piperazine Oestrone Sulphate

Piperidolate 50mg (MD) Hydrochloride 150mg (MDD)

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

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

Pipothiazine

**Palmitate** 

Piracetam

Pirbuterol

Acetate

Pirbuterol

Hydrochloride

[F59Pirenzepine Dihydrochloride

Monohydrate]

Pirenzepine

Hydrochloride

Piretanide

Piroxicam 0.5 per cent External

For maximum period of 7 days

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

For the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries

For use in adults and children not less than 12 years

[<sup>F29</sup>Piroxicam Betacyclodextrin]

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 administrationse or pharmaceute form	•	Column 5 Maximum quantity		
Pituitary Gland (Whole Dried)		By inhaler				
Pituitary Powdered (Posterior Lobe)		By inhaler				
Pivampicillin	1					
Pivampicillir Hydrochlorid						
Pivmecillina	m					
Pivmecillina Hydrochlorid						
Pizotifen						
Pizotifen Malate						
Plicamycin						
Podophylloto	oxin					
Podophyllum	1					
Podophyllum Indian	1					
Podophyllum		External				
Resin	cent	Ointment or impregnated plaster				
Poldine			2mg (MD)			
Methylsulpha	ate		6mg (MDD)			
Polidexide						
Polyestradiol Phosphate						
Polymyxin B Sulphate						
Polythiazide						

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

Poppy Capsule

Potassium Arsenite 0.0127 per cent

Potassium Bromide

Potassium Canrenoate

Potassium Clavulanate

Potassium Perchlorate

Practolol

Pralidoxime Chloride

Pralidoxime Iodide

Pralidoxime Mesylate

Pravastatin Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone Butylacetate

Prednisolone Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

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Status: Point in time view as at 01/01/2001.

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

Prednisolone

Pivalate

Prednisolone Sodium Phosphate

Prednisolone Steaglate

Prednisone

Prednisone Acetate

Prenalterol Hydrochloride

Prenylamine Lactate

Prilocaine Hydrochloride Nonophthalmic

use

Primidone

Probenecid

Probucol

Procainamide Hydrochloride

Procaine Hydrochloride Nonophthalmic

use

Procaine Penicillin

Procarbazine Hydrochloride

Prochlorperazine

Prochlorperazine

Edisylate

Prochlorperazine

Maleate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength Route of Tadministration,

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Prochlorperazine

Mesylate

Procyclidine Hydrochloride

Progesterone

Prolactin

Proligestone

Prolintane Hydrochloride

Promazine Embonate

Promazine Hydrochloride

Propafenone

Propafenone Hydrochloride

Propanidid

Propantheline Bromide 15mg (MD)

45mg (MDD)

[F23Propiverine Hydrochloride]

Propofol

Propranolol Hydrochloride

Propylthiouracil

Proquazone

Protamine Sulphate

Prothionamide

Protirelin

Protriptyline Hydrochloride

Tartrate

Status: Point in time view as at 01/01/2001.

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

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

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colum Substance Maxin

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Pyrazinamide

Pyridostigmine

Bromide

Pyrimethamine

[<sup>F23</sup>Quetiapine Fumarate]

[<sup>F10</sup>Quinagolide Hydrochloride]

Quinapril

[F59Quinapril Hydrochloride]

Quinestradol

**Ouinestrol** 

Quinethazone

Quinidine

Quinidine Bisulphate

Quinidine

Polygalacturonate

Quinidine Sulphate

Quinine 100mg (MD)

300mg (MDD)

Quinine Equivalent of 100mg of

Bisulphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Cinchophen Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Dihydrochloride Quinine (MD)

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

		from the restrictions on the sale and su only medicines	pply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
		Equivalent of 300mg of Quinine (MDD)	
Quinine Ethyl		Equivalent of 100mg of Quinine (MD)	
Carbonate		Equivalent of 300mg of Quinine (MDD)	
Quinine Glycerophos	phate	Equivalent of 100mg of Quinine (MD)	
		Equivalent of 300mg of Quinine (MDD)	,
Quinine Hydrobromio	de	Equivalent of 100mg of Quinine (MD)	,
		Equivalent of 300mg of Quinine (MDD)	
Quinine Hydrochlorid	de	Equivalent of 100mg of Quinine (MD)	,
		Equivalent of 300mg of Quinine (MDD)	,
Quinine Iodobismuth	ate	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)	,

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

> Equivalent of 300mg of Quinine (MDD)

Quinine in combination with Urea Hydrochloride

Ramipril

[F9Ranitidine Bismuth Citrate]

Ranitidine Hydrochloride For the short term symptomatic relief of

heartburn, dyspepsia,

indigestion, acid indigestion

and hyperacidity

with consuming food and drink]

[F60] or the prevention of these symptoms when associated

Vomitoria Razoxane Remoxipride Hydrochloride

Rauwolfia Serpentina Rauwolfia

Equivalent to 75mg of Ranitidine (MD)

Equivalent to 300mg of Ranitidine (MDD)

For a maximum period of

14 days

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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

Reproterol

Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

[F9Rimexolone]

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

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

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

Semisodium

Valproate

[<sup>F9</sup>Sertraline Hydrochloride]

Serum

Gonadotrophin

[F9Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

Sodium 0.013 per Arsenite cent

Sodium

Bromide

Sodium Clodronate

Sodium Cromoglycate (a) For nasal admistration

(b) 2.0 per (b) For the cent treatment

(b) Container

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 restric only medicines	ctions on the sale and si	upply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceuti	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		of acute seasonal allergic conjunctivitis  I <sup>F61</sup> or perennial allergic conjunctivitis In the form of aqueous eye drops		or package containing not more than 10ml of medicinal product
	(c) 4.0 per cent	(c) For the treatment of acute seasonal allergic conjunctivitis		(c) Container or package containing not more than 5g of
		In the form of an eye ointment		medicinal product
Sodium Ethacrynate				
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices		
		(2) Other preparations for use in the prevention 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		

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 (c) 0.05 per (c) mouth cent rinses for daily use Sodium Fusidate Sodium Metrizoate Dentrifrice Sodium 1.14 per Monofluorophoenthate Sodium Oxidronate Sodium Stibogluconate Sodium Valproate Somatorelin Acetate Sotalol Hydrochloride [F10Sparfloxacin] Spectinomycin Spectinomycin Hydrochloride Spiramycin Spiramycin Adipate Spironolactone Dentifrice Stannous 0.62 per Fluoride cent Stilboestrol Stilboestrol Dipropionate Streptodornase External

External

Streptokinase

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Streptomycin

Streptomycin

Sulphate

Strychnine

Strychnine

Arsenate

Strychnine

Hydrochloride

[F11Strychnine

Nitrate]

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

Sulbenicillin

Sulbenicillin

Sodium

Sulconazole Nitrate External (except

vaginal)

[F11Sulfabenzamide]

Sulfacytine

Sulfadoxine

Sulfamerazine

Sulfamerazine

Sodium

Sulfametopyrazine

Sulfamonomethoxine

Sulindac

Sulphacetamide

Sulphacetamide

Sodium

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Sulphadiazine

Sulphadiazine

Sodium

Sulphadimethoxine

Sulphadimidine

Sulphadimidine

Sodium

Sulphafurazole

Sulphafurazole

Diethanolamine

Sulphaguanidine

Sulphaloxic

Acid

Sulphamethizole

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

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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 Column 4
Route of Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

Suxethonium

Bromide

[F23Tacalcitol

Monohydrate]

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin

Napsylate

Tamoxifen

Tamoxifen

Citrate

[F22Tamsulosin

Hydrochloride]

[F9Tazarotene]

Tazobactam

Sodium

Teicoplanin

Temocillin

Sodium

Tenoxicam

Status: Point in time view as at 01/01/2001.

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 sup	ply of
Column 1	prescription Column 2	n only medicine Column 3	s Column 4	Column 5
Substance Maximum strength		Route of administration use or pharmaceutic form	,	Maximum quantity
Terazosin Hydrochlorid	de			
Terbinafine				
[ <sup>F62</sup> Terbinafi Hydrochlorid		[F62External use for the treatment of tinea pedis and tinea cruris]		[F62Container or package containing not more than 15 g of medicinal product.]
Terbutaline				
Terbutaline Sulphate				
Terfenadine			F63	F63
			• • •	
Terlipressin				
Terodiline Hydrochlorio	de			
Tetrabenazin	e			
Tetracosactri	n			
Tetracosactri Acetate	n			
Tetracycline				
Tetracycline Hydrochlorid	de			
Tetracycline Phosphate Complex				
Tetroxoprim				
Гhallium Acetate				
Thallous Chloride				
Thiabendazo	le			

Thiambutosine

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

use or

Column 4
Treatment limitations

Column 5 Maximum quantity

pharmaceutical form

Thiethylperazine

Malate

Thiethylperazine

Maleate

Thiocarlide

Thioguanine

Thiopentone

Sodium

Thiopropazate

Hydrochloride

Thioproperazine

Mesylate

Thioridazine

Thioridazine

Hydrochloride

Thiosinamine

Thiotepa

Thiothixene

Thiouracil

Thymoxamine

Hydrochloride

Thyroid

Thyrotrophin

Thyroxine

Sodium

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

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

[F22Ticlopidine Hydrochloride]

Tigloidine Hydrobromide

[F22Tiludronate Disodium]

Timolol Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except

vaginal)

(2) Vaginal

for treatment of vaginal candidiasis

[F10Tizanidine Hydrochloride]

Tobramycin

Tobramycin Sulphate

Tocainide Hydrochloride

Tofenacin Hydrochloride

Tolazamide

Tolazoline External

Hydrochloride

Tolbutamide

Tolbutamide Sodium

Tolfenamic 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)

		es	
Column 2	Column 3	Column 4	Column 5
Maximum strength	administrati use or	ion,	Maximum quantity
		strength administrat use or pharmaceut	strength administration, use or pharmaceutical

Tolmetin Sodium

[F9Topiramate]

[F29Torasemide]

[F22Toremifene]

Tramadol

Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone

Hydrochloride

Treosulfan

Tretinoin

11001110111				
Triamcinolon	e			
Triamcinolon Acetonide	For the treatmen of comm mouth ulcers  [F65(2) In	For the treatment of common mouth		[F64(1)] Container or package containing not more than 5g of medicinal product
		I <sup>F65</sup> (2) In the form of a non- pressurised nasal spray, for the treatment of symptoms of seasonal allergic	[F65(2) 110mcg per nostril (MD)  110mcg per nostril (MDD)  For a maximum period of 3 months]	[F65Container or package containing not more than 3.575mg of Triamcinolone Acetonide]

rhinitis in persons

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

		from the restres only medicin	ictions on the sale and suppers	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administrat	Treatment limitations ion,	Maximum quantity
		use or pharmaceut	tical	
		form		
		aged 18		
		years and		
		overl		

Triamcinolone

Diacetate

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

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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

Tropisetron Hydrochloride

Troxidone

L- (1) Oral

Tryptophan Dietary

supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

Tulobuterol Hydrochloride

Tyrothricin Throat

lozenges or throat pastilles

Uramustine

Urea

Stibamine

Urethane

Uridine 5'triphosphate

Urofollitrophin

Urokinase

Ursodeoxychoic

Acid

Vaccine:

Bacillus

Salmonella

Typhi

Vaccine:

Poliomyelitis

(Oral)

[F10 Valaciclovir Hydrochloride]

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

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

Valproic

Acid

Vancomycin Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

[F10 Venlafaxine 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)

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	y 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
		(2) External		
Vitamin A Acetate		(1) Internal	(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Palmitate		(1) Internal	(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Warfarin				
Warfarin Sodium				
Xamoterol Fumarate				
Xipamide				
Yohimbine Hydrochloride	;			
[F10Zalcitabine	e]			
Zidovudine				
Zimeldine Hydrochloride	;			
Zolpidem Tartrate				
Zomepirac Sodium				
Zopiclone				
Zuclopenthixo Acetate	ol			
Zuclopenthixo Decanoate	ol			
Zuclopenthixo 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)

#### **Textual Amendments**

- F9 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)
- F10 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)
- F11 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.
- F12 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
- F13 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)
- F14 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)
- F15 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)
- F16 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)
- F17 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(a)
- F18 Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(a)
- F19 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)
- **F20** 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)
- F21 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)
- **F22** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(h)
- F23 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)
- F24 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)
- F25 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(b)
- **F26** 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)**
- F27 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)
- **F28** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(c)
- **F29** 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)**
- F30 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)
- **F31** 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)**
- **F32** 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)**
- **F33** 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)**

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)

- F34 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)
- F35 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)
- F36 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)
- F37 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)
- F38 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)
- **F39** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(d)
- **F40** 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)**
- **F41** 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)
- **F42** 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)
- **F43** 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)
- **F44** 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)**
- F45 Sch. 1 entries inserted (1.1.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2000 (S.I. 2000/3231), arts. 1(1), 2
- **F46** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(e)(i)
- F47 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(e)(ii)
- F48 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)
- **F49** 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)**
- **F50** 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)**
- F51 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)
- F52 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)
- F53 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)
- F54 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)
- **F55** Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(i)
- **F56** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(ii)
- F57 Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(f)(iii)
- **F58** 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)**
- **F59** 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)**

- **F60** 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)**
- **F61** 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)
- **F62** 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)**
- **F63** 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)**
- F64 Sch. 1 entries re-numbered (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)
- F65 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)

#### SCHEDULE 2

Articles 6(1) and 10

	Circumstances excludi prescription only medi		from the class of
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical Form	Column 4 Maximum Dose
Codeine and its salts	Equivalent of 1.5 per cent of codeine monohydrate		Equivalent of 20 mg of codeine monohydrate
Dihydrocodeine and its salts	Equivalent of 1.5 per cent of dihydrocodeine		Equivalent of 10 mg of dihydrocodeine
Ethylmorphine andits salts	Equivalent of 0.2 per cent of ethylmorphine		Equivalent of 7.5 mg of ethylmorphine
Morphine and its salts	(1) Equivalent of 0.02 per cent anhydrous morphine	(1) Liquid	(1) Equivalent of 3 mg of anhydrous morphine
	(2) Equivalent of 0.04 per cent of anhydrous morphine; equivalent of 300 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

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 3**

Article 2(b)

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

[F66Co-danthramer Capsules NPF]

[F66Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F66Co-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

#### **Textual Amendments**

**F66** 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

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)

Sodium Bromide Strychnine Hydrochloride Tacrine Hydrochloride Thiopentone Sodium

#### SCHEDULE 5

Article 11(1)(a)

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

## PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies		lumn 3 nditions	_		
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines	1.	be— (a) su pr an by of co ed re ap of in sp	the institution for which the prescription only medicine is required, the purpose for which the prescription only medicine is required, and		

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 Persons	I exempted	Column 2 Prescription only medicines to which the exemption applies	Column : Condition	
			(b)	for the purposes of the education or research with which the institution is concerned.
sup only	sons selling or plying prescription y medicines to any of following— a public analyst appointed under section 27 of the Food Safety Act 1990(21) or article 36 of the Food (Northern Ireland) Order 1989(22), an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990, a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989, a person duly authorized by an enforcement authority under sections 111 and 112, a sampling officer within the meaning of Schedule 3 to the	2. All prescription only medicines.	subject to an order s of any per 1 of this p status of t and the ar only medi shall be or with the e	e or supply shall be the presentation of igned by or on behalf son listed in column aragraph stating the he person signing it nount of prescription cine required, and anly in connection xercise by those if their statutory
Act.  3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a		3. All prescription only medicines.	3. The be— (a)	sale or supply shall subject to the

<sup>(21) 1990</sup> c. 16.

engaged in connection with a

scheme for testing the quality

<sup>(22)</sup> S.I. 1989/846 (N.I. 6).

be-

subject to the (a) presentation of an order signed by or

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	to w	vhich	ion only medicines the exemption	Condition	
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 Services (Northern Ireland) Order 1972(25), or under any subordinate legislation made under those Acts or that Order.	арр	dies		(b)	on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only medicine required, and for the purposes of a scheme referred to in column 1 in this paragraph.
4. Registered midwives.	4.	med any	cription only icines containing of the following stances— Chloral hydrate Ergometrine maleate Pentazocine hydrochloride [F67Phytomenadione] Triclofos sodium.	be only in profession case of Er only wher medicinal for parent	e or supply shall the course of their nal 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.	med not	cription only icines which are for parenteral inistration and ch— are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or are eye ointments and are prescription only medicines by reason only that they contain not more than	subject to an order s	e or supply shall be the presentation of igned by a registered c optician.

<sup>(23) 1977</sup> c. 49. (24) 1978 c. 29. (25) S.I. 1972/1265 (N.I. 14).

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
	1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any of the following substances: Atropine sulphate Bethanecol chloride Carbachol 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.	<ul> <li>6. The sale or supply shall be only—</li> <li>(a) in the course of their professional practice and</li> <li>(b) in an emergency.</li> </ul>
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.	7. The sale or supply shall be—  (a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of

Status: Point in time view as at 01/01/2001.

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

<sup>(</sup>**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 Persons exempted	Column 2 Prescription only medicines to which the exemption	Column 3 Conditions
[F6810. State registered chiropodists who hold a certificate of competence in the use of the medicines specified in Column 2 issued by or with the approval of the Chiropodists Board.	applies  10. The following prescription only medicines—  (a) Co-dydramol 10/500 tablets;  (b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;  (c) Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume;	10. The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.]
	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**

- **F67** 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)**
- **F68** 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)

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 EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

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

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

Article 11(2)

PART III
EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column I 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—  [F69] Bupivacaine hydrochloride	1. The administration shall be only in the course of their professional practice.

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

Column 1	Co.	lumn 2	Column 3
Persons exempted	to v	escription only medicines which the exemption plies	Conditions
		Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride Lignocaine hydrochloride Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride  [F70 Mepivacaine hydrochloride] Prilocaine hydrochloride.]	
2. Registered midwives.	2.	Prescription only medicines for parenteral	2. The administration shall be only in the course of their professional practice and

administration containing professional practice and any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order-

Ergometrine maleate Lignocaine Lignocaine hydrochloride Naloxone hydrochloride Oxytocins, natural and synthetic Pentazocine lactate Pethidine hydrochloride Phytomenadione Promazine hydrochloride.

in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.

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

- 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

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
	TE CONTRACTOR	the description in question are to be used on the aircraft.
7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.	7. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).	7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and ir that person's presence to use his own judgement as to the treatment required.
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescription only medicines that are for parenteral administration.	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State [F71 or persons who are state registered paramedics].	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;  (bb) [F72 medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient]  (d) prescription only medicines containing one or more of the following substances, but no active ingredient—Adrenaline	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose o cannula flushing.

Acid Tartrate

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	
	Anhydrous	
	Glucose	
	[ <sup>F73</sup> Benzylpe	
	[ <sup>F74</sup> Bretyliur	n
	Tosylate]	
	Compound	
	Sodium	
	Lactate	
	Intravenous	
	Infusion	
	(Hartmann's	3
	Solution)	
	Ergometrine	
	Maleate	
	[ <sup>F73</sup> Frusemic	de]
	Glucose	
	Heparin	
	Sodium	
	Lignocaine	1
	Hydrochlori	
	[ <sup>F73</sup> Metoclop	
	[ <sup>F73</sup> Morphin	e
	Sulphate]	
	Nalbuphine	
	Hydrochlori	de
	Naloxone	
	Hydrochlori	de
	Polygeline	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride F73 c	
	[ <sup>F73</sup> Streptoki	inasej

#### **Textual Amendments**

- **F69** 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)**
- **F70** 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)
- F71 Words in Sch. 5 Pt. 3 para. 9 added (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 5(a)
- **F72** Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **5(b)**
- F73 Words in Sch. 5 Pt. 3 para. 9 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 5(c)

F74 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
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

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 (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

#### F<sup>75</sup>SCHEDULE 7

Articles 12A to 12C

#### **Textual Amendments**

F75 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;

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)

- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;
- (i) the strength, or maximum strength, at which prescription only medicines of that description or class are to be administered;
- (j) the applicable dosage or maximum dosage;
- (k) the route of administration;
- (l) the frequency of administration;
- (m) any minimum or maximum period of administration applicable to prescription only medicines of that description or class;
- (n) whether there are any relevant warnings to note, and, if so, what warnings;
- (o) whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- (p) arrangements for referral for medical advice;
- (q) details of the records to be kept of the supply, or the administration, of medicines under the Direction.

#### **PART II**

## PERSONS ON WHOSE BEHALF A PATIENT GROUP DIRECTION MUST BE SIGNED

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

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 III**

## CLASSES OF INDIVIDUAL [F76BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### **Textual Amendments**

F76 Words in Sch. 7 Pt. 3 heading substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 3(2)

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

Pharmacists.

Registered health visitors.

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

State registered chiropodists.

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).]

#### 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).

Status: Point in time view as at 01/01/2001.

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)

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

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

- (a) the deletion from Column 1 of substances which are no longer used in those medicinal products which are on the market;
- (b) the use of current names for the substances which are specified in that Column where their names have changed;
- (c) the incorporation in that Schedule of provisions from article 4 of, and Part IV of Schedule 1 to, the 1983 Order as amended so that they may be found more easily;
- (d) a change in the legal base for the entries in Columns 2 to 4 so that those entries now form the criteria for exemptions from the sale or supply requirements of section 58(2) of the Medicines Act 1968 instead of the criteria for excluding medicinal products from the class of prescription only medicines (*see also* article 5);
- (e) the introduction of a fifth Column which specifies the maximum pack sizes to which exemptions apply.

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

#### **Status:**

Point in time view as at 01/01/2001.

#### **Changes to legislation:**

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