#### 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;

I<sup>F1</sup>"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>(3) 1979</sup> c. 36; the Parts of the professional register were determined by S.I. 1983/667, amended by S.I. 1989/104 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,

- "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**

- F1 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.

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

#### **Textual Amendments**

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**

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** 

## 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.

- (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-

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- (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.

#### [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

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

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

[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

form

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

Status: Point in time view as at 16/11/2000.

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity		
Acrivastine		V	24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine		
Acrosoxacin						
Actinomycin C						
Actinomycin D						
[ <sup>F10</sup> Adapalene	]					
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	1					
Albendazole						
Alclofenac						
Alclometason Dipropionate	e					
Alcuronium Chloride						
Aldesleukin						
Aldosterone						

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

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

[F9Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F11 Aloxiprin (1) 620 mg

(1) Noneffervescent tablets and capsules (1) The quantity sold or supplied in one container or package shall not exceed 32

The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100

(2) All preparations other than non-effervescent tablets or capsules

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength

Column 3 Route of administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F10 Altretamine]

Amantadine

Hydrochloride

Ambenonium

Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine Gentisate

Nonophthalmic

use

Amethocaine

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

pharmaceutical

form

Amygdalin

Column 1

Substance

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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Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Antimony

Trichloride

Antimony

Trioxide

Antimony Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F10Apraclonidine

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 16/11/2000.

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

		from the restric	ctions on the sale and sup	ply of
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 capsulor or a capsulor of tablets or a capsulor of tabl	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	

		from the restrictions on the sale and supply of nonly medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		(2) External (except ophthalmic)			
Atropine	1	(1) Internal			
Methobromic	le	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		Internal			
Methonitrate		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
Atropine		(1) Internal			
Oxide Hydrochlorid	le	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			
Atropine		(1) Internal			
Sulphate		(a) by inhaler			

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

			ictions on the sale and suppl	ly of
Column 1	prescription Column 2	n only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceut	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	2	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

administration (nonaerosol)

For nasal

100mcg per nostril (MD)

or package containing not more than  $[^{\text{F19}}20,000]$ mcg] of Beclomethasone

Dipropionate

Container

For the prevention and

200 mcg per nostril (MDD)

[F20For a maximum period of 3 months]

treatment of allergic

rhinitis

30

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 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 Column 3 C Route of T administration,

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 Colu Substance Max

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Bethane chol

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 200mcg per nostril (MD) administration

For the prevention or treatment

[F20For a maximum period of 3 months]

of seasonal allergic rhinitis Container or package containing not more than 10mg of Budesonide

Status: Point in time view as at 16/11/2000.

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1	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

[F22Cabergoline]

form

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)

		ns from the restrictions on the sale and supply of ion only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Carbaryl					
Carbenicillin Sodium					
Carbenoxolone Sodium		(1) Pellet	(1) 5mg (MD) 25mg (MDD)		
	(2) 2.0 per cent	(2) Gel			
	(3) 1.0 per cent	(3) Granules for mouthwash in adults and children not less than 12 years	(3) 20mg (MD) 80mg (MDD)	(3) Container or package containing not more than [F <sup>24</sup> 560mg] of Carbenoxolone Sodium	
Carbidopa					
Carbimazole					
Carbocisteine	e				
Carbon Tetrachloride					
Carboplatin					
Carboprost					

Trometamol
Carbuterol
Hydrochloride
Carfecillin
Sodium

Carindacillin Sodium

Carisoprodol Carmustine Carperidine Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Column 3 Column 4
Route of Treatment limitations administration,

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

Cephamandoi

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

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

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

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 heartburn,

For a maximum period of 14 days

dyspepsia, indigestion, acid indigestion

and

hyperacidity and for the prophylaxis of mealinduced heartburn

(b) For the

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

management night

of nocturnal heartburn

For a maximum period of 14 days

by a single dose taken at night

Cimetidine Hydrochloride

Cinchocaine 3.0 per cent Non-

ophthalmic

use

Cinchocaine Equivalent Hydrochloride f 3.0 per

Nonophthalmic use

cent of Cinchocaine

Cinchophen

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

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

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[<sup>F10</sup>Citalopram Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin

Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin

Phosphate

Clioquinol

(1) External (other than

treatment of mouth ulcers)

uicc

(2) 35mg

(2) 350mg (MDD)

Treatment of mouth ulcers

(2)

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: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

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

form

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

Cyclopentolate

Hydrochloride

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cyproterone

Acetate

Cytarabine

Cytarabine

Hydrochloride

Dacarbazine

Dalteparin

Sodium

Danazol

Danthron

Dantrolene

Sodium

Dapsone

Dapsone

Ethane

Ortho

Sulphonate

Daunorubicin

Hydrochloride

Trydrocinoriae

Deanol

Bitartrate

Debrisoquine

Sulphate

Demecarium

Bromide

Demeclocycline

Demeclocycline

Calcium

44

26mg (MDD)

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone

Pivalate

Deptropine

Citrate

Dequalinium (1) 0.25mg

Chloride

(1) Internal: throat lozenges or throat pastilles

(2) 1.0 per cent

(2) External: paint

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine

Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Changes to 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 Diethylammorciant

External For local symptomatic relief of

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 Co Substance Mo

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

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 Domperidone [F2510mg of Domperidone the relief (MD)of post-[F2540mg of Domperidone prandial (MDD)] symptoms than of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied

I<sup>F25</sup>Container or package containing not more 200mg of Domperidone]

Domperidone Maleate

[F26For the relief of postprandial symptoms

epigastric discomfort and heartburn]

by

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

or package containing not more than

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity	
		of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and	[F2740 mg of Domperidone as Domperidone Maleate (MDD)]	[F28200mg] of Domperidone as Domperidone Maleate;]	
Dopamine Hydrochlorid	le	heartburn,]			
Dopexamine Hydrochlorid					
[ <sup>F10</sup> Dorzolam Hydrochlorid					
Dothiepin					
Dothiepin Hydrochlorid	le				
Doxapram Hydrochlorid	le				
Doxazosin Mesylate					
Doxepin Hydrochlorid	le				
Doxorubicin					
Doxorubicin Hydrochlorid	le				
Doxycycline					
Doxycycline Calcium Chelate					

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

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

Estolate

Status: Point in time view as at 16/11/2000.

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

			ictions on the sale and supply	vof
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administrati use or pharmaceut	Treatment limitations on,	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 Hydrochlorid	le			
Epithiazide				
Epoetin Alfa				
Epoetin Beta				
Epoprostenol Sodium				
Ergometrine Maleate				
Ergometrine Tartrate				
Ergot, Prepared				
Ergotamine Tartrate				
Erythromycir	1			
Erythromycir	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

Column 3 Route of administration,

pharmaceutical

use or

form

Column 4 Treatment limitations Column 5 Maximum quantity

Erythromycin Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin Lactobionate

Erythromycin

Phosphate

Erythromycin Stearate

Erythromycin Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

[F29 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 Route of Tadministration,

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 short-ter

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 16/11/2000.

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

		Exemptions from the restrictions on the sale and supply of						
Column 1	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				
		and drink, including nocturnal symptoms						
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		•						
Felypressin								
Fenbufen								
Fenclofenac								
Fenfluramine Hydrochlorid								
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 Substance

Column 2 Column 3 Maximum Route of administration, strength

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 16/11/2000.

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of 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 Column 3 C Route of T administration,

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

60

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Status: Point in time view as at 16/11/2000.

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

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

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

External

(a) 2.0 per

(a) Soaps

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 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of prescription only medicines						
~ .	• •	•		~		
Column 1	Column 2	Column 3	Column 4	Column 5		
Substance	Maximum	Route of	Treatment limitations	Maximum		
	strength	administrati	ion,	quantity		
		use or				
		pharmaceut	ical			
		form				
		(b) For				
		use in				
		adults				
		and				
		childre	n			
		not				
		less				
		than				
		10				
		years]				
	$[^{F36}(2)]1.0$	$[^{F36}(2)]$ E	xternal			
	per cent	$\begin{array}{ccc} (a) & \text{For} \end{array}$	AMITTU	or package		
	per cent	use		containing		
		either		not more		
		alone		than 15g		
		or in		of medicinal		
		conjun	ction	product		
		with	CHOH	(cream or		
		Crotan	niton	ointment) or		
		in	11011	30ml (spray)		
		irritant		s omi (opiwy)		
		dermat				
		contact				
		allergio				
		dermat				
		insect	,			
		bite				
		reactio	ns.			
		mild	•			
		to				
		modera	ate			
		eczema	a,			
		and	,			
		either				
		in				
		combir	nation			
		with				
		Clotrin	nazole			
		[F37or				
		Micon	azole			
		Nitrate				
			,			
		for				
		for athlete	's			

Changes to 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 prescription			ictions on the sal	e and suppl	y of
Column 1 Substance	Column 2 Maximum	Col Rou	umn 3 ite of	Column 4 Treatment limi	tations	Column 5 Maximum
	strength	aan use	iinistrati or	ton,		quantity
			rmaceut	ical		
		forn	n			
			and	1		
			candida intertri			
			or in	go		
			combin	nation		
			with			
			lignoca	nine		
			for			
			anal and			
			periana	ıl		
			itch			
			associa	ited		
			with haemon	rrhoids		
		(b)	For	iiiioius		
		(0)	use in			
			adults			
			and			
			childre not	n		
			less			
			than			
			10			
		(a)	years			
		(c)	Cream ointme			
			or			
			spray			
Hydrocortiso	on <b>E</b> quivalent	Exte	rnal			
Acetate	to 1.0	For				Container
	per cent					or package
	Hydrocortisc	ne dern	natitis,			containing
		cont	act			not more
		aller				than 15g of
			natitis, ct bite			medicinal product
			tions,			_
		mild				In the
			erate			case of suppositories,
		ecze				container
		and	in bination			or package
			one or			containing
		** 1111	0110 01	65		

Status: Point in time view as at 16/11/2000.

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

		Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti	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)

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	
		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 Hydrochlorid		(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	

			ictions on the sale and sup	ply of
C-1 1		only medicine		C-1 5
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or	,	Column 5 Maximum quantity
		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		
Butylbromid	le	(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 Hydrobromi	de	<ul><li>(1) Internal</li><li>(a) by</li></ul>		
Trydrobronni	Hydrobromide			
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine Methobromi	de	(1) Internal		

		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				
		(a) by inhaler						
		(b)	(b) 2.5mg (MD)					
		otherwise than by inhaler	7.5mg (MDD)					
		(2) External						
Hyoscine		(1) Internal						
Methonitrate		(a) by inhaler						
		(b)	(b) 2.5mg (MD)					
		otherwise than by inhaler	7.5mg (MDD)					
		(2) External						
Hyoscyamine		(1) Internal						
		(a) by inhaler						
		(b)	(b) 300mcg (MD)					
		otherwise than by inhaler	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 16/11/2000.

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

	_	-	ctions on the sale and suppl	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)

Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical			from the restres only medicing	ictions on the sale and sup <sub>l</sub> es	ply of
	Column 1 Substance	Maximum	Route of administrat use or	Treatment limitations ion,	Maximum

medicinal 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 Column 2 Substance Maximum

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

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

Jaborandi External

Kanamycin Acid Sulphate

Status: Point in time view as at 16/11/2000.

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

		Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
Kanamycin Sulphate						
Ketamine Hydrochlorid	le					
Ketoconazolo	e 2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	相相側] 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 16/11/2000.

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

		from the restri n only medicine	ctions on the sale and supp	ply of
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		allergic conjunctivitis	5	medicinal product]
[ <sup>F44</sup> Levocarni	tine]	[F44For dietary supplementat	tion]	
Levodopa				
Levonorgestr	el			
Lidoflazine				
Lignocaine		Non- ophthalmic use		
Lignocaine Hydrochlorid	e	Non- ophthalmic use		
Lincomycin				
Lincomycin Hydrochlorid	e			
Liothyronine Sodium				
Lisinopril				
Lithium Carbonate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lithium Citrate				
Lithium Succinate				
Lithium Sulphate			Equivalent of 5mg of Lithium (MD)	
			Equivalent of 15mg of Lithium (MDD)	
Lobeline		(1) Internal	(1) 3mg (MD)	
			9mg (MDD)	
		(2) External		

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

-	Exemptions	from the restri	ctions on the sale and suppl	Ty of
	prescription	only medicine	es s	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		use or pharmaceuti form	ical	
Lobeline Hydrochloric	le	(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lobeline Sulphate		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lodoxamide Trometamol	[F45] equivalent of 0.1 per cent Lodoxamide]	treatment of ocular	5,	
Lofepramine				
Lofepramine Hydrochloric				
Lofexidine Hydrochlorid	le			
Lomefloxaci Hydrochlorid				
Lomustine				
Loperamide Hydrochloric	le	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	Container or package containing not more than
			77	

Changes to 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 supp es	ply of	
Column 1 Substance	Column 2 Maximum strength			Column 5 Maximum quantity	
		<del>-</del>		100mg of	

100mg of Loratidine

[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

Magnesium

Metrizoate

Mandragora

Autumnalis

Mannomustine

Hydrochloride

Maprotiline

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)

			ctions on the sale and supp	ply of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administration use or pharmaceuti	Column 4 Treatment limitations on,	Column 5 Maximum quantity
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 Hydrochloride		[F47(a) For the symptomatic relief of irritable bowel syndrome	[F47(a) 135 mg (MD) 405 mg (MDD)]	
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[F47(b) 100 mg (MD) 300 mg (MDD)]	
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylami Hydrochlorid				
Mecillinam				
Meclofenoxa Hydrochlorid				
Medigoxin				
Medrogeston	e			

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 1 Column 1

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

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

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Any use Hydrochloride except

Changes to 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

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

Methixene

Hydrochloride

Methocarbamol

Methocidin

lozenges and throat pastilles

Throat

Changes to 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

ph

pharmaceutical

form

use or

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine

Hydrochloride

Methotrimeprazine

Maleate

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

Methsuximide

Methyclothiazide

Methyldopa

Methyldopate Hydrochloride

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

Methylprednisolone

Methylprednisolone

Acetate

Methylprednisolone

Sodium Succinate

Methylthiouracil

Methysergide

Maleate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

Metoprolol

Fumarate

Metoprolol

Succinate

Metoprolol Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

Mezlocillin

Sodium

Mianserin

Hydrochloride

Miconazole

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

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

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

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

Minoxidil

Minocycline Hydrochloride

[F48(1) 2.0 per cent]

[F48(1) External

[F48(2) 5.0 per cent

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

[F9Mirtazapine]

Misoprostol

Mitobronitol

Mitomycin

Mitozantrone

Hydrochloride

Mivacurium

Chloride

[F29Mizolastine]

Moclobemide

[F10 Moexipril Hydrochloride]

Molgramostim

Changes to 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

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

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

Naphazoline (1) 0.05 per

Hydrochlorideent

(1) Nasal sprays

Status: Point in time view as at 16/11/2000.

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

		from the restric	ctions on the sale and sup	ply of
Column 1 Substance	prescription Column 2 Maximum strength	Column 3  Route of  administration use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		or nasal drops not containing liquid paraffin as a vehicle		
	(2) 0.015 per cent	(2) Eye drops		
Naphazoline Nitrate	0.05 per cent	Nasal sprays or nasal drops not containing liquid paraffin as a vehicle		
Naproxen				
Naproxen Sodium				
Natamycin				
[ <sup>F23</sup> Nebivolol Hydrochloric				
Nedocromil Sodium	[F492.0 per cent]	[F49For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis	]	[F49]Container or package containing not more than 3 ml of medicinal product]
Nefazodone Hydrochlorid	le			
Nefopam Hydrochlorid	le			
Neomycin				
Neomycin Oleate				
Neomycin Palmitate				

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Co Substance M

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Neomycin Sulphate

Neomycin Undecanoate

Neostigmine Bromide

Neostigmine Methylsulphate

Netilmicin Sulphate

Nicardipine Hydrochloride

Nicergoline

[F29Niceritrol]

Nicotinic Acid Any use, 600mg (MDD)

except for the treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F11Nilutamide]

Nimodipine

Niridazole

[F23Nisoldipine]

Nitrendipine

Nitrofurantoin

Nitrofurazone

Nizatidine

For the prevention

75mg (MD)

[F51150mg (MDD)]

[F50and treatment]

Status: Point in time view as at 16/11/2000.

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

	prescription	only medicine			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form		Column 5 Maximum quantity	
		of the symptoms of food-related heartburn [F50 and meal-induced indigestion]	[F52For a maximum period of 14 days]		
		For use in adults and children not less than 16 years		_	
Nomifensine Maleate					
Noradrenaline					
Noradrenaline Acid Tartrate					
Norethisterone	e				
Norethisterone Acetate	e				
Norethisterone Enanthate	e				
Norethynodre	l				
Norfloxacin					
Norgestimate					
Norgestrel					
Nortriptyline Hydrochloride	<b>)</b>				
Noscapine					
Noscapine Hydrochloride	;				

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

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

Novobiocin

Calcium

Novobiocin Sodium

Nux Vomica

Seed

Nystatin [F533.0 per

cent]

[F53External

For use in combination

with

Hydrocortisone

of maximum strength 0.5 per cent for intertrigo

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

Octacosactrin

Octreotide

Oestradiol

Oestradiol

Benzoate

Oestradiol

Cypionate

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

Oestradiol

Phenylpropionate

[F53]Container or package containing not more than 15g of medicinal product]

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

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

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

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

Oxatomide

Changes to 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

Oxedrine Tartrate

Oxethazaine 10mg (MD) Container or package containing

not more than 400mg of Oxethazaine

Oxitropium Bromide Oxolinic

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Oxybuprocaine Hydrochloride

Nonophthalmic use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

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

Oxytetracycline Oxytetracycline

Calcium

Oxytetracycline Dihydrate

Oxytetracycline Hydrochloride

Status: Point in time view as at 16/11/2000.

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

		from the restri	ctions on the sale and supply	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Oxytocin, natural				
Oxytocin, synthetic				
Pancreatin	(1) 21,000 European Pharmacopo units of lipase per capsule	(1) capsules		
	(2) 25,000 European Pharmacopo units of lipase per gram	(2) powder		
Pancuroniur Bromide	m			
[F22Pantopra Sodium]	zole			
Papaverine		(1) By inhaler		
		(2) Otherwise than by inhaler	(2) 50mg (MD) 150mg (MDD)	
Papaverine Hydrochlori	de	(1) By inhaler		
		(2) Otherwise than by inhaler	(2) Equivalent of 50mg of Papaverine (MD) Equivalent of 150mg of Papaverine (MDD)	
[F12Paracetar	mol (1) [ <sup>F54</sup> 25	50mg(1) Non- effervescent tablets and capsules [F55wholly or mainly] for use in	02	(1) 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)

		from the restric	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutic	Column 4 Treatment limitations on,	Column 5 Maximum quantity
	(2) 500 mg	children aged less than 12 years		shall not exceed 32  The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100
		(3) All preparations other than non-effervescent tablets and capsules		(2) The quantity sold or supplied in one container or package shall not exceed 32  The quantity of non-effervescent tablets, capsules or a combination of both

Changes to 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

> 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]

Penicillamine

Penicillamine Hydrochloride

Pentamidine Isethionate

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

Pentolinium Tartrate

Perfluamine

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Status: Point in time view as at 16/11/2000.

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

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

pharmaceutical

form

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

[F57Phenolphthalein.]

Phenoxybenzamine

Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Changes to 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

Phensuximide

Phentolamine

Hydrochloride Phentolamine

Mesylate

Phenylbutazone

Phenylbutazone Sodium

Phenylpropanolamine Hydrochloride Internal

(1) all (preparations except 1

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

except prolonged release capsules, nasal sprays

nasal spra and nasal drops

(2) 50mg (MD)

release capsules

(2) prolonged

100mg (MDD)

(3) 2.0 per cent

(3) nasal sprays and nasal drops

Phenytoin

Phenytoin Sodium

Phthalylsulphathiazole

Physostigmine

Physostigmine Aminoxide

Salicylate

Physostigmine Salicylate

Physostigmine Sulphate

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

	F., out :: 4: -	C	otions on the rule and	ah, of
	•	from the restric only medicines	ctions on the sale and sup	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceution form	,	Maximum quantity
[ <sup>F11</sup> Phytomen	adione	Any use except the prevention or treatment of haemorrhagic disorders]		
Picrotoxin				
Pilocarpine				
Pilocarpine Hydrochlorid	e			
Pilocarpine Nitrate				
Pimozide				
Pindolol				
Pipenzolate			5mg (MD)	
Bromide			15mg (MDD)	
Piperacillin Sodium				
Piperazine Oestrone Sulphate				
Piperidolate			50mg (MD)	
Hydrochlorid	e		150mg (MDD)	
Pipothiazine Palmitate				
Piracetam				
Pirbuterol Acetate				
Pirbuterol Hydrochlorid	e			
[F58Pirenzepir Dihydrochlor Monohydrate	ride			

Status: Point in time view as at 16/11/2000.

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

		from the restri only medicine	ctions on the sale and suppl s	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Pirenzepine Hydrochloric	le			
Piretanide				
Piroxicam	0.5 per cent	External For the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries For use in adults and children not less than 12 years	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
[ <sup>F29</sup> Piroxicam Beta- cyclodextrin]				
Pituitary Gland (Whole Dried)		By inhaler		
Pituitary Powdered (Posterior Lobe)		By inhaler		

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Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pivampicillin

Hydrochloride

Pivmecillinam

Pivmecillinam

Hydrochloride

Pizotifen

Pizotifen

Malate

Plicamycin

Podophyllotoxin

Podophyllum

Podophyllum

Indian

Podophyllum 20.0 per

Resin

cent

External

Ointment or impregnated

plaster

Poldine

2mg (MD)

Methylsulphate

6mg (MDD)

Polidexide

Polyestradiol

Phosphate

Polymyxin

B Sulphate

Polythiazide

Poppy Capsule

Potassium

0.0127 per

Arsenite

cent

Potassium

Bromide

Potassium

Canrenoate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

use or

Column 4
Treatment limitations

Column 5 Maximum quantity

pharmaceutical form

Potassium

Clavula nate

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

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

Prednisolone

Steaglate

Prednisone

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Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

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

Prochlorperazine

Mesylate

Procyclidine Hydrochloride

Progesterone

Prolactin

Proligestone

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)

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column Substance Maximi

Column 2 C Maximum Restrength ac

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

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

Proxymetacaine Hydrochloride Nonophthalmic

use

Pseudoephedrine Hydrochloride Internal

(a) In the case of a prolonged release

preparation 120mg (MD) 240mg (MDD)

(b) in any other case 60mg

(MD)

Changes to 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 supply of			
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
			240mg (MDD)			
Pseudoephed	lrine		60mg (MD)			
Sulphate			180mg (MDD)			
Pyrantel Embonate		(a) For the treatment of enterobiosis, in adults and children not less than 12 years	(a) 750mg MDD (as a single dose)	(a) Container or package containing not more than 750mg of Pyrantel Embonate		
		(b) For the treatment of enterobiosis, in children less than 12 years but not less than 6 years	(b) 500mg MDD (as a single dose)	(b) Container or package containing not more than 750mg of Pyrantel Embonate		
		(c) For the treatment of enterobiosis in children less than 6 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						
Pyrazinamid	e					
Pyridostigmi Bromide						
Pyrimethami	ne					
[ <sup>F23</sup> Quetiapin Fumarate]	e					
[ <sup>F10</sup> Quinagol: Hydrochlorid						
Quinapril						

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

[F58Quinapril Hydrochloride]

Quinestradol

Quinestrol

Quinethazone

Quinidine

Quinidine Bisulphate

Quinidine

Polygalacturonate

Quinidine Sulphate

Quinine 100mg (MD)

300mg (MDD)

Quinine Equivalent of 100mg of

Bisulphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Cinchophen Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Dihydrochloride Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Ethyl Quinine (MD)

Carbonate Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Glycerophosphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Changes to 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 Quinine Equivalent of 100mg of Hydrobromide Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Hydrochloride Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Equivalent of 100mg of Quinine

Iodobismuthate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Phosphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Salicylate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Equivalent of 100mg of Quinine

Sulphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Ouinine Equivalent of 100mg of

Tannate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine in combination with Urea Hydrochloride

Ramipril

[F9Ranitidine Bismuth Citrate]

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

	prescription	Exemptions from the restrictions on the sale and supply of prescription only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity	
Ranitidine Hydrochlorid	de	For the short term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity [F59] or the prevention of these symptoms when associated with consuming	Equivalent to 75mg of Ranitidine (MD)  Equivalent to 300mg of Ranitidine (MDD)  For a maximum period of 14 days		
Rauwolfia Serpentina		food and drink]			
Rauwolfia Vomitoria					
Razoxane					
Remoxipride Hydrochlorid					
Reproterol Hydrochlorio	de				
Rescinnamin	ie				
Reserpine					
Rifabutin					
Rifampicin					
Rifampicin Sodium					
Rifamycin					
[F9Rimexolo	ne]				

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F9Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F9Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Changes to 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

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) For the

(b) 2.0 per cent

treatment
of acute
seasonal
allergic
conjunctivitis

[F60]
or
perennial

allergic conjunctivitis] In the form of aqueous eye drops

(c) 4.0 per cent

(c) For the treatment of acute

(b)
Container
or package
containing
not more
than 10ml
of medicinal
product

(c) Container or package

		from the restric	ctions on the sale and sup	oply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutic form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		seasonal allergic conjunctivitis In the form of an eye ointment		containing not more than 5g of 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		
	(c) 0.05 per cent	(c) mouth rinses for daily use		
Sodium Fusidate				
Sodium Metrizoate				
Sodium Monofluoroj	1.14 per phæspthate	Dentrifrice		
Sodium Oxidronate				
Sodium Stiboglucona	ate			

Changes to 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

Sodium

Valproate

Somatorelin

Acetate

Sotalol

Hydrochloride

[F10Sparfloxacin]

Spectinomycin

Spectinomycin Hydrochloride

Spiramycin

Spiramycin

Adipate

Spironolactone

Stannous

0.62 per

Dentifrice

Fluoride cent

Stilboestrol

Stilboestrol

Dipropionate

Streptodornase External

Streptokinase

External

Streptomycin

Streptomycin Sulphate

Strychnine

Strychnine Arsenate

Strychnine

Hydrochloride

[F11Strychnine

Nitrate]

Styramate

Succinylsulphathiazole

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Sucralfate

Sulbactam

Sodium

Sulbenicillin

Sulbenicillin Sodium

Sulconazole Nitrate External (except vaginal)

[F11Sulfabenzamide]

Sulfacytine

Sulfadoxine

Sulfamerazine

Sulfamerazine

Sodium

Sulfametopyrazine

Sulfamonomethoxine

Sulindac

Sulphacetamide

Sulphacetamide

Sodium

Sulphadiazine

Sulphadiazine

Sodium

Sulphadimethoxine

Sulphadimidine

Sulphadimidine

Sodium

Sulphafurazole

Sulphafurazole

Diethanolamine

Sulphaguanidine

Changes to 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

Sulphaloxic

Acid

Sulphamethizole

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

Changes to 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

Suxethonium Bromide

[F23Tacalcitol Monohydrate]

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin Napsylate

Tamoxifen

Tamoxifen Citrate

[F22 Tamsulosin Hydrochloride]

[F9Tazarotene]

Tazobactam Sodium

Teicoplanin

Temocillin Sodium

Tenoxicam

Terazosin Hydrochloride

Terbinafine

[F61TerbinafindF611.0 per Hydrochloridedent]

[F61 External use for the treatment of tinea pedis and tinea cruris]

[F61 Container or package containing not more than 15 g of medicinal product.]

Terbutaline

Status: Point in time view as at 16/11/2000.

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceuti form		Column 5 Maximum quantity		
Terbutaline Sulphate						
Terfenadine			F62	F62		
Terlipressin						
Terodiline Hydrochloride						
Tetrabenazine						
Tetracosactrin						
Tetracosactrin Acetate						
Tetracycline						
Tetracycline Hydrochloride						
Tetracycline Phosphate Complex						
Tetroxoprim						
Thallium Acetate						
Thallous Chloride						
Thiabendazole						
Thiambutosine	:					
Thiethylperazi Malate	ne					
Thiethylperazi Maleate	ne					
Thiocarlide						
Thioguanine						
Thiopentone Sodium						
Thiopropazate Hydrochloride						

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Status: Point in time view as at 16/11/2000.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Thioproperazine

Mesylate

Thioridazine

Thioridazine

Hydrochloride

Thiosinamine

Thiotepa

Thiothixene

Thiouracil

Thymoxamine

Hydrochloride

Thyroid

Thyrotrophin

Thyroxine

Sodium

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

Sodium

 $[^{F22} \\ Ticlopidine$ 

Hydrochloride]

Tigloidine

Hydrobromide

[F22Tiludronate

Disodium]

Timolol

Maleate

Tinidazole

Tinzaparin

Status: Point in time view as at 16/11/2000.

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	•	Column 5 Maximum quantity		
Tioconazole	(1) 2.0 per cent	(1) External (except vaginal)				
		(2) Vaginal for treatment of vaginal candidiasis				
[ <sup>F10</sup> Tizanidine Hydrochloric						
Tobramycin						
Tobramycin Sulphate						
Tocainide Hydrochlorid	le					
Tofenacin Hydrochlorid	le					
Tolazamide						
Tolazoline Hydrochlorid	le	External				
Tolbutamide						
Tolbutamide Sodium						
Tolfenamic Acid						
Tolmetin Sodium						
[ <sup>F9</sup> Topiramate	e]					
[ <sup>F29</sup> Torasemic	de]					
[F22Toremifer	ne]					
Tramadol Hydrochlorid						
Trandolapril						

Changes to 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

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolong<sup>F63</sup>(1)] 0.1 Acetonide per cent

 $[^{F63}(1)]$ For the treatment of common mouth ulcers

[F64(2)] In the form of a nonpressurised nasal spray, for the treatment of

symptoms of seasonal allergic rhinitis in persons

aged 18 years and over]

[F64(2) 110mcg per nostril (MD)

110mcg per nostril (MDD)

For a maximum period of 3 months]

 $[^{F63}(1)]$ Container or package containing not more than 5g of medicinal product

[F64Container or package containing not more than

3.575mg of Triamcinolone Acetonide]

Triamcinolone Diacetate

Triamcinolone Hexacetonide

Triamterene

Tribavirin

Changes to 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

Triclofos Sodium

Trientine

Dihydrochloride

Trifluoperazine

Trifluoperazine

Hydrochloride

Trifluperidol

Trifluperidol Hydrochloride

Trilostane

Trimeprazine

Trimeprazine

Tartrate

Trimetaphan Camsylate

Trimetazidine

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

L-Tryptophan (1) Oral

Dietary

supplementation

(2) External

Tubocurarine Chloride Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

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

Column 1 Column 2 C

Maximum strength Column 3 Column 4
Route of Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Tulobuterol

Substance

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]

Trydrocinori

Valproic

Acid

Vancomycin

Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form IF10Venlafaxine 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) 7,500iu (2,250mcg (1) Internal

(2) External

Vitamin A Acetate (1) Internal (1) Equivalent to 7,500iu

(MDD)

Vitamin A (2,250mcg Retinol equivalent)

Retinol equivalent)

(MDD)

(2) External

Vitamin A Palmitate (1) Internal (

(1) Equivalent to 7,500iu Vitamin A (2,250mcg Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

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

Retinol equivalent (MDD)

(2) External

Warfarin

Warfarin

Sodium

Xamoterol

Fumarate

Xipamide

Yohimbine

Hydrochloride

[F10Zalcitabine]

Zidovudine

Zimeldine

Hydrochloride

Zolpidem

Tartrate

Zomepirac

Sodium

Zopiclone

Zuclopenthixol

Acetate

Zuclopenthixol

Decanoate

Zuclopenthixol

Hydrochloride]

#### **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)
- 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** 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)
- **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)(ii)
- F47 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)
- **F48** 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)**
- **F49** 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)**
- **F50** 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)
- 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)(ii)
- F52 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)
- F53 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)
- **F54** 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)
- F55 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)
- 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)(iii)
- **F57** 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)**
- **F58** 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)**
- F59 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)
- **F60** 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)**
- **F61** 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)**
- **F62** 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)**
- **F63** 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)

F64 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)

#### SCHEDULE 2

Articles 6(1) and 10

	Circumstances excluding prescription only media		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

#### SCHEDULE 3

Article 2(b)

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

[F65Co-danthramer Capsules NPF]

[F65Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

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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)

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F65Co-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**

**F65** Words in Sch. 3 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 4

#### SCHEDULE 4

Article 8(4)(c)

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

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone Sodium

Hydrobromic Acid

Meclofenoxate Hydrochloride

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

#### SCHEDULE 5

Article 11(1)(a)

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

# PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1	Column 2	Column 3 Conditions		
Persons exempted	Prescription only medicines to which the exemption applies			
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	b (i	subjection of the concession of the concession of definition of the spection of the spection of the spection of the spection of the concession of the spection	r supply shall ect to the entation of rder signed he principal e institution erned with ation or herch or the opriate head epartment harge of a iffied course of herch stating— the name of the institution for which the prescription only medicine is required, the purpose for which the prescription only medicine is required, and the total quantity required, and he purposes e education search which the tution is

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
only medicines to any of		of any person listed in column
the following-		1 of this paragraph stating the
(1) 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), (2) an authorized		status of the person signing it and the amount of prescription only medicine required, and shall be only in connection with the exercise by those persons of their statutory functions.
(2) an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990,		
(3) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989,		
(4) a person duly authorized by an enforcement authority under sections 111 and 112,		
(5) a sampling officer within the meaning of Schedule 3 to the Act.		
3. Persons selling or supplying	3. All prescription only	3. The sale or supply shall

prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(23), the National Health Service (Scotland) Act 1978(24) and the Health and Personal Social

<sup>3.</sup> All prescription only medicines.

<sup>3.</sup> The sale or supply shall be–

<sup>(</sup>a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only

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

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

<sup>(23) 1977</sup> c. 49.

<sup>(24) 1978</sup> c. 29.

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies		oted Prescription only medi- to which the exemption applies			
Services (Northern Ireland) Order 1972(25), or under any subordinate legislation made under those Acts or that Order.			(b)	medicine required, and for the purposes of a scheme referred to in column 1 in this paragraph.		
4. Registered midwives.	4.	Prescription only medicines containing any of the following substances—  Chloral hydrate Ergometrine maleate Pentazocine hydrochloride  [F66Phytomenadione] Triclofos sodium.	be only in profession case of Er only when medicinal for parente	e or supply shall the course of their tal practice and in the gometrine maleate a contained in a product which is not eral administration.		
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	5.	Prescription only medicines which are not for parenteral administration and which—  (a) are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or  (b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or  (c) are prescription only medicines by reason only that they contain any	subject to an order si	e or supply shall be the presentation of igned by a registered c optician.		

Column 1	Column 2	Column 3		
Persons exempted	Prescription only medicines to which the exemption applies	Condii		
	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.		their professional practice and	
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.	7. T	he sale or supply shall e- a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and	

professional practice and (a)

in the case of Co-dydramol

10/500 tablets the quantity sold

or supplied to a person at any

one time shall not exceed the

Status: Point in time view as at 16/11/2000.

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

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions		
		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.		
[F6710. State registered chiropodists who hold a	<b>10.</b> The following prescription only medicines—	10. The sale or supply shall be only in the course of their professional practice and (a)		

Board.

certificate of competence in the

use of the medicines specified

in Column 2 issued by or with

the approval of the Chiropodists

(a) Co-dydramol 10/500

hydrochloride

cream where the

tablets;

(b) Amorolfine

<sup>(</sup>**26**) 1972 c. 66.

<sup>(27)</sup> S.I. 1976/1214 (N.I. 23).

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

Column 1	Column	2	Column 3	
Persons exempted		tion only medicines the exemption	Conditions	
		maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;	amount sufficient for 3 days' treatment to a maximum of 24 tablets.]	
	(c)	Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume; and		
	(d)	Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.		

#### **Textual Amendments**

**F66** 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)

**F67** Sch. 5 Pt. 1 para. 10 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), art. 1, **Sch.** 

Article 11(1)(b)

# PART II EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

Column 1	Column 2	Column 3	
Persons exempted	Prescription only medicines to which the exemption applies	Conditions	
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines.	1. The supply shall be only so far as is necessary for the the treatment of sick or injured persons in the exercise of the functions of the Institution.	

health scheme.

#### Status: Point in time view as at 16/11/2000.

Column I Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
2. The owner or the master of a ship which does not carry a doctor on board as part of her complement.	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the treatment of persons on the ship.
3. Persons authorized by licences granted under regulation 5 of the Misuse of Drugs Regulations to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	4. Such prescription only medicines as may be specified in the relevant enactment.	4. The supply shall be—  (a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and  (b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.
5. Persons operating an occupational health scheme.	5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	5. —  (1) The supply shall be in the course of an occupational health scheme.  (2) The individual supplying the prescription only medicine, if not a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme

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

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

Article 11(2)

PART III
EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	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—  [F68Bupivacaine hydrochloride Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride  Lignocaine hydrochloride  133	1. The administration shall be only in the course of their professional practice.

Status: Point in time view as at 16/11/2000.

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

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
	Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride [F69]Mepivacaine hydrochloride] Prilocaine hydrochloride.]	
2. Registered midwives.	2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order—  Ergometrine maleate  Lignocaine  Lignocaine  Lignocaine  hydrochloride  Oxytocins, natural and synthetic  Pentazocine lactate  Pethidine  hydrochloride  Phytomenadione  Promazine  hydrochloride.	2. The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.
3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of her complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
5. Persons operating an occupational health scheme.	5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	5. —  (1) The administration shall be in the course of an occupational health scheme.  (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy,	7. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).	7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgement as to the treatment required.

Status: Point in time view as at 16/11/2000.

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

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
acupuncture or other similar field except chiropody.		
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescription only medicines that are for parenteral administration.	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State [F70 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) [F71 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 Acid Tartrate Anhydrous Glucose  [F72 Benzylpeni [F73 Bretylium Tosylate] Compound Sodium Lactate Intravenous Infusion	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption	Conditions
	applies	
	(Hartmann's	
	Solution)	
	Ergometrine	
	Maleate	
	[ <sup>F72</sup> Frusemide	c]
	Glucose	
	Heparin	
	Sodium	
	Lignocaine	
	Hydrochlorid	e
	[ <sup>F72</sup> Metoclopr	ramide]
	[F72Morphine	-
	Sulphate]	
	Nalbuphine	
	Hydrochlorid	e
	Naloxone	
	Hydrochlorid	e
	Polygeline	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride	
	[ <sup>F72</sup> Streptokin	ase]

#### **Textual Amendments**

- **F68** 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)**
- **F69** 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)**
- **F70** 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)
- **F71** 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)**
- 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(c)
- F73 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 Orders	Column 2 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
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994	S.I. 1994/3016

Document Generated: 2024-07-12

Status: Point in time view as at 16/11/2000.

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

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (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

### [F74SCHEDULE 7

Articles 12A to 12C

#### **Textual Amendments**

F74 Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(e)

### **PART I**

#### PARTICULARS TO BE INCLUDED IN A PATIENT GROUP DIRECTION

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what restrictions;
- (d) the clinical situations which prescription only medicines of that description or class may be used to treat;
- (e) the clinical criteria under which a person shall be eligible for treatment;
- (f) whether any class of person is excluded from treatment under the Direction and, if so, what class of person;
- (g) whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances;
- (h) the pharmaceutical form or forms in which prescription only medicines of that description or class are to be administered;

Changes to 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 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

#### **PART III**

## CLASSES OF INDIVIDUAL [F75BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### **Textual Amendments**

F75 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)

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

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).

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—

Status: Point in time view as at 16/11/2000.

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

- (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 16/11/2000.

### **Changes to legislation:**

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