#### STATUTORY INSTRUMENTS

## 1997 No. 1830

## **MEDICINES**

The Prescription Only Medicines (Human Use) Order 1997

Made - - - - 25th July 1997

Laid before Parliament 28th July 1997

Coming into force - - 18th August 1997

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

#### Citation, commencement and interpretation

- 1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Order 1997 and shall come into force on 18th August 1997.
  - (2) In this Order, unless the context otherwise requires-

"the Act" means the Medicines Act 1968;

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

F1....

[F2:"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;]

<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).

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

[F2: Community marketing authorization" means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93;]

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

"cyanogenetic substances" means preparations which-

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

[F3" district nurse/health visitor prescriber" means—

- (a) a person who—
  - (i) is registered in Part 1 or 12 of the professional register, and
  - (ii) has a district nursing qualification additionally recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983; or
- (b) a person who is registered in Part 11 of the professional register as a health visitor, against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients;] "dosage unit" means—
- (a) where a medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other article, or
- (b) where a medicinal product is not in any such form, the unit of measurement which is used as the unit by reference to which the dose of the medicinal product is measured;

[F4":Extended Formulary" means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;]

[F4" extended formulary nurse prescriber" means a person—

- (a) who is registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register; and
- (b) against whose name is recorded in that register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Extended Formulary;

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

[F2"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;]

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

"health prescription" means a prescription issued by a doctor, dentist [F5, a district nurse/health visitor prescriber or an extended formulary nurse prescriber] under or by virtue of—

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

[F2"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;

[F2"marketing authorization" includes a reference both to a United Kingdom marketing authorization and to a Community marketing authorization;]

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

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

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

"maximum strength" means-

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

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

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

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

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

[F2"NHS trust"—

<sup>(4) 1977</sup> c. 49.

<sup>(5) 1978</sup> c. 29.

<sup>(6)</sup> S.I. 1972/1265 (N.I. 14).

<sup>(</sup>**7**) 1995 c. 21.

<sup>(8)</sup> S.I. 1985/2066.

<sup>(9)</sup> SR 1986 No. 52.

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

- (a) in 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;]
- "occupational health scheme" means a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease;
- "offshore installation" means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(10) which is within—
- (a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(11); "operator", in relation to an aircraft, means the person for the time being having the management of the aircraft;
- "parenteral administration" means administration by breach of the skin or mucous membrane; IF2". 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;
- [F2"Primary Care Trust" has the same meaning as in the National Health Service Act 1977;]
- [F6" professional register" means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001;]
- "prolonged release" in relation to a medicinal product means a formulation of that product which-
- (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 [F7the professional register];
- "registered nurse" means a person who is registered in [F8the professional register];

<sup>(10) 1971</sup> c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).

<sup>(11) 1964</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)

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

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

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

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

[F2"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 [F9the register of chiropodists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001];

[F24] state registered paramedic" means a person who is registered in [F10] the register of paramedics maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001];]

"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.

[F2:"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 [F11Schedules 1, 2, 3A and 5]—

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

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"g" for gram,
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"iu" for international unit of activity,

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

- (6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.
- [F12(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 adminstration 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 omitted (1.4.2002) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(a)
- **F2** 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 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(b)
- F4 Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(c)
- Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(d)
- **F6** Words in art. 1 inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(e)**
- F7 Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(f)
- Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(g)
- **F9** Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(h)**
- F10 Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(2)(i)
- F11 Words in art. 1(5) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 2(3)
- **F12** 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)**

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

#### 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;
  - [F13(b)] in relation to the descriptions and classes of medicinal products specified in Schedule 3, district nurse/health visitor prescribers;
    - (c) in relation to the descriptions and classes of medicinal products specified in article 3A(1), extended formulary nurse prescribers.]

#### **Textual Amendments**

F13 Art. 2(b)(c) substituted for art. 2(b) (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 3

#### [F14Medicinal products on prescription only

- **3.** The following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—
  - (a) medicinal products in respect of which a marketing authorization has been granted, which in the marketing authorization are classified as being prescription only medicines;
  - (b) medicinal products in respect of which no marketing authorization has been granted consisting of or containing a substance listed in column 1 of Schedule 1;
  - (c) medicinal products that are for parenteral administration;
  - (d) medicinal products that are controlled drugs unless a marketing authorization has been granted in respect of that medicinal product in which the product is classified as being a pharmacy only or on general sale list medicine;
  - (e) cyanogenetic substances, other than preparations for external use;
  - (f) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used.]

#### **Textual Amendments**

F14 Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4

#### [F15Prescribing by extended formulary nurse prescribers

- **3A.**—(1) Subject to paragraph (2), the description and classes of medicinal products in relation to which extended formulary nurse prescribers are appropriate practitioners are those prescription only medicines which consist of, or contain, one or more of the substances specified in column 1 of Schedule 3A, but which do not contain any other substance or combination of substances which is a prescription only medicine not included in Schedule 3A.
  - (2) An extended formulary nurse prescriber may—
    - (a) give a prescription for a medicinal product referred to in paragraph (1); or
    - (b) if that medicinal product is for parenteral administration—

- (i) administer that medicinal product, or
- (ii) give directions for the administration of that medicinal product,
- only where he complies with any condition as to the cases or circumstances in which he may do so that is specified by virtue of paragraph (3).
- (3) If the entry in column 2 of Schedule 3A relating to a substance specifies one or more requirements as to use, route of administration or pharmaceutical form, it is a condition for the purposes of paragraph (2) that a medicinal product which consists of, or contains, that substance is administered, or is prescribed or directed for administration, in accordance with the specified requirements.]

#### **Textual Amendments**

F15 Art. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 5

#### Duration of special provisions in relation to new medicinal products

F164.																

#### **Textual Amendments**

F16 Art. 4 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 11

#### **Exempt medicinal products**

- **5.**—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there—
  - (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or
  - (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.
- (2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.
- (3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.
- (4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use—
  - (a) where a purpose for which it may be used is so specified, for that purpose;

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(b) where the class of persons in whom it may be used is so specified, in persons of that class  $I^{F17}$ .

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**

F17 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

<sup>F18</sup> 6
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#### **Textual Amendments**

F18 Art. 6 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 11

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

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

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

Atropine Sulphate Injection

Chlorpheniramine Injection

**Cobalt Edetate Injection** 

Dextrose Injection Strong B.P.C.

Diphenhydramine Injection

Glucagon Injection

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum

Sodium Nitrite Injection

Sodium Thiosulphate Injection

Sterile Pralidoxime

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

#### **Exemptions for emergency sale or supply**

- **8.**—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.
  - (2) The conditions referred to in paragraph (1) are-
    - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor [F19, a

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- district nurse/health visitor prescriber or an extended formulary nurse prescriber] who by reason of an emergency is unable to furnish a prescription immediately;
- (b) that the doctor [F20, district nurse/health visitor prescriber or extended formulary nurse prescriber] has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;
- (c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor [F21, district nurse/health visitor prescriber or extended formulary nurse prescriber] requesting it;
- (d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(13) within the time specified in that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.
- (3) The restrictions imposed by section 58(2)(a) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (4) are satisfied.
  - (4) The conditions referred to in paragraph (3) are-
    - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself—
      - (i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,
      - (ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor [F22, district nurse/health visitor prescriber or extended formulary nurse prescriber] for the person requesting it, and
      - (iii) as to the dose which in the circumstances it would be appropriate for that person to take;
    - (b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment is sold or supplied except that where the prescription only medicine—
      - (i) is [F23a preparation of insulin,] an aerosol for the relief of asthma, an ointment or cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply may be sold or supplied,
      - (ii) is an oral contraceptive, a quantity sufficient for a full treatment cycle may be sold or supplied,
      - (iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment may be sold or supplied;
    - (c) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
    - (d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;

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

#### **Textual Amendments**

- **F19** Words in art. 8(2)(a) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 6(a)(i)
- **F20** Words in art. 8(2)(b) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 6(a)(ii)
- **F21** Words in art. 8(2)(c) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(a)(iii)**
- **F22** Words in art. 8(4)(a)(ii) inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **6(b)**
- **F23** 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—

Changes to 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) 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.

#### [F24Exemption 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**

F24 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)

## [F25] Exemptions for the supply and administration of prescription only medicines by national health service bodies

- **12A.**—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the supply of a prescription only medicine by—
  - (a) the Common Services Agency;
  - (b) a Health Authority or Special Health Authority;
  - (c) an NHS trust;
  - (d) a Primary Care Trust; or
  - (e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply of prescription only medicines,

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

- (2) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by—
  - (a) the Common Services Agency;
  - (b) a Health Authority or Special Health Authority;
  - (c) an NHS trust;
  - (d) a Primary Care Trust; or

(e) where sub-paragraphs (a) to (d) do not apply, a person other than an excepted person, pursuant to an arrangement made with one of the persons specified in those sub-paragraphs for the supply or, as the case may be, the administration of prescription only medicines,

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

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

#### **Textual Amendments**

**F25** 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.

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

- (2) The conditions referred to are that—
  - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the doctor or dentist in question in providing the services referred to in paragraph (1)(a) (whether or not it also relates to such supply or administration in order to assist any other doctor or dentist);
  - (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
  - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
  - (d) the Patient Group Direction is signed—
    - (i) by the doctor or dentist in question or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
    - (ii) on behalf of the health authority—
      - (a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or
      - (b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;
  - (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
  - (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (3) In this article—
  - (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
    - (i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997;
    - (ii) in relation to Scotland, the provision of general dental services under Part II of the National Health Service (Scotland) Act 1978, or the performance of personal dental services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1997; and
    - (iii) in relation to Northern Ireland, the provision of general dental services under the Health and Personal Social Services (Northern Ireland) Order 1972, or the performance of personal dental services in connection with a pilot scheme under the Health Services (Primary Care) (Northern Ireland) Order 1997;
  - (b) a reference to the provision of NHS primary medical services shall be construed as a reference to—

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

#### **Textual Amendments**

F25 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

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

- 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**

- **F25** 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)**
- **F26** 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.

#### [F27 Exemptions relating to prescriptions given by nurses

- **13A.**—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by a registered nurse or registered midwife who is not an appropriate practitioner in relation to that medicine where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.
- (2) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by an extended formulary nurse prescriber where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the extended formulary nurse prescriber has complied with any condition with which he is required to comply by virtue of article 3A(2) and (3).]

#### **Textual Amendments**

**F27** Art. 13A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 7

#### 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) [<sup>F28</sup>, and subject to paragraph (2A),] a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.

- (2) The conditions referred to in paragraph (1) are that the prescription—
  - (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
  - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;
  - (c) shall contain the following particulars—
    - (i) the address of the appropriate practitioner giving it,
    - (ii) the appropriate date,
    - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, [F29] district nurse/health visitor prescriber, an extended formulary nurse prescriber], a veterinary surgeon or a veterinary practitioner,
    - (iv) where the appropriate practitioner giving it is a doctor, dentist [F30, a district nurse/health visitor prescriber or an extended formulary nurse prescriber], the name, address and the age, if under 12, of the person for whose treatment it is given, and
    - (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
  - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
  - (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.
- [F31(2A)] For the purposes of paragraph (1), where a prescription is issued and dispensed in England and the conditions specified in paragraph (2C) are fulfilled, the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (2B).
  - (2B) The conditions referred to are that the prescription shall be—
    - (a) created in an electronic form and signed with an electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries); or
    - (b) entered on a document where—
      - (i) the prescription is created electronically and signed with an electronic signature and both the data and the signature are entered on the document in a non-legible manner;
      - (ii) the prescription is created in writing on the document, as referred to in paragraph (2) (b), and is signed with an electronic signature which is entered on the document in a non-legible manner; or
      - (iii) the prescription is created in an electronic form which is entered on the document in a non-legible manner, and is signed as referred to in paragraph (2)(a),

and transferred to the person by whom it is dispensed by physical means.

(2C) The conditions referred to are that—

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- (a) the prescription is issued by a doctor—
  - (i) under or by virtue of the National Health Service Act 1997; or
  - (ii) as part of the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1977,

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

- (b) the Secretary of State is satisfied that—
  - (i) the use of electronic means in order to create, sign and transfer prescriptions (or whichever of those purposes is applicable) is appropriate for the purposes of a pilot scheme on the use of electronic prescribing, in relation to both the doctor and the person lawfully conducting a retail pharmacy business concerned, and in relation to the premises at which the prescription is dispensed; and
  - (ii) the particular electronic means used by both the doctor and the person lawfully conducting a retail pharmacy business concerned are suitable for the purposes of such a pilot scheme.]
- (3) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to a sale or supply of a prescription only medicine which is not in accordance with a prescription given by an appropriate practitioner by reason only that a condition specified in paragraph (2) [F32 or, where applicable, paragraph (2B)] is not satisfied where the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that that condition is satisfied in relation to that sale or supply.
  - (4) In paragraph (2) "the appropriate date" means-
    - (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
    - (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it;

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

 $[^{F33}(5)]$  In paragraphs (2B) and (2C)—

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

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

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

#### **Textual Amendments**

- **F28** Words in art. 15(1) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(a)**
- **F29** Words in art. 15(2)(c)(iii) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 8(a)
- **F30** Words in art. 15(2)(c)(iv) substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **8(b)**
- F31 Art. 15(2A)-(2C) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(b)**

Status: Point in time view as at 01/04/2002.

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

- **F32** Words in art. 15(3) inserted (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, **2(c)**
- F33 Art. 15(5) added (E.W.S.) (11.9.2001) by The Prescription Only Medicines (Human Use) (Electronic Communications) Order 2001 (S.I. 2001/2889), arts. 1, 2(d)

#### Revocations

- **16.**—(1) The Orders specified in Schedule 6 are revoked.
- (2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(14) articles 2 to 6 and Schedules 1 and 2 are revoked.

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

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

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



D. C. Gowdy
Permanent Secretary

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



*P. Small* Permanent Secretary

#### SCHEDULE 1

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

Container or package

containing

not more

than 2g of

medicinal

product

#### 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

[F34Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F34Aceclofenac]

Acemetacin

Acetarsol

Acetazolamide

Acetazolamide

Sodium

Acetohexamide

Acetylcholine 0.2 per cent External

Chloride

Acetylcysteine

Acipimox

Aciclovir 5.0 per cent External

> For treatment of herpes simplex virus infections of the lips and

form

face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

22

Aldosterone

Status: Point in time view as at 01/04/2002.

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

	prescription	n only medicine	ctions on the sale and sup s	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
Acrivastine			24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine
Acrosoxacin				
Actinomycin C				
Actinomycin D				
[F35Adapalene	]			
Adenosine				
Adrenaline		(1) By inhaler		
		(2) External [F36(except ophthalmic)]		
Adrenaline Acid		(1) By inhaler		
Tartrate		(2) External		
Adrenaline Hydrochloride	<b>;</b>	(1) By inhaler		
		(2) External		
Adrenocortica Extract	1			
Albendazole				
Alclofenac				
Alclometason Dipropionate	e			
Alcuronium Chloride				
Aldesleukin				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

 $[^{F34}$ Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F37Aloxiprin (1) 620 mg

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

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

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

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F35Altretamine]

Amantadine

Hydrochloride

Ambenonium

Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine

Nonophthalmic

use

Amethocaine Gentisate Nonophthalmic

use

Amethocaine Hydrochloride Nonophthalmic

use

Amikacin Sulphate

Amiloride Hydrochloride

Aminocaproic

Acid

Aminoglutethimide

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

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

Column 2

strength

Column 1 Substance Maximum

Column 3 Route of administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Aminopterin

Sodium

Amiodarone

Hydrochloride

Amiphenazole

Hydrochloride

[F38 Amisulpride]

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

Document Generated: 2024-06-07

Status: Point in time view as at 01/04/2002.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

strength

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Amsacrine

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic use

[F34Anastrozole]

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

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

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

prescription only mealci umn 1 Column 2 Column 3

Column 1 Column 2 Substance Maximum

Maximum Route of T strength administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Antimony

Sulphate

Antimony

Trichloride

Antimony

Trioxide

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F35Apraclonidine

Hydrochloride]

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

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

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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
Arsenic
Trioxide
Arsphenamine
[F39Aspirin
             <sup>F40</sup>(1) 75mg]
                           F40(1) Non-
                                                                             The
                           effervescent
                                                                    quantity
                           tablets and
                                                                    sold
                                                                               or
                           capsules]
                                                                    supplied
                                                                    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]
                                                                       [F42(2)The
                                                                    quantity
                           effervescent
             mg]
                           tablets and
                                                                    sold
                           capsules
                                                                    supplied
                                                                    one
                                                                    container or
                                                                    package
```

Status: Point in time view as at 01/04/2002.

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

		from the restri	ictions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
				shall not exceed 32
		[F42(3)]All preparations other than non-effervescent tablets or capsules		The quantity of non-effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100]
Astemizole		F43	F43	F43
		F43 F43		
Atenolol				
Atracurium Besylate				
Atropine		<ul><li>(1) Internal</li><li>(a) by inhaler</li></ul>		
		(b) otherwise	(b) 300mcg (MD)	

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

		from the restri	ictions on the sale and suppers	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form than by		Column 5 Maximum quantity	
		inhaler			
			1mg (MDD)		
		(2) External (except ophthalmic)			
Atropine Methobromic	1.	(1) Internal			
Methobromic	16	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		Internal			
Methonitrate		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
Atropine Oxide		(1) Internal			
Hydrochloric	le	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			

Status: Point in time view as at 01/04/2002.

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

			ictions on the sale and suppl	ly of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Atropine Sulphate		(1) Internal (a) by inhaler		
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD)	
		(2) External (except ophthalmic)		
Auranofin				
Azapropazon	e			
Azathioprine				
Azathioprine Sodium				
Azelaic Acid				
Azelastine Hydrochlorid	e	For nasal administration	140mcg per nostril (MD)	Container or package
		For the treatment of seasonal allergic rhinitis [F44 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 [F455 years]		
		As a non-aerosol,		

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 aqueous form Azidocillin Potassium Azithromycin Azlocillin Sodium Aztreonam Bacampicillin Hydrochloride Bacitracin Bacitracin Methylene Disalicylate Bacitracin Zinc Baclofen [F38Balsalazide Sodium]

Bambuterol

Hydrochloride

Barium Carbonate

Barium Chloride

Barium Sulphide

Beclamide

Beclomethasone

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

aerosol)

Container or package containing not more than [F4620,000 mcg] of

Status: Point in time view as at 01/04/2002.

Changes to 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	ictions on the sale and supply	y of
Column 1	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		For the prevention and treatment of allergic rhinitis	200 mcg per nostril (MDD)  [F47For a maximum period of 3 months]	Beclomethasone Dipropionate
		[F48For 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				
[F38Benserazid	e]			
Benserazide Hydrochloride	:			
Bentiromide				
Benzathine Penicillin				
Benzbromaror	ne			

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Benzhexol Hydrochloride

Benzilonium Bromide

Benzocaine

Any use except ophthalmic use

Benzoctamine Hydrochloride

Benzoyl 10.0 per

External

Peroxide cent

N-Benzoyl Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine Hydrochloride

Betamethasone

Betamethasone Adamantoate

Betamethasone Benzoate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Betamethasone

Dipropionate

Betamethasone

Sodium

Phosphate

Betamethasone

Valerate

Betaxolol

Hydrochloride

Bethanechol

Chloride

Bethanidine

Sulphate

Bezafibrate

[F35Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

**Fumarate** 

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

[F38Brimonidine

Tartrate]

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

			ictions on the sale and suppl	y of
Column 1 Substance	prescription Column 2 Maximum strength	conly medicine Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Bromvaleton	e			
Brotizolam				
Budesonide		For nasal administration	200mcg per nostril (MD)	Container or package
		For the prevention or treatment of seasonal allergic rhinitis	[F47For a maximum period of 3 months]	containing not more than 10mg of Budesonide
		200 mcg per nostril (MDD)		
		[F48For use in persons aged 18 years and over]		
		As a non- aerosol, aqueous form		
Bufexamac				
Bumetanide				
Buphenine Hydrochlorid	ام		6mg (MD)	
-	ic		18mg (MDD)	
Bupivacaine		Any use except ophthalmic use		
Bupivacaine Hydrochlorid	le	Any use except ophthalmic use		
Buserelin Acetate				

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Buspirone Hydrochloride

Busulphan

Butacaine Sulphate Any use except ophthalmic use

Butorphanol Tartrate

Butriptyline Hydrochloride

[F49Cabergoline]

Calcipotriol

[F35Calcipotriol

Hydrate]

Calcitonin

Calcitriol

Calcium Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium

Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

 $\c|^{F50} Can desart an$ 

Cilexetil]

Carbon Tetrachloride Carboplatin Status: Point in time view as at 01/04/2002.

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form Candicidin Canrenoic Acid Cantharidin 0.01 per External cent Capreomycin Sulphate Captopril Carbachol Carbamazepine Carbaryl [F38Carbasalate Calcium] Carbenicillin Sodium Carbenoxolone (1) Pellet (1) 5mg (MD) Sodium 25mg (MDD) (2) 2.0 per(2) Gel cent (3) 20mg (MD) (3) (3) 1.0 per (3) Granules for cent Container 80mg (MDD) mouthwash or package in adults containing and children not more not less than than 12 years [F51560mg] Carbenoxolone Sodium Carbidopa Carbimazole Carbocisteine

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

[F38Cefdinir]

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

[F49Cefprozil]

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

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

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

Sodium

Cefuroxime

Axetil

Cefuroxime

Sodium

Celiprolol

Hydrochloride

Cephalexin

Cephalexin

Sodium

Cephaloridine

Cephalothin

Sodium

Cephamandole

Nafate

Cephazolin

Sodium

Cephradine

Cerium

Oxalate

Cerivastatin

[F38Cerivastatin

Sodium]

Ceruletide

Diethylamine

F52 Cetirizine 10mg (MDD) Hydrochloride

Chenodeoxycholic

Acid

Chloral External

Hydrate

Chlorambucil

Chloramphenicol

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

strength

2 Column 3 um Route of Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

administration,

form

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium

Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(15)) 5.0 per

cent

(1) Internal

(2) External

of malaria

Chloroquine Prophylaxis
Phosphate of malaria
Chloroquine Prophylaxis

Chlorothiazide

Sulphate

Chlorotrianisene

Chlorphenoxamine Hydrochloride

Chlorpromazine

Chlorpromazine

**Embonate** 

Chlorpromazine Hydrochloride

Chlorpropamide

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

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength

Column 3 Route of administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical form

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

(a) For the short-term

(a) 200mg (MD)

800mg (MDD) symptomatic

heartburn,

relief of For a maximum period of

14 days

dyspepsia, indigestion, acid indigestion and hyperacidity

and for the prophylaxis of mealinduced heartburn

(b) For the management night

of nocturnal heartburn by a single

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

For a maximum period of

14 days

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

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

dose taken at night

Cimetidine Hydrochloride

Cinchocaine 3.0 per cent Non-

ophthalmic

use Non-

Cinchocaine Equivalent

Hydrochloride of 3.0 per ophthalmic

cent of use Cinchocaine

Cinchophen

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[F35Citalopram

Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin

Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin

Phosphate

			ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum	only medicine Column 3 Route of	Column 4 Treatment limitations	Column 5 Maximum
	strength	administration use or pharmaceutic form	,	quantity
Clioquinol		(1) External (other than treatment of mouth ulcers)		
	(2) 35mg	(2) Treatment of mouth ulcers	(2) 350mg (MDD)	
Clobetasol Propionate				
Clobetasone Butyrate	[F530.05 per cent]	[F53]Cream for use in adults and in children aged 12 years and over, for external use for the short term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis)]		[F53Container or package containing not more than 15g of medicinal product]
Clofazimine				
Clofibrate Clomiphene				
Citrate				
Clomipramin				
Clomipramin Hydrochlorid	e			
Clomocycline	e			

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Clomocycline

Sodium

Clonidine

Clonidine

Hydrochloride

Clopamide

Clopenthixol

Decanoate

Clopenthixol

Hydrochloride

Clorexolone

Clotrimazole

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

Cloxacillin Benzathine

Cloxacillin Sodium

Clozapine

Cocculus Indicus

Co-

dergocrine Mesylate

Colaspase

Colchicine

Colestipol Hydrochloride

Colfosceril Palmitate Document Generated: 2024-06-07

Status: Point in time view as at 01/04/2002.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Colistin

Sulphate

Colistin

Sulphomethate

Colistin

Sulphomethate

Sodium

Coniine

Conium

7.0 per cent External

Leaf

Corticotrophin

Cortisone

Cortisone

Acetate

Co-

tetroxazine

Co-

trimoxazole

Cropropamide

Crotethamide

Croton Oil

Croton Seed

Curare

Cyclofenil

Cyclopenthiazide

Cyclopentolate

Hydrochloride

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cyproterone

Acetate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Column 1 Substance Maximum Route of Treatment limitations

form

administration, strength

Maximum quantity use or pharmaceutical

Cytarabine

Cytarabine Hydrochloride

Dacarbazine

Dalteparin Sodium

Danazol

Danthron

Dantrolene Sodium

Dapsone

Dapsone Ethane

Ortho

Sulphonate

Daunorubicin Hydrochloride

Deanol 26mg (MDD)

Bitartrate

Debrisoquine Sulphate

Demecarium Bromide

Demeclocycline

Demeclocycline

Calcium

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone

Pivalate

Deptropine

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)

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 Dequalinium (1) 0.25mg (1) Internal:

Chloride

throat lozenges or throat pastilles

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

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Dexamethasone

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

Dexamethasone

Sodium

Phosphate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

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 Diethylammoreinn External

For local symptomatic relief of pain and inflammation in trauma of the tendons.

inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of For maximum period of 7 days

or package containing not more than 30g of medicinal product

Container

Sulphate

Status: Point in time view as at 01/04/2002.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 soft tissue rheumatism For use in adults and children not less than 12 years Diclofenac Potassium Diclofenac Sodium Dicyclomine 10mg (MD) Hydrochloride 60mg (MDD) [F34Didanosine] Dienoestrol Diethanolamine Fusidate Diflucortolone Valerate Diflunisal Digitalin **Digitalis** Leaf Digitalis Prepared Digitoxin Digoxin Dihydralazine Sulphate Dihydroergotamine Mesylate Dihydrostreptomycin Dihydrostreptomycin

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

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

Diloxanide

Furoate

Diltiazem Hydrochloride

Dimercaprol

Dimethisoquin Hydrochloride Nonophthalmic

use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost Trometamol

Dinoprostone

[F37DiphenhydAlmine Hydrochloridepreparations

except liquid-filled capsules]

[F54Diphenoxy[5542.5 mg]

Hydrochloride]

[F54In combination with Atropine Sulphate for short term

use as an adjunctive therapy to

[F54Container or package containing not more than 20 tablets]

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	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity		
		appropriate rehydration in acute diarrhoea				
		For use in persons aged 16 years and over				
		Tablets]				
Dipivefrin Hydrochloride	e					
Dipyridamole						
Disodium Etidronate						
Disodium Pamidronate						
Disopyramide	;					
Disopyramide Phosphate	;					
Distigmine Bromide						
Disulfiram						
Dithranol	1.0 per cent					
Dobutamine Hydrochloride	e					
[ <sup>F54</sup> Dolasetron Mesilate]	ı					
Domperidone		[F55For the relief of post- prandial symptoms of excessive fullness, nausea, epigastric	[F5510mg of Domperidone (MD)] [F5540mg of Domperidone (MDD)]	[F55]Container or package containing not more than 200mg of Domperidone]		

	_	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 pharmaceuti	Column 4 Treatment limitations on,	Column 5 Maximum quantity			
		bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]					
Domperidone Maleate		[F56For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,]	[F5710 mg of Domperidone as Domperidone Maleate (MD)] [F5740 mg of Domperidone as Domperidone Maleate (MDD)]	[F56Container or package containing not more than [F58200mg] of Domperidone as Domperidone Maleate;]			
[ <sup>F38</sup> Donepezil Hydrochloride	e]						
Dopamine Hydrochloride	)						
Dopexamine Hydrochloride	e						
<sup>F35</sup> Dorzolami Hydrochloride							
Dothiepin							
Dothiepin Hydrochloride	)						
Doxapram Hydrochloride	<b>:</b>						

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 C Substance M

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

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Doxazosin

Mesylate

Doxepin

Hydrochloride

Doxorubicin

Doxorubicin

Hydrochloride

Doxycycline

Doxycycline Calcium Chelate

Doxycycline Hydrochloride

Droperidol

Dydrogesterone

Dyflos

Econazole

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

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

Ecothiopate Iodide

Edrophonium Chloride

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

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

Eflornithine Hydrochloride

[<sup>F34</sup>Eformoterol Fumarate]

Embutramide

Emepronium Bromide

Emetine 1.0 per cent

Emetine Bismuth Iodide

Emetine Equivalent Hydrochloride 1.0 per

cent of
Emetine

Enalapril Maleate

Encephalitis Virus, Tickborne, Cent

Eur

Enoxacin

Enoxaparin Sodium

Enoximone

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

(other than nasal sprays or nasal drops)

60mg (MDD)

(2) 2.0 per cent

(2) Nasal sprays or nasal drops

(3) External

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

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Ergometrine

Tartrate

Ergot,

Prepared

Ergotamine

Tartrate

Erythromycin

Erythromycin

Estolate

Erythromycin Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin Lactobionate

Erythromycin Phosphate

Erythromycin

Stearate

Engthromygin

Erythromycin Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

[F59 Estramustine

Sodium

Phosphate]

Etafedrine

Hydrochloride

Ethacrynic

Acid

Ethambutol

Hydrochloride

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Ethamivan

Ethamsylate

Ethiazide

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol

Diacetate

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

[F35 Exemestane]

Famciclovir

Famotidine

For the short-term symptomatic relief of

10mg (MD)

20mg (MDD)

For maximum period of

heartburn, 14 days

dyspepsia, indigestion,

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	prescription	from the restriction	ctions on the sale and suppl s	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
		acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms		
Fazadinium Bromide				
Felbinac	3.17 per cent	External  [F61] 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 [F60 50g] of medicinal product
		-		
Felodipine				
Felodipine Felypressin Fenbufen				

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or pharmaceutical

form

Fenfluramine Hydrochloride

Fenofibrate

Fenoprofen

Fenoprofen Calcium

Fenoterol Hydrobromide

Fenticonazole Nitrate [F53 External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)]

Feprazone

Ferrous Arsenate

[F35Ferumoxsil]

[F38Fexofenadine Hydrochloride]

Filgrastim

Finasteride

Flavoxate Hydrochloride

Flecainide Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone Acetonide

Flucloxacillin Magnesium

			ictions on the sale and sup	ply of
Column 1	prescription Column 2	n only medicine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceut form	Treatment limitations ion,	Maximum quantity
Flucloxacilli Sodium	n			
Fluconazole		For oral administration for the treatment of vaginal candidiasis [F62 or associated candidal balanitis] in persons aged not less than 16 but less than 60 years	150mg (MD) on	Container or package containing not more than 150mg of Fluconazole
Flucytosine		•		
Fludrocortise Acetate	one			
Flufenamic Acid				
Flumazenil				
Flumethasor	ne			
Flumethasor Pivalate	ne			
Flunisolide	0.025 per cent	(a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever	(a) 50mcg per nostril (MD) 100mcg per nostril (MDD)	(a) Container or package containing not more than 6,000mcg of Flunisolide
		I <sup>F63</sup> For use in persons aged 18	[F64For a maximum period of 3 months]	

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

		from the restr	ictions on the sale and sup es	ply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratiuse or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity	
		years and over			
		In the form of a non- pressurised nasal spray		_	
		F65	F65	F65	
			F65		
			• • •		
		F65			
		 F65			
Fluocinolone Acetonide	;				
Fluocinonide	;				
Fluocortin Butyl					
Fluocortolon	e				
Fluocortolon Hexanoate	e				
Fluocortolon Pivalate	e				
Fluorescein Dilaurate					
Fluorometho	lone				
Fluorouracil					
Fluorouracil Trometamol					
Fluoxetine Hydrochloric	le				
Flupenthixol Decanoate					

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

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

Flupenthixol Hydrochloride

Fluperolone

Acetate

Fluphenazine

Decanoate

Fluphenazine

Enanthate

Fluphenazine Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen [F668.75 mg] [F67Throat [F6843.75 mg (MDD)]

lozenges

[F69Container or package containing not more than 140 mg of Flurbiprofen]

Flurbiprofen Sodium

Fluspirilene

Flutamide

Fluticasone **Propionate** 

[F38Flutrimazole]

Fluvastatin Sodium

Fluvoxamine Maleate

Folic Acic 500mcg (MDD)

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

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

Formestane

Formocortal

Foscarnet

Sodium

Fosfestrol

Sodium

Fosfomycin

Trometamol

Fosinopril

Sodium

Framycetin

Sulphate

Frusemide

Furazolidone

Fusafungine

Fusidic

Acid

Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

Ganciclovir

Sodium

Gelsemine

0.1 per cent

deisemme 0.1 per eem

Gelsemium 25mg (MD)

75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin

Sulphate

Gestodene

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Glucagon

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

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride

Griseofulvin

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

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

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

Halofantrine Hydrochloride

Haloperidol

Haloperidol Decanoate

Heparin External External

Calcium

Heparin Sodium

Hexachlorophane External

(a) 2.0 per cent

(a) Soaps

(b) 0.1 per

(b) Aerosols

cent

(c) 0.75 per

cent

(c) preparations

other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

Hexobarbitone

Sodium

Hexoestrol

Hexoestrol Dipropionate

L-Histidine Dietary

Hydrochloride supplementation

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

0.45mg (MDD)

(2) External (except ophthalmic)

		from the restrictions on the sale and sup only medicines	oply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
Homatropine		0.2mg (MD)	
Hydrobromi	ae	0.6mg (MDD)	
Homatropine		2mg (MD)	
Methylbrom	iue	6mg (MDD)	
Hydralazine Hydrochlorio	de		
Hydrargaphe	en	Local application to skin	
Hydrobromio Acid	e		
Hydrochloro	thiazide		
Hydrocortiso	one [F70(1) 0.5 per cent]	[F70(1) External (a) For     use in     combination     with     Nystatin     of     maximum     strength     3.0 per     cent     for     intertrigo (b) For     use in     adults     and     children     not     less     than     10     years]	containing not more than 15g of medicinal product]
	[ <sup>F71</sup> (2)]1.0 per cent	[F71(2)] External (a) For use either alone	Containing not more than 15g

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

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

conjunction product with (cream Crotamiton ointment) or in 30ml (spray) irritant dermatitis, contact allergic dermatitis, insect bite reactions,

or

moderate eczema, and either in combination with

mild

Clotrimazole

[F72 or Miconazole

Nitrate]

for

athlete's

foot

and

candidal

intertrigo

or in

combination

with

lignocaine

for

anal

and perianal

itch

associated

with

haemorrhoids

		from the restr only medicine	ictions on the sale and sup	ply of
Column 1	Column 2	conty meatcine Column 3	es Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or	Treatment limitations	Maximum quantity
		pharmaceut form	ical	
		(b) For		
		use in		
		adults and		
		childre	n	
		not	11	
		less		
		than		
		10		
		years		
		(c) Cream		
		ointme	III.	
		or spray		
Hydrocortisc	-	External		
Acetate	to 1.0	For use		Container
	per cent	in irritant		or package
	Hydrocortiso	dermatitis,		containing
		contact		not more
		allergic		than 15g of
		dermatitis, insect bite		medicinal
		reactions,		product
		mild to		In the
		moderate		case of
		eczema,		suppositories,
		and in		container or package
		combination		containing
		with one or		no more
		more of the		than 12
		following: Benzyl		
		Benzoate,		
		Bismuth		
		Oxide,		
		Bismuth		
		Subgallate,		
		Peru		
		Balsam,		
		Pramoxine	da	
		Hydrochloric Zinc	uc,	
		Oxide, for		

		from the restric	ctions on the sale and sup	oply 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
		I <sup>F73</sup> or in combination with Miconazole Nitrate, for athlete's foot and candidal intertrigo]		
		For use in adults and children not less than 10 years		
		Cream, ointment or suppositories		
Hydrocortisc Butyrate Hydrocortisc				
Caprylate Hydrocortisc Hydrogen Succinate	one			
Hydrocortisc Sodium Phosphate	one			
Hydrocortisc Sodium Succinate	onEquivalent to 2.5mg Hydrocortiso	For aphthous ulceration of the mouth for adults and children not less than 12 years In the form of pellets		Container or package containing not more than equivalent to 50mg of Hydrocortisone

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
[F37Hydrocya Acid]	anic			
Hydroflumet	thiazide			
Hydroxychloroquine Sulphate		Prophylaxis of malaria		
Hydroxypro	gesterone			
Hydroxyprog Enanthate	gesterone			
Hydroxypros Hexanoate	gesterone			
Hydroxyurea	a			
Hydroxyzine Embonate	e			
Hydroxyzine Hydrochlorio		(a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride
		(b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis,	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride

		from the restri	ictions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		in children not less than 6 years but less than 12 years		
Hyoscine	(1) 0.15 per cent	(1) Internal		
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Butylbromide	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 20mg (MD) 80mg (MDD)	(b) Container or package containing not more than 240mg of Hyoscine Butylbromide
		(2) External		
Hyoscine		(1) Internal		
Hydrobromi	de	(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Methobromi	de	(a) by inhaler		
		(b) otherwise	(b) 2.5mg (MD) 7.5mg (MDD)	

		from the restri	ictions on the sale and supply	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form than by	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
		inhaler		
Uvagaina		(2) External		
Hyoscine Methonitrate		<ul><li>(1) Internal</li><li>(a) by</li></ul>		
		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	lmg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Hydrobromid	e	(a) by inhaler		
		(b) otherwise	(b) Equivalent of 300mcg	
		than by	of Hyoscyamine (MD) Equivalent of 1mg of	
		inhaler	Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Sulphate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		

		from the restri	ctions on the sale and suppl	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Ibuprofen		Rheumatic and muscular pain, pain of non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrho feverishness, symptoms of colds and influenza	ea,	
		(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		
	[F74(3) 10.0 per cent]	[F74(3) External]	[F74(3) 125 mg (MD) 500 mg (MDD)]	[F74(3)] Container or package containing not more than [F7550g] of medicinal product]
[ <sup>F37</sup> Ibuprofen Lysine	ı	Rheumatic and muscular pain, pain of non-serious arthritic	(a) in the case of a prolonged release preparation 600 mg (MD) 1,200 mg (MDD)	

		from the restri	ictions on the sale and supp	ly of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administratiuse or pharmaceut	Treatment limitations on,	Maximum quantity	
		conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrho feverishness, symptoms of colds and influenza			
		Internal	(b) in any other case 400 mg (MD) 1,200 mg (MDD)]		
Idarubicin Hydrochlorid	le				
Idoxuridine					
Ifosfamide					
Ignatius Bean					
[ <sup>F34</sup> Imidapril Hydrochlorid	le]				
Imipenem Hydrochlorid	le				
Imipramine					
Imipramine Hydrochlorid	le				
Imipramine Ion Exchange Resin Bound Salt or Complex					
[ <sup>F49</sup> Indapami	de]				
•	-				

Indapamide Hemihydrate

Indomethacin

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 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

Indomethacin

Sodium

Indoprofen

Indoramin

Hydrochloride

Inosine

Pranobex

[F76Insulin]

Iodamide

Iodamide

Meglumine

Iodamide

Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic

Acid

Ipratropium

Bromide

Iprindole

Hydrochloride

**Iproniazid** 

Phosphate

[F38 Irbesartan]

Isoaminile

Isoaminile

Citrate

Isocarboxazid

	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 ion,	Column 5 Maximum quantity	
Isoconazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis			
Isoetharine					
Isoetharine Hydrochlorid	e				
Isoetharine Mesylate					
Isoniazid					
Isoprenaline Hydrochlorid	e				
Isoprenaline Sulphate					
Isopropamide Iodide			Equivalent of 2.5mg of Isopropamide ion (MD)		
			Equivalent of 5.0mg of Isopropamide ion (MDD)		
Isotretinoin					
Isradipine					
Itraconazole					
Jaborandi		External			
Kanamycin Acid Sulphate					
Kanamycin Sulphate					
Ketamine Hydrochlorid	e				

			ctions on the sale and suppl	y of
Column 1 Substance	prescription Column 2 Maximum strength	only medicine. Column 3 Route of administration use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Ketoconazole	2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	母祝祖)] Maximum frequency of application of once every 3 days	[F77(a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole
		[F79(b)] For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo]		
Ketoprofen	2.5 per cent	External  For rheumatic and muscular pain in adults and children not less than 12	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
Ketorolac Trometamol				
Ketotifen Fumarate				
Labetalol Hydrocholorio	de			

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Lachesine Chloride Lacidipine Lamotrigine Lanatoside C Lanatoside Complex A, B and C [F49Lansoprazole] Latamoxef Disodium [F49Lercanidipine Hydrochloride] Levallorphan Tartrate Levobunolol Hydrochloride [F37Levocabast Figurivalent (1) Nasal (1) Hydrochloride of 0.05 Container sprays per cent or package Levocabastine symptomatic containing not more treatment than 10 ml of seasonal of medicinal allergic product rhinitis (2) Aqueous (2) eye drops Container or package For the containing symptomatic not more treatment than 4 ml of of seasonal medicinal allergic product] conjunctivitis [F80For [F80 Levocarnitine] dietary

supplementation]

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength

Column 3 Route of

Column 4

Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Levodopa

[F38Levofloxacin]

Levonorgestre|F810.75mg|

[F81 for use as an emergency contraceptive in women aged 16 years and over

Lidoflazine

Lignocaine

Nonophthalmic

use

Lignocaine Hydrochloride Nonophthalmic

use

Lincomycin

Lincomycin Hydrochloride

Liothyronine Sodium

Lisinopril

Lithium Carbonate Equivalent of 5mg of

Lithium (MD)

Equivalent of 15mg of Lithium (MDD)

Lithium Citrate

Lithium Succinate

Lithium Equivalent of 5mg of Lithium (MD) Sulphate

Equivalent of 15mg of Lithium (MDD)

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

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		from the restric	ctions on the sale and suppl	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceuti form		Column 5 Maximum quantity
		jorni	9mg (MDD)	
		(2) External		
Lobeline Hydrochlorid	le	(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lobeline Sulphate		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lodoxamide Trometamol	[F82equivalent of 0.1 per cent Lodoxamide]	treatment of ocular	·,	
Lofepramine				
Lofepramine Hydrochloric	le			
Lofexidine Hydrochlorid	le			
Lomefloxacii Hydrochloric				
Lomustine				
Loperamide Hydrochlorid	le	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	F84

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

. . .

[F50Lornoxicam]

[F50Losartan

Potassium]

Loxapine

Succinate

Lung

Surfactant

Porcine

Luteinising

Hormone

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Maleate

Mafenide

Mafenide

Acetate

Mafenide

Hydrochloride

Mafenide

5.0 per cent Eye drops

Propionate

Magnesium

Fluoride

Magnesium

Metrizoate

Mandragora

Autumnalis

Mannomustine

Hydrochloride

Maprotiline

Hydrochloride

Mebanazine

	• •	•	ctions on the sale and sup	ply of
Column 1 Substance	orescription Column 2 Maximum strength	only medicine. Column 3 Route of administration use or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Mebendazole		For oral use in the treatment of enterobiasis in adults and in children not less than 2 years	100mg (MD)	Container or package containing not more than 800mg of Mebendazole
Mebeverine Hydrochloride		[F85(a) For the symptomatic relief of irritable bowel syndrome	[F85(a) 135 mg (MD) 405 mg (MDD)]	
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[ <sup>F85</sup> (b) 100 mg (MD) 300 mg (MDD)]	
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride	:			
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyproges Acetate	sterone			

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Mefenamic

Acid

Mefloquine Hydrochloride

Mefruside

Megestrol

Megestrol Acetate

Meglumine Gadopentetate

Meglumine Iodoxamate

Meglumine Ioglycamate

Meglumine Iothalamate

Meglumine Iotroxate

Meglumine Ioxaglate

[F49Meloxicam]

Melphalan

Melphalan Hydrochloride

Menotrophin

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic use

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Meptazinol

Hydrochloride

Mequitazine

[F38Mercaptamine

Bitartrate]

Mercaptopurine

Mersalyl

Mersalyl

Acid

Mesalazine

Mesna

Mestranol

Metaraminol

Tartrate

Metergoline

Metformin

Hydrochloride

Methacycline

Methacycline

Calcium

Methacycline

Hydrochloride

Methallenoestril

Methicillin

Sodium

Methixene

Methixene

Hydrochloride

Methocarbamol

Methocidin

Throat lozenges and throat pastilles

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine Hydrochloride

Methotrimeprazine

Maleate

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

Methsuximide

Methyclothiazide

Methyldopa

Methyldopate Hydrochloride

Methylephedrine Hydrochloride

30mg (MD) 60mg (MDD)

Methylprednisolone

Methylprednisolone

Acetate

Methylprednisolone

Sodium Succinate

Methylthiouracil

Methysergide Maleate

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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

Succinate

Metoprolol Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

Mezlocillin

Sodium

Mianserin

Hydrochloride

Miconazole

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

External but

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

candidiasis

Mifepristone

Miglitol

Milrinone

Milrinone

Lactate

Minocycline

Minocycline Hydrochloride

Minoxidil

 $I^{F86}(1) 2.0$ per cent]

[F86(1)]External

 $[^{F86}(2) 5.0]$ per cent

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

[F34Mirtazapine]

Misoprostol

Mitobronitol

Mitomycin

Mitozantrone

Hydrochloride

Mivacurium

Chloride

[F59Mizolastine]

Moclobemide

[F38Modafinil]

[F35Moexipril Hydrochloride]

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength

Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

Hydrochloride

Morazone

Hydrochloride

[F34Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

	prescription	from the restrice only medicines	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutio form	•	Column 5 Maximum quantity
Naphazoline Hydrochlorid		(1) Nasal sprays or nasal drops not containing liquid paraffin as a vehicle		
	(2) 0.015 per cent	(2) Eye drops		
Naphazoline Nitrate	0.05 per cent	Nasal sprays or nasal drops not containing liquid paraffin as a vehicle		
Naproxen				
Naproxen Sodium				
[ <sup>F38</sup> Naratripta Hydrochlorid				
Natamycin				
[ <sup>F50</sup> Nebivolol Hydrochlorid				
Nedocromil Sodium	[F872.0 per cent]	[F87]For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis	1	[F87]Container or package containing not more than 3 ml of medicinal product]
Nefazodone Hydrochlorid	le			
Nefopam Hydrochlorid	le			
Neomycin				

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

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

Neomycin

Oleate

Neomycin

Palmitate

Neomycin

Sulphate

Neomycin Undecanoate

Neostigmine

Bromide

Neostigmine Methylsulphate

Netilmicin Sulphate

Nicardipine Hydrochloride

Nicergoline

[F59Niceritrol]

Nicotinic Any use, 600mg (MDD)

Acid except for the

for the treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F37Nilutamide]

Nimodipine

Niridazole

[F50Nisoldipine]

Nitrendipine

Nitrofurantoin

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

	•	from the restr	ictions on the sale and suppers	ply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administrat use or pharmaceur form	,	Maximum quantity	

Nitrofurazone

Nizatidine

75mg (MD) For the prevention [F89150mg (MDD)] [F88and treatment] [F90For a maximum period of the of 14 days] symptoms of foodrelated heartburn [F88 and mealinduced indigestion]

For use in adults and children not less than 16 years

Nomifensine Maleate

Noradrenaline

Noradrenaline

Acid

Tartrate

Norethisterone

Norethisterone

Acetate

Norethisterone

Enanthate

Norethynodrel

Norfloxacin

Norgestimate

Norgestrel

Nortriptyline

Hydrochloride

Noscapine

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Noscapine

Hydrochloride

Novobiocin

Calcium

Novobiocin

Sodium

Nux Vomica

Seed

Nystatin

[F913.0 per cent]

[F91External

For use in combination with

Hydrocortisone

of ma

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

[F91 Container or package containing not more than 15g of medicinal product]

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Oestradiol

Phenylpropionate

Oestradiol

Undecanoate

Oestradiol

Valerate

Oestriol

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

[F34Omeprazole

Magnesium]

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

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

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

Oxatomide

Oxedrine Tartrate

Oxethazaine 10mg (MD) Container or package

30mg (MDD) or package containing not more

than 400mg of Oxethazaine

Oxitropium Bromide

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Oxybuprocaine Non-Hydrochloride ophthalmic use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

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

Oxytetracycline Oxytetracycline Calcium

Oxytetracycline Dihydrate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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				
Oxytetracyc Hydrochlori								
Oxytocin, natural								
Oxytocin, synthetic								
Pancreatin	(1) 21,000 European Pharmacopo units of lipase per capsule	(1) capsules						
	(2) 25,000 European Pharmacopo units of lipase per gram	(2) powder eia						
Pancuronium Bromide	n							
[F49Pantopra: Sodium]	zole							
Papaverine		(1) By inhaler						
		(2)	(2) 50mg (MD)					
		Otherwise than by inhaler	150mg (MDD)					
Papaverine Hydrochlori	de	(1) By inhaler						
		(2) Otherwise	(2) Equivalent of 50mg of Papaverine (MD)					
		than by inhaler	Equivalent of 150mg of Papaverine (MDD)					
[F39Paracetar	mol (1) [ <sup>F92</sup> 25	0mg(1) Non- effervescent tablets and capsules		(1) The quantity sold or supplied in				

	Exemptions from the restrictions on the sale and supply of						
$\alpha$ .	prescription only medicines						
Column 1	Column 2	Column 3	Column 4	Column 5			
Substance	Maximum strength	Route of administrati use or	Treatment limitations on,	Maximum quantity			
		pharmaceut	ical				
		form					
		[ <sup>F93</sup> wholly or		one			
		mainly] for		container or			
		use in		package			
		children		shall not			
		aged less		exceed 32			
		than 12		The			
		years		quantity			
	(2) 50	0 (2) Non-		of —			
	mg (2)	effervescent		non-			
	3	tablets and		effervescent			
		capsules		tablets,			
		[ <sup>F94</sup> wholly or		capsules or a			
		mainly] for		combination			
		use in adults		of			
		and children		both			
		not less than		sold or			
		12 years		supplied			
				to a			
				person			
				at any			
				one			
				time			
				shall			
				not			
				exceed			
				100			
		(3) All		(2) The			
		preparations		quantity			
		other than		sold or			
		non-		supplied in			
		effervescent		one			
		tablets and		container or			
		capsules		package			
				shall not			
				exceed 32			
				The			
				quantity			
				of			
				non-			
				effervescent			
				tablets,			
				capsules			
				or a			

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

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

combination
of
both
sold or
supplied
to a
person
at any
one
time
shall
not
exceed
100]

Paraldehyde

Paramethadione

Paramethasone

Acetate

Parathyroid

Gland

Pargyline Hydrochloride

Paroxetine

Hydrochloride

Pecilocin

Penamecillin

Penbutolol Sulphate

[F49Penciclovir]

Penicillamine

Penicillamine Hydrochloride

Pentamidine Isethionate

Penthienate 5mg (MD)Bromide 15mg (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 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pentolinium

Tartrate

Perfluamine

Pergolide

Mesylate

Perhexiline

Maleate

Pericyazine

Perindopril

Perindopril

Erbumine

Perphenazine

Phenacetin 0.1 per cent

Phenazone External

Phenazone Salicylate

Phenbutrazate

Hydrochloride

Phenelzine

Sulphate

Phenethicillin

Potassium

Phenformin

Hydrochloride

Phenglutarimide

Hydrochloride

Phenindione

[F95Phenolphthalein.]

Phenoxybenzamine

Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

pharmaceutical

form

use or

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine Hydrochloride

Phentolamine Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine Hydrochloride Internal

(1) all preparations except

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

prolonged release capsules, nasal sprays and nasal drops

(2) prolonged release capsules

(2) 50mg (MD)

100mg (MDD)

(3) 2.0 per cent

(3) nasal sprays and nasal drops

Phenytoin

Phenytoin Sodium

Phthalylsulphathiazole

Physostigmine

Physostigmine Aminoxide Salicylate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Physostigmine Salicylate

Physostigmine Sulphate

[F37Phytomenadione

Any use except the prevention

treatment of haemorrhagic disorders

Picrotoxin

Pilocarpine

Pilocarpine Hydrochloride

Pilocarpine Nitrate

Pimozide

Pindolol

Pipenzolate Bromide 5mg (MD)

15mg (MDD)

Piperacillin Sodium

Piperazine Oestrone Sulphate

Piperidolate Hydrochloride 50mg (MD)

150mg (MDD)

Pipothiazine Palmitate

Piracetam Pirbuterol

Acetate

Pirbuterol Hydrochloride

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 [F96Pirenzepine Dihydrochloride Monohydrate] Pirenzepine Hydrochloride Piretanide Piroxicam 0.5 per cent External For maximum period of 7 Container days or package For the containing relief of not more rheumatic than 30g of pain, pain of medicinal non-serious product 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 [F59Piroxicam Betacyclodextrin] **Pituitary** By inhaler Gland (Whole Dried) Pituitary By inhaler Powdered (Posterior Lobe)

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Pivampicillin

Pivampicillin Hydrochloride

Pivmecillinam

Pivmecillinam Hydrochloride

Pizotifen

Pizotifen Malate

Plicamycin

Podophyllotoxin

Podophyllum

Podophyllum

Indian

Podophyllum 20.0 per

Resin cent

External

Ointment or impregnated plaster

Poldine Methylsulphate 2mg (MD)

6mg (MDD)

Polidexide

Polyestradiol

Phosphate

Polymyxin B Sulphate

Polythiazide

Poppy Capsule

Potassium 0.0127 per Arsenite cent

Potassium Bromide

Potassium Canrenoate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Potassium

Clavulanate

Potassium

Perchlorate

Practolol

Pralidoxime

Chloride

Pralidoxime

Iodide

Pralidoxime

Mesylate

[F38Pramipexole

Hydrochloride]

Pravastatin

Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone

Butylacetate

Prednisolone

Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

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

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

Prednisolone Steaglate

Prednisone

Prednisone Acetate

Prenalterol Hydrochloride

Prenylamine Lactate

Prilocaine Hydrochloride Nonophthalmic

use

Primidone

Probenecid

Probucol

Procainamide Hydrochloride

Procaine Hydrochloride

Nonophthalmic

use

Procaine Penicillin

Procarbazine Hydrochloride

Prochlorperazine

Prochlorperazine

Edisylate

Prochlorperazine 3mg Maleate

[F53Buccal tablets for the treatment of nausea and vomiting in cases of previously diagnosed

migraine

[F5312mg (MDD)]

[F53Container or package containing not more than 8 tablets]

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

	Exemptions from the restrictions on the sale and supply of						
$C \cdot 1$	prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form		Column 5 Maximum quantity			
		only. For use in persons aged 18 years and over.]					
Prochlorperaz Mesylate	zine						
Procyclidine Hydrochlorid	e						
Progesterone							
Prolactin							
Proligestone							
Prolintane Hydrochlorid	e						
Promazine Embonate							
Promazine Hydrochlorid	e						
Propafenone							
Propafenone Hydrochlorid	e						
Propanidid							
Propantheline Bromide	•		15mg (MD) 45mg (MDD)				
[ <sup>F50</sup> Propiverin Hydrochlorid			· /				
Propofol							
Propranolol Hydrochlorid	e						
Propylthioura	cil						
Proquazone							
Protamine Sulphate							

	-	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity			
Prothionami	de						
Protirelin							
Protriptyline Hydrochloric							
Proxymetacaine Hydrochloride		Non- ophthalmic use					
Pseudoephedrine Hydrochloride		Internal	(a) In the case of a prolonged release preparation				
			120mg (MD)				
			240mg (MDD)				
			(b) in any other case 60mg (MD)				
			240mg (MDD)				
Pseudoepheo	drine		60mg (MD)				
Sulphate			180mg (MDD)				
Pyrantel Embonate		(a) For the treatment of enterobiosis, in adults and children not less than 12 years	(a) 750mg MDD (as a single dose)	(a) Container or package containing not more than 750mg of Pyrantel Embonate			
		(b) For the treatment of enterobiosis, in children less than 12 years but not less than 6 years	(b) 500mg MDD (as a single dose)	(b) Container or package containing not more than 750mg of Pyrantel Embonate			
		(c) For the treatment of enterobiosis in children less than 6	(c) 250mg MDD (as a single dose)	(c) Container or package containing not more			

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

		from the restr only medicine	ictions on the sale and sup es	ply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administratiuse or pharmaceut form		Maximum quantity
		years but		than 750mg
		not less than		of Pyrantel
		2 years		Embonate

Pyrantel Tartrate

Pyrazinamide

Pyridostigmine

Bromide

Pyrimethamine

[F50Quetiapine Fumarate]

[F35Quinagolide Hydrochloride]

Quinapril

[<sup>F96</sup>Quinapril 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)

Status: Point in time view as at 01/04/2002.

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

		from the restrictions on the sale and su only medicines	upply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Dihydrochlo	ride	Equivalent of 100mg of Quinine (MD)	f
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Ethyl		Equivalent of 100mg of Quinine (MD)	f
Carbonate		Equivalent of 300mg of Quinine (MDD)	f
Quinine Glycerophos	phate	Equivalent of 100mg or Quinine (MD)	f
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Hydrobromio	de	Equivalent of 100mg or Quinine (MD)	f
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Hydrochlorid	de	Equivalent of 100mg of Quinine (MD)	f
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Iodobismuth	ate	Equivalent of 100mg of Quinine (MD)	f
		Equivalent of 300mg of Quinine (MDD)	f
Quinine Phosphate		Equivalent of 100mg of Quinine (MD)	f
-		Equivalent of 300mg of Quinine (MDD)	f
Quinine Salicylate		Equivalent of 100mg of Quinine (MD)	f
-		Equivalent of 300mg of Quinine (MDD)	f
Quinine Sulphate		Equivalent of 100mg of Quinine (MD)	f
- · · ·		110	

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

		from the restriction only medicine	ctions on the sale and supply s	v of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
		v	Equivalent of 300mg of Quinine (MDD)	
Quinine Fannate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine in combination with Urea Hydrochloride	÷			
Ramipril				
[F34]Ranitidine Bismuth Citrate]				
Ranitidine Hydrochloride	<b>;</b>	For the short term	Equivalent to 75mg of Ranitidine (MD)	
		symptomatic relief of	Equivalent to 300mg of Ranitidine (MDD)	
		heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity [F97 or the prevention of these symptoms when associated with consuming food and drink]	For a maximum period of 14 days	
Rauwolfia Serpentina				
Rauwolfia Vomitoria				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Razoxane

[F38Reboxetine

Mesilate]

Remoxipride

Hydrochloride

Reproterol

Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

 $[^{F34}$ Rimexolone]

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

[F54Ropinirole

Hydrochloride]

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F38Sertindole]

[F34Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F34Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

Status: Point in time view as at 01/04/2002.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 pharmaceution form	Column 4 Treatment limitations on,	Column 5 Maximum quantity			
Sodium Arsenite	0.013 per cent						
Sodium Bromide							
Sodium Clodronate							
Sodium Cromoglyca	te	(a) For nasal admistration					
	(b) 2.0 per cent	(b) For the treatment of acute seasonal allergic conjunctivitis [F98 or perennial allergic conjunctivitis In the form of aqueous		(b) Container or package containing not more than 10ml of medicinal product			
	(c) 4.0 per cent	eye drops (c) For the treatment of acute seasonal allergic conjunctivitis		(c) Container or package containing not more than 5g of			
		In the form of an eye ointment		medicinal product			
Sodium Ethacrynate							
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices					
		(2) Other preparations for use in the prevention					

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

			ctions on the sale and sup	ply of	
Column 1	Column 2	only medicine. Column 3	s Column 4	Column 5	
Substance	Maximum strength	Route of administration use or pharmaceutiform of dental caries	Treatment limitations on,	Maximum quantity	
		In the form of			
		(a) tablets or drops	(a) 2.2 mg (MDD)		
	(b) 0.2 per cent	(b) mouth rinses other than those for daily use			
	(c) 0.05 per cent	(c) mouth rinses for daily use			
Sodium Fusidate					
Sodium Metrizoate					
Sodium Monofluoroj	1.14 per phæspthate	Dentrifrice			
Sodium Oxidronate					
Sodium Stiboglucona	ate				
Sodium Valproate					
Somatorelin Acetate					
Sotalol Hydrochlorid	de				
<sup>F35</sup> Sparfloxa	ncin]				
Spectinomy	ein				
Spectinomyo Hydrochlorio					
Spiramycin					
Spiramycin Adipate					

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

Spironolactone

Stannous Fluoride

 $([^{F99}1]) 0.62$ per cent

 $([^{F99}1])$ Dentifrice

 $[^{F99}(2) 0.4]$ per]

 $[^{F99}(2)]$ Dental

gels for use in the prevention and treatment of dental caries and decalcification of the teeth]

Stilboestrol

Stilboestrol Dipropionate

Streptodornase

External

Streptokinase

External

Streptomycin

Streptomycin Sulphate

Strychnine

Strychnine Arsenate

Strychnine Hydrochloride

[F37Strychnine Nitrate]

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

Sulbenicillin

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Sulbenicillin

Sodium

Sulconazole External Nitrate (except vaginal)

[F37Sulfabenzamide]

Sulfacytine

Sulfadoxine

Sulfamerazine

Sulfamerazine

Sodium

Sulfametopyrazine

Sulfamonomethoxine

Sulindac

Sulphacetamide

Sulphacetamide

Sodium

Sulphadiazine

Sulphadiazine

Sodium

Sulphadimethoxine

Sulphadimidine

Sulphadimidine

Sodium

Sulphafurazole

Sulphafurazole

Diethanolamine

Sulphaguanidine

Sulphaloxic

Acid

Sulphamethizole

Sulphamethoxazole

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

Suxethonium

Bromide

[F50Tacalcitol

Monohydrate]

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

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

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin Napsylate

Tamoxifen

Tamoxifen

Citrate

[<sup>F49</sup>Tamsulosin Hydrochloride]

[F34Tazarotene]

Tazobactam

Sodium

Teicoplanin

[F38Temocapril Hydrochloride]

Temocillin Sodium

Tenoxicam

Terazosin Hydrochloride

Terbinafine [F1001.0 per cent]	[F101] External use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel]	[F102] Container or package containing not more than 30 grams of medicinal product]
[F103]TerbinafingF103]1.0 per Hydrochloridedent]	([ <sup>F104</sup> 1]) [ <sup>F105</sup> Preparations, other than spray	([ <sup>F104</sup> 1]) [ <sup>F103</sup> Container or package containing

Status: Point in time view as at 01/04/2002.

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

			ctions on the sale and sup	ply of
Column 1 Substance	prescription Column 2 Maximum strength	conly medicine Column 3 Route of administration	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		pharmaceuti form  solutions, for][F103 extern use for the treatment of tinea pedis and tinea cruris]  [F106(2) Spray solutions for external use for the treatment of tinea		not more than 15 g of medicinal product.]  [F106(2) Container containing not more than 30ml of medicinal product]
Terbutaline Terbutaline		corporis, tinea cruris and tinea pedis]		
Sulphate Terfenadine			F107	F107
Terlipressin Terodiline Hydrochloride				
[F38 Testosteron Tetrabenazine	e]			
Tetracosactrin Tetracosactrin Acetate				
Tetracycline Tetracycline Hydrochloride				
Tetracycline Phosphate Complex				

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Tetroxoprim

Thallium

Acetate

Thallous

Chloride

Thiabendazole

Thiambutosine

Thiethylperazine

Malate

Thiethylperazine

Maleate

Thiocarlide

Thioguanine

Thiopentone

Sodium

Thiopropazate

Hydrochloride

Thioproperazine

Mesylate

Thioridazine

Thioridazine

Hydrochloride

Thiosinamine

Thiotepa

Thiothixene

Thiouracil

Thymoxamine

Hydrochloride

Thyroid

Thyrotrophin

Thyroxine

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

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

Sodium

[F49Ticlopidine

Hydrochloride]

Tigloidine

Hydrobromide

[F49Tiludronate

Disodium]

Timolol

Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except

vaginal)

(2) Vaginal

for treatment

of vaginal candidiasis

[F35Tizanidine Hydrochloride]

Tobramycin

Tobramycin

Sulphate

Tocainide Hydrochloride

Tofenacin

Hydrochloride

Tolazamide

Status: Point in time view as at 01/04/2002.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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
Tolazoline Hydrochlorid	e	External		
Tolbutamide				
Tolbutamide Sodium				
Tolfenamic Acid				
Tolmetin Sodium				
[F34Topiramat	e]			
[F59Torasemid	le]			
[F49Toremifen	e]			
Tramadol Hydrochlorid	e			
Trandolapril				
Tranexamic Acid				
Tranylcypron Sulphate	nine			
Trazodone Hydrochlorid	e			
Treosulfan				
Tretinoin				
Triamcinolon	e			
Triamcinolon Acetonide	q <sup>F108</sup> (1)] 0.1         per cent	[F108(1)] For the treatment of common mouth ulcers		[F108(1)] Container or package containing not more than 5g of medicinal product
		[F109(2) In the form of a non-	[F109(2) 110mcg per nostril (MD)	•

Status: Point in time view as at 01/04/2002.

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

			ctions on the sale and suppl	ly of
Column 1	prescription Column 2	only medicine Column 3	es Column 4	Column 5
Substance	Maximum	Route of	Treatment limitations	Maximum
	strength	administrati use or	on,	quantity
		pharmaceut	ical	
		form		
		pressurised nasal spray,	110mcg per nostril	not more than
		for the	(MDD)	3.575mg of ———
		treatment of	For a maximum period of 3 months	Triamcinolone
		symptoms of seasonal	5 months <sub>j</sub>	Acetonide]
		allergic		
		rhinitis in		
		persons aged 18		
		years and		
		over]		
Friamcinolor Diacetate	ne			
Triamcinolor Hexacetonid				
Triamterene				
Tribavirin				
Triclofos Sodium				
Trientine Dihydrochlo	ride			
Trifluoperaz	ine			
Trifluoperaz Hydrochlori				
Trifluperidol				
Trifluperidol Hydrochlori				
Trilostane				
Γrimeprazin	e			
Trimeprazin Tartrate	e			
Trimetaphan Camsylate	ı			

Trimetazidine

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine

Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

L- (1) Oral

Tryptophan Dietary

supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

Tulobuterol Hydrochloride

Tyrothricin Throat

lozenges or throat pastilles

Uramustine

Urea Stibamine

Urethane

Uridine 5'triphosphate

Urofollitrophin

Urokinase

Ursodeoxychoic

Acid

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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

Vaccine:

Bacillus

Salmonella

Typhi

Vaccine:

Poliomyelitis

(Oral)

 $[^{F35} Valaci clovir \\$ 

Hydrochloride]

Valproic

Acid

[F38Valsartan]

Vancomycin

Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

 $I^{F35}$ Venlafaxine

Hydrochloride]

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

Veratrum,

White

Vidarabine

Vigabatrin

Viloxazine

Hydrochloride

Vinblastine

Sulphate

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Vincristine Sulphate Vindesine Sulphate Viomycin Pantothenate Viomycin Sulphate Vitamin A (1) 7,500iu (2,250mcg (1) Internal Retinol equivalent) (MDD) (2) External Vitamin A (1) Equivalent to 7,500iu (1) Internal Acetate Vitamin A (2,250mcg Retinol equivalent) (MDD) (2) External Vitamin A (1) Equivalent to 7,500iu (1) Internal Palmitate Vitamin A (2,250mcg Retinol equivalent) (MDD) (2) External Warfarin Warfarin Sodium Xamoterol Fumarate Xipamide Yohimbine Hydrochloride [F35Zalcitabine] Zidovudine Zimeldine Hydrochloride

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

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

Zolpidem

Tartrate

Zomepirac

Sodium

Zopiclone

Zuclopenthixol

Acetate

Zuclopenthixol

Decanoate

Zuclopenthixol

Hydrochloride]

#### **Textual Amendments**

- **F34** 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)**
- **F35** 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)**
- **F36** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(a)
- **F37** 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.**
- F38 Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(g)
- **F39** 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**
- **F40** 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)**
- **F41** 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)**
- F42 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)
- F43 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)
- F44 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)
- F45 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)
- **F46** 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)**

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

- F47 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)
- F48 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)
- **F49** 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)
- F50 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)
- F51 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)
- **F52** Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(a)**
- F53 Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(f)
- F54 Sch. 1 entries inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(e)
- F55 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)
- F56 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)
- F57 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)
- F58 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)
- **F59** 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)
- **F60** 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)**
- F61 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)
- **F62** Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(b)
- **F63** 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)**
- **F64** 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)**
- F65 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)
- **F66** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(i)**
- **F67** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(ii)**
- **F68** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(iii)**
- **F69** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(b)(iv)**
- F70 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)
- F71 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)
- F72 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)

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

- Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(c)
- F74 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)
- F75 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)
- F76 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)
- F77 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)
- **F78** 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)
- F79 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)
- **F80** 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)**
- F81 Sch. 1 entries inserted (1.1.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2000 (S.I. 2000/3231), arts. 1(1), 2
- **F82** Words in Sch. 1 inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(e)(i)
- **F83** 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)
- **F84** Words in Sch. 1 revoked (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(c)**
- F85 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)
- **F86** 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)**
- F87 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)
- **F88** 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)
- **F89** 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)
- **F90** 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)
- F91 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)
- F92 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)
- **F93** 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)
- F94 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)
- F95 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)
- F96 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)
- F97 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)
- F98 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)

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

- F99 Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(d)
- **F100** Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), **2(d)(i)**
- F101 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(d)(ii)
- F102 Words in Sch. 1 inserted (31.12.2001) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2001 (S.I. 2001/3942), arts. 1(1), 2(d)(iii)
- F103 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)
- **F104** Sch. 1: entries renumbered (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), **3(e)**
- F105 Words in Sch. 1 inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(e)
- **F106** Sch. 1 entries inserted (24.8.2001) by The Prescription Only Medicines (Human Use) Amendment Order 2001 (S.I. 2001/2777), arts. 1(1), 3(e)
- F107 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)
- **F108** 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)
- F109 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)

#### **SCHEDULE 2**

Articles 6(1) and 10

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

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

	Circumstances excluding medicinal products from the class of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical Form	Column 4 Maximum Dose			
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

[F110 Co-danthramer Capsules NPF]

[F110 Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F110 Co-danthrusate Oral Suspension NPF]

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

#### **Textual Amendments**

**F110** 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

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

### [F111]SCHEDULE 3A

Article 3A

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

#### **Textual Amendments**

F111 Sch. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 9

Column 1	Column 2

Substance Requirements as to use, route of

administration, or pharmaceutical form

Aciclovir External use

Acrivastine Oral

Adapalene External use
Alclometasone dipropionate External use

Alimemazine tartrate (trimeprazine tartrate) Oral

Amorolfine hydrochloride External use

Amoxycillin trihydrate Oral Aspirin Oral

Azelaic acid External use

Azelastine hydrochloride Ophthalmic use or nasal

Baclofen Oral administration in palliative care

Beclometasone dipropionate External use or nasal

Betamethasone dipropionate External use
Betamethasone sodium phosphate Aural or nasal
Betamethasone valerate External use

Budesonide Nasal

Carbaryl External use
Carbenoxolone sodium Mouthwash

Cetirizine hydrochloride Oral

Chloramphenicol Ophthalmic use

Cimetidine Oral

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

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

Column 1	Column 2
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Substance Requirements as to use, route of

administration, or pharmaceutical form

Cyclizine Parenteral administration in palliative care

Dantrolene sodium Oral administration in palliative care

Dantron Oral
Desogestrel Oral

Desoximetasone (Desoxymethasone) External use

Dexamethasone Aural
Dexamethasone isonicotinate Nasal

Diclofenac diethylammonium External use

Domperidone Oral or rectal administration in palliative care

Domperidone maleate Oral administration in palliative care

Doxycycline Oral

Econazole nitrate External use Erythromycin External use

Ethinylestradiol Oral
Etynodiol diacetate (ethynodiol diacetate) Oral
Famotidine Oral

Felbinac External use
Fenticonazole nitrate External use

Fexofenadine hydrochloride Oral Flucloxacillin sodium Oral Fluconazole Oral

Fludroxycortide (Flurandrenolone) External use

Flumetasone pivalate Aural Flunisolide Nasal

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

Fluticasone propionate External use or nasal

Fusidic acid Ophthalmic use

Gentamicin sulphate Aural
Gestodene Oral

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

Column 1	Column 2
Substance	Requirements as to use, route of
	administration, or pharmaceutical form
Hydrocortisone	External use

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

Hyoscine butylbromide Parenteral administration in palliative care

Hyoscine hydrobromide Oral, parenteral or transdermal administration

in palliative care

Ibuprofen External use or oral

Ibuprofen lysineOralIpratropium bromideNasal

IsotretinoinExternal useKetoconazoleExternal useKetoprofenExternal use

Levocabastine hydrochloride Ophthalmic use or nasal

Levomepromazine (methotrimeprazine)

maleate

Oral administration in palliative care

Levomepromazine (methotrimeprazine)

hydrochloride

Parenteral administration in palliative care

Levonorgestrel Oral

Lithium succinate External use

Lodoxamide trometamol Ophthalmic use

Loperamide hydrochloride Oral
Loratadine Oral
Mebendazole Oral

Medroxyprogesterone acetate Parenteral

Mestranol Oral

Metoclopramide hydrochloride Oral or parenteral administration in palliative

care

Metronidazole External use or oral

Metronidazole benzoate Oral

Miconazole Dental lacquer
Miconazole nitrate External use

Minocycline Oral

Mometasone furoate External use or nasal

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

Column 1 Substance	Column 2 Requirements as to use, route of
Substance	administration, or pharmaceutical form
Nedocromil sodium	Ophthalmic use
Nefopam hydrochloride	Oral
Neomycin sulphate	Aural
Neomycin undecenoate	Aural
Nitrofurantoin	Oral
Nizatidine	Oral
Norethisterone 9	Oral
Norethisterone acetate	Oral
Norethisterone enanthate	Parenteral
Norgestimate	Oral
Norgestrel	Oral
Nystatin	External use
Oxytetracycline dihydrate	Oral
Paracetamol	Oral
Penciclovir	External use
Piroxicam	External use
Prednisolone hexanoate	External use
Prednisolone sodium phosphate	Aural
Ranitidine hydrochloride	Oral
Silver sulphadiazine	External use
Sodium cromoglycate	Ophthalmic use
Streptodornase	External use
Streptokinase	External use
Sulconazole nitrate	External use
Terbinafine hydrochloride	External use
Tetracycline hydrochloride	External use or oral
Tretinoin	External use
Triamcinolone acetonide	External use, aural, nasal or oral paste
Trimethoprim	Oral
Tuberculin PPD	Parenteral
Vaccine, Adsorbed Diphtheria	Parenteral
Vaccine, Adsorbed Diphtheria And Tetanus	Parenteral

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

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
Vaccine, Adsorbed Diphtheria And Tetanus For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria For Adults And Adolescents	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Adsorbed Diphtheria, Tetanus And Pertussis (Acellular Component)	Parenteral
Vaccine, BCG	Parenteral
Vaccine, BCG Percutaneous	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib)	Parenteral
Vaccine, Haemophilus Influenzae Type B (Hib) with Diphtheria, Tetanus And Pertussis	Parenteral
Vaccine, Haemophilus Influenzae Type B, Diphtheria, Tetanus And Acellular Pertussis	Parenteral
Vaccine, Hepatitis A	Parenteral
Vaccine, Hepatitis A With Typhoid	Parenteral
Vaccine, Hepatitis A, Inactivated, With Recombinant (DNA) Hepatitis B	Parenteral
Vaccine, Hepatitis B	Parenteral
Vaccine, Influenza	Parenteral
Vaccine, Live Measles, Mumps And Rubella (MMR)	Parenteral
Vaccine, Meningococcal Group C Conjugate	Parenteral
Vaccine, Meningococcal Polysaccharide A and C	Parenteral
Vaccine, Pneumococcal	Parenteral
Vaccine, Poliomyelitis, Inactivated	Parenteral
Vaccine, Poliomyelitis, Live (Oral)	Oral
Vaccine, Rubella, Live	Parenteral
Vaccine, Tetanus, Adsorbed	Parenteral
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Parenteral]

#### SCHEDULE 4

Article 8(4)(c)

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

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone Sodium

Hydrobromic Acid

Meclofenoxate Hydrochloride

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

## SCHEDULE 5

Article 11(1)(a)

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

## PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies		lumn 3 nditions
1. Persons selling or supplying prescription only medicines to universities, other institutions concerned with higher education or institutions concerned with research.	1. All prescription only medicines	1.	The sale or supply shall be—  (a) subject to the presentation of an order signed by the principal of the institution

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

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

concerned with education or research or the appropriate head of department in charge of a specified course of research stating—

- the name of the institution for which the prescription only medicine is required,
- (ii) the purpose for which the prescription only medicine is required, and
- (iii) the total quantity required, and
- (b) for the purposes of the education or research with which the institution is concerned.

- 2. Persons selling or supplying prescription only medicines to any of the following
  - a public analyst appointed under section 27 of the Food Safety Act 1990(16) or article 36 of the Food (Northern Ireland) Order 1989(17),
  - (2) an authorized officer within the meaning of section 5(6) of the

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

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

<sup>(17)</sup> S.I. 1989/846 (N.I. 6).

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

Column 1		Column 2	Column 3
Persons e	xempted	Prescription only medicines to which the exemption applies	Conditions
	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 prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(18), the National Health Service (Scotland) Act 1978(19) and the Health and Personal Social Services (Northern Ireland) Order 1972(**20**), or under any subordinate legislation made under those Acts or that Order.
- 3. All prescription only medicines.

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

> Chloral hydrate Ergometrine maleate

- 3. The sale or supply shall be-
  - (a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only medicine required, and
  - (b) for the purposes of a scheme referred to in column 1 in this paragraph.
- 4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.

4. Registered midwives.

<sup>(18) 1977</sup> c. 49.

<sup>(19) 1978</sup> c. 29.

<sup>(20)</sup> S.I. 1972/1265 (N.I. 14).

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

Column I	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
	Pentazocine hydrochloride [ <sup>F112</sup> Phytomenadione Triclofos sodium.	e]
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	5. Prescription only medicines which are not for parenteral administration and which—  (a) are eyes drops and are prescription only medicines by reason only	5. The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.

(b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol,

that they contain not more than 0.5 per cent Chloramphenicol,

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

Atropine sulphate Bethanecol chloride Carbachol Cyclopentolate hydrochloride Homatropine hydrobromide Naphazoline hydrochloride Naphazoline nitrate Physostigmine salicylate

Status: Point in time view as at 01/04/2002.

Changes to 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
	Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.	
6. Registered ophthalmic opticians.	<ul><li>6. Prescription only medicines listed in column 2 of paragraph</li><li>5.</li></ul>	<ul> <li>6. The sale or supply shall be only— <ul> <li>(a) in the course of their professional practice and</li> <li>(b) in an emergency.</li> </ul> </li> </ul>
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.	7. The sale or supply shall be—  (a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and  (b) only for the purpose of testing containers of medicinal products or determining the standards for such containers.
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	8. The sale or supply shall be only—  (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medic to which the exemption applies	cines Conditions
		guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(21) or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons) or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(22).	9. Amyl nitrite.	9. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.
IF11310 State registered	<b>10</b> . The fol	llowing 10. The sale or supply shall

[F11310. State registered chiropodists who hold a certificate of competence in the use of the medicines specified in Column 2 issued by or with the approval of the Chiropodists Board.

- registered 10. The following hold a prescription only medicines—
  - (a) Co-dydramol 10/500 tablets;
  - (b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;
  - (c) Amorolfine
    hydrochloride
    lacquer where the
    maximum strength
    of the Amorolfine in
    the lacquer does not
    exceed 5 per cent by
    weight in volume;
    and
- 10. The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.]

<sup>(21) 1972</sup> c. 66.

<sup>(22)</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	Prescription only medicines	Conditions
	to which the exemption	
	applies	
	(d) Topical	
	hydrocortisone	
	where the maximum	
	strength of the	
	hydrocortisone in the	
	medicinal product	
	does not exceed 1	
	per cent by weight in	
	weight.	

#### **Textual Amendments**

- **F112** 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)**
- F113 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

<u> </u>	<i>C</i> 1 2	<i>C</i> 1 2
Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines.	1. The supply shall be only so far as is necessary for the the treatment of sick or injured persons in the exercise of the functions of the Institution.
2. The owner or the master of a ship which does not carry a doctor on board as part of her complement.	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the treatment of persons on the ship.
3. Persons authorized by licences granted under regulation 5 of the Misuse of Drugs Regulations to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any	4. Such prescription only medicines as may be specified in the relevant enactment.	4. The supply shall be—  (a) for the purpose of enabling them to comply with
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Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.		any requirements made by or in pursuance of any such enactment, and (b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.
5. Persons operating an occupational health scheme.	5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	<ul> <li>(1) The supply shall be in the course of an occupational health scheme.</li> <li>(2) The individual supplying the prescription only medicine, if not a doctor, shall be a registered nurse acting in accordance with the 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.</li> </ul>
6. The operator or commander of an aircraft.	6. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
7. Persons employed as qualified first-aid personnel on offshore installations.	7. All prescription only medicines.	7. The supply shall be only so far as is necessary for the treatment of persons on the installation.

Article 11(2)

# PART III EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
1. State registered chiropodists who hold a certificate of competence in the use of analgesics issued by or with the approval of the Chiropodists Board.	1. Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than one of the following substances—  [FII4Bupivacaine hydrochloride Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride Lignocaine hydrochloride Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride  [FII5Mepivacaine hydrochloride]	1. The administration shall be only in the course of their professional practice.

Column 1 Column 2		Column 3
Persons exempted	Prescription only medicines to which the exemption	Conditions
	applies 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  hydrochloride  Naloxone  hydrochloride  Oxytocins, natural and synthetic  Pentazocine lactate  Pethidine  hydrochloride  Phytomenadione  Promazine  hydrochloride.	2. The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.
3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of her complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.
5. Persons operating an occupational health scheme.	5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	<ul> <li>5. — <ul> <li>(1) The administration shall be in the course of an occupational health scheme.</li> <li>(2) The individual administering the prescription only medicine, if neither</li> </ul> </li> </ul>

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
		in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.	7. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).	7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgement as to the treatment required.
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescription only medicines that are for parenteral administration.	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State	9. The following prescription only medicines for parenteral administration—	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium

Column 1	Column 2		Column 3
Persons exempted	Prescripti	on only medicines	Conditions
		he exemption	
	applies		
[F116] or persons who are state	(a)	Diazepam 5 mg per	shall be only for the purpose of
registered paramedics].		ml emulsion for	cannula flushing.
		injection;	
	(b)	Succinylated	
		Modified Fluid	
		Gelatin 4 per	
		cent intravenous	
	(1.1.)	infusion;	
	(bb)	[F117 medicines	
		containing the	
		substances	
		Ergometrine	
		Maleate 500mcg	
		per ml with	
		Oxytocin 5 iu per	
		ml, but no other	
	(4)	active ingredient]	
	(d)	prescription	
		only medicines	
		containing one or more of	
		the following	
		substances, but no	
		active ingredient–	
		Adrenaline	
		Acid Tartrate	
		Anhydrous	
		Glucose	
		[F118Benzylpen	icillinl
		[ <sup>F119</sup> Bretylium	
		Tosylate]	
		Compound	
		Sodium	
		Lactate	
		Intravenous	
		Infusion	
		(Hartmann's	
		Solution)	
		Ergometrine	
		Maleate	
		[F118Frusemide	1
		Glucose	-
		Heparin	
		Sodium	
		Lignocaine	
		Hydrochloride	
		[F118Metoclopri	

Changes to 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	
	[F118Morphine	
	Sulphate]	
	Nalbuphine	
	Hydrochloride	9
	Naloxone	
	Hydrochloride	9
	Polygeline	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride	
	[F118Streptokin	ase]

#### **Textual Amendments**

- F114 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)
- **F115** 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)**
- **F116** 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)**
- **F117** 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)**
- **F118** 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)
- **F119** Words in Sch. 5 Pt. 3 para. 9 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), 3

#### SCHEDULE 6

Article 16(1)

### ORDERS REVOKED

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Order 1983	S.I. 1983/1212
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1984	S.I. 1984/756
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1986	S.I. 1986/586

	G 1 2
Column 1 Orders	Column 2 References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1987	S.I. 1987/674
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1987	S.I. 1987/1250
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1988	S.I. 1988/2017
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1991	S.I. 1991/962
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1992	S.I. 1992/1534
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1992	S.I. 1992/2937
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1993	S.I. 1993/1890
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993	S.I. 1993/3256
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1994	S.I. 1994/558
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994	S.I. 1994/3016
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 3) Order 1994	S.I. 1994/3050
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1995	S.I. 1995/1384
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995	S.I. 1995/3174
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1996	S.I. 1996/1514

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

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

# [F120SCHEDULE 7

Articles 12A to 12C

#### **Textual Amendments**

F120 Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(e)

#### PART I

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

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

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

# **PART II**

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

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 [F121BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### **Textual Amendments**

**F121** Words in Sch. 7 Pt. 3 heading substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), **3(2)** 

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

Pharmacists.

Registered health visitors.

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

State registered chiropodists.

[F122 Individuals who are registered in the register of orthoptists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered orthoptists).]

[F122Individuals who are registered in the register of physiotherapists maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered physiotherapists).]

Status: Point in time view as at 01/04/2002.

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

[F122 Individuals who are registered in the register of radiographers maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001 (state registered radiographers).]]

#### **Textual Amendments**

F122 Words in Sch. 7 Pt. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 10

#### **EXPLANATORY NOTE**

(This note is not part of the Order)

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

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

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

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

- (a) the deletion from Column 1 of substances which are no longer used in those medicinal products which are on the market;
- (b) the use of current names for the substances which are specified in that Column where their names have changed;
- (c) the incorporation in that Schedule of provisions from article 4 of, and Part IV of Schedule 1 to, the 1983 Order as amended so that they may be found more easily;
- (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);

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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)

(e) the introduction of a fifth Column which specifies the maximum pack sizes to which exemptions apply.

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

# **Status:**

Point in time view as at 01/04/2002.

# **Changes to legislation:**

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