#### STATUTORY INSTRUMENTS

# 1997 No. 1830

# **MEDICINES**

The Prescription Only Medicines (Human Use) Order 1997

Made - - - - 25th July 1997

Laid before Parliament 28th July 1997

Coming into force - - 18th August 1997

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

# Citation, commencement and interpretation

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

"the Act" means the Medicines Act 1968;

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

[F1: clinical management plan" means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by—

(a) the patient to whom the plan relates,

<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)

- (b) the doctor or dentist who is a party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan;

[F2"clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003:]

F3

[F4"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;]

[F4":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  $\alpha$ -Cyanobenzyl-6-O- $\beta$ -d-glucopyranosyl- $\beta$ -d-glucopyranoside or  $\alpha$ -Cyanobenzyl- $\beta$ -d-glucopy ranosiduronic acid;

[F5" 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;

[F6"Extended Formulary" means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary;]

[F6" extended formulary nurse prescriber" means a person—

- (a) [F7who is a first level nurse, and]
- (b) against whose name is recorded in [F8 the professional register] an annotation signifying that he is qualified to order drugs, medicines and appliances from the Extended Formulary;]

"external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read

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

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;

[F9": first level nurse" means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;]

[F4":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;]

[F10chealth care" means services for or in connection with the prevention, diagnosis or treatment of disease;]

"health prescription" means a prescription issued by a doctor, dentist [F11, supplementary prescriber][F12, 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);

[F13" health record" has the meaning given by section 68(2) of the Data Protection Act 1998(6);]

[F4"homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;

I<sup>F14</sup>"independent clinic"—

- (a) in relation to England and Wales, has the meaning given by section 2(4) of the Care Standards Act 2000(8), and
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;]

[F14"independent hospital"—

- (a) in relation to England and Wales, shall be construed in accordance with section 2(2), (3) and (6) of the Care Standards Act 2000, and
- (b) in relation to Scotland, means—
  - (i) an independent hospital, or
  - (ii) a private psychiatric hospital,

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

[F14" independent medical agency"—

(a) in relation to England and Wales, has the meaning given by section 2(5) of the Care Standards Act 2000, and

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

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

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

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

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

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

(b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act 2001;]

"inhaler" does not include an aerosol;

[F4"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);

IF4"NHS trust"—

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

[F15"NHS foundation trust" has the same meaning as in section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003;]

<sup>(7) 1995</sup> 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)

[F16"nursing home" has the meaning given by article 16 of the Registered Homes (Northern Ireland) Order 1992;]

"occupational health scheme" means a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease;

"offshore installation" means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(10) which is within—

- (a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(11); "operator", in relation to an aircraft, means the person for the time being having the management of the aircraft;

"parenteral administration" means administration by breach of the skin or mucous membrane;

[F4" Patient Group Direction" means—

- (a) in connection with the supply of a prescription only medicine as referred to in article 12A(2), [F1712B, 12C, 12D or 12E], 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;

[F4":Primary Care Trust" has the same meaning as in the National Health Service Act 1977;]
[F18":prison service" means—

- (a) in relation to England and Wales, a Minister of the Crown exercising functions in relation to prisons (within the meaning of the Prison Act 1952),
- (b) in relation to Scotland, the Scottish Ministers exercising functions in relation to prisons (within the meaning of the Prisons (Scotland) Act 1989), and
- (c) in relation to Northern Ireland, the Northern Ireland Department exercising functions in relation to prisons (within the meaning of the Prison Act (Northern Ireland) 1953);]

[F19" 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;

<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)

[F20" registered chiropodist" means a person who is registered in Part 2 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;];

"registered midwife" means a person who is registered in Part 10 of [F21the professional register];

"registered nurse" means a person who is registered in [F22the professional register];

"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);

[F20" registered orthoptist" means a person who is registered in Part 7 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;];

[F20" registered paramedic" means a person who is registered in Part 8 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[F20ccregistered physiotherapist" means a person who is registered in Part 9 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[F23" registered provider" means—

- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
  - (i) in relation to England and Wales, the person who is registered under Part II of the Care Standards Act 2000 as the person carrying on the establishment or agency,
  - (ii) in relation to Scotland, the person who is registered under Part 1 of the Regulation of Care (Scotland) Act 2001 as the person providing the establishment or agency, and
- (b) in relation to a nursing home, the person registered under Part III of the Registered Homes (Northern Ireland) Order 1992 as the person carrying on the nursing home, other than a manager who is to be treated as carrying on the home by virtue of article 17(2) of that order;

[F20c'registered radiographer" means a person who is registered in Part 11 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001:1

"relevant manager" means—

- (a) in relation to an independent hospital, an independent clinic or an independent medical agency—
  - (i) in relation to England and Wales—
    - (aa) a person who is registered under Part II of the Care Standards Act 2000 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
    - (bb) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person,
  - (ii) in relation to Scotland, a person, other than the registered provider, who was identified as an individual who is to manage the establishment or agency on the application for registration of that establishment or agency under Part 1 of Regulation of Care (Scotland) Act 2001, and

(12) 1989 c. 44.

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

(b) in relation to a nursing home, the manager of the nursing home, unless they are the registered provider for that home;

"relevant register" means—

- (a) in relation to a first level nurse, the professional register, and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;]

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

"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;

[F4"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;]

F24 ...

[F25"Strategic Health Authority" means a Strategic Health Authority established under section 8 of the National Health Service Act 1977;]

[F26" supplementary prescriber" means—

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

against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;]

"supply" means supply in circumstances corresponding to retail sale as defined in section 131 of the Act;

"unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being diluted tenfold or one hundredfold, either once or repeatedly, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances.

[F4":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 [F27Schedules 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:

```
"g" for gram,
```

"iu" for international unit of activity,

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

- (6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.
- F28(7) In articles 12 to [F2912E], a reference to a prescription only medicine being sold or supplied for the purpose of being administered in accordance with the written directions of a doctor or dentist relating to a particular person, or in accordance with a Patient Group Direction, includes a reference to it being sold or supplied in accordance with such directions or such a Direction.
- (8) In articles 12A and 12C, a reference to an arrangement for the supply or administration of prescription only medicines includes a reference to an arrangement which covers such supply or administration and other matters.
- (9) In Schedule 7, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.]

#### **Textual Amendments**

- F1 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(a)
- F2 Words in art. 1(2) substituted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, Sch. 10 Pt. 2 para. 13(a)
- 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)
- **F4** 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)
- **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)(c)
- F7 Words in art. 1(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(b)(i)

- F8 Words in art. 1(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(b)(ii)
- F9 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(c)
- F10 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(d)
- F11 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(e)
- F12 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)
- F13 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(f)
- F14 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(g)
- F15 Words in art. 1(2) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(8), Sch. 8
- F16 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(h)
- F17 Words in art. 1 substituted (10.12.2003) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2003 (S.I. 2003/2915), arts. 1(1), 2
- F18 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(i)
- F19 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)
- **F20** Words in art. 1 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(2)(a)**
- **F21** Words in art. 1 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **2(2)(f)**
- F22 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)
- F23 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(j)
- **F24** Words in art. 1 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, **Sch. para. 21(2)(b)**
- **F25** Words in art. 1(2) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), regs. 1, 7, **Sch. 4**
- F26 Words in art. 1(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 2(2)(k)
- **F27** 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)**
- F28 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)
- **F29** Word in art. 1(7) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **2(3)**

### **Appropriate practitioners**

**2.** For the purposes of section 58 (medicinal products on prescription only), the following shall be appropriate practitioners—

Changes to 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 the descriptions and classes of medicinal products specified in article 3, doctors, dentists [F30, supplementary prescribers], veterinary surgeons and veterinary practitioners;
- [F31(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**

- **F30** Words in art. 2(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 3
- F31 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

# [F32Medicinal 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.
  - [F33(g) medicinal products in respect of which a marketing authorization has been granted consisting of or containing aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules which in the marketing authorization are classified as being pharmacy only or general sale list medicines.]]

## **Textual Amendments**

- **F32** Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4
- F33 Art. 3(g) added (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 4

# [F34Prescribing 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

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

Schedule 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) [F35Subject to paragraph (4),] an extended formulary nurse prescriber may—
  - (a) give a prescription for a medicinal product referred to in paragraph (1); or
  - (b) if that medicinal product is for parenteral administration—
    - (i) administer that medicinal product, or
    - (ii) give directions for the administration of that medicinal product,
    - only where he complies with any condition as to the cases or circumstances in which he may do so that is specified by virtue of paragraph (3).
- (3) If the entry in column 2 of Schedule 3A relating to a substance specifies one or more requirements as to use, route of administration or pharmaceutical form, it is a condition for the purposes of paragraph (2) that a medicinal product which consists of, or contains, that substance is administered, or is prescribed or directed for administration, in accordance with the specified requirements.
- F36(4) An extended formulary nurse prescriber may prescribe or administer a medicinal product referred to in paragraph (1), or give directions for administration of such a product, without complying with any condition specified by virtue of paragraph (3) if—
  - (a) he is a supplementary prescriber; and
  - (b) he complies with the applicable conditions set out in article 3B(3).

#### **Textual Amendments**

- **F34** Art. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 5
- F35 Words in art. 3A(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 5(a)
- **F36** Art. 3A(4) added (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **5(b)**

# [F37Prescribing and administration by supplementary prescribers

- **3B.**—(1) Subject to paragraph (2), a supplementary prescriber may—
  - (a) give a prescription for a medicinal product referred to in article 3; or
  - (b) if that medicinal product is for parenteral administration—
    - (i) administer that medicinal product, or
    - (ii) give directions for the administration of that medicinal product,
    - only where he complies with the conditions as to the cases or circumstances in which he may do so specified in paragraph (3).
- (2) Paragraph (1) does not apply if—
  - (a) the supplementary prescriber is a district nurse/health visitor prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3: or
  - (b) the supplementary prescriber is an extended formulary nurse prescriber and—

- (i) the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in article 3A(1), and
- (ii) he satisfies any applicable condition specified by virtue of article 3A(3).
- (3) The conditions referred to in paragraph (1) are that—
  - (a) the supplementary prescriber is acting in accordance with the terms of a clinical management plan which—
    - (i) relates to the patient for whom the product is prescribed or to whom it is, or is to be, administered,
    - (ii) is in effect at the time the prescription or direction is given or, as the case may be, the product is administered, and
    - (iii) includes the particulars specified in Schedule 3B;
  - (b) at the time the prescription or directions are given or, as the case may be, the product is administered—
    - (i) a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of the product, or
    - (ii) the product is, or is to be, administered in the course of a clinical trial [F38] which has been authorised, or is to be treated as having been authorised, by the licensing authority in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2003];
  - (c) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan.

#### **Textual Amendments**

- F37 Arts. 3B, 3C inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 6
- **F38** Words in art. 3B(3)(b)(ii) substituted (1.5.2004) by The Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, Sch. 10 Pt. 2 para. 13(b)

# Exemptions from conditions in respect of the cases or circumstances in which an extended formulary nurse prescriber or supplementary prescriber may administer a medicinal product

- **3C.** The conditions specified by virtue of article 3A(3) and in article 3B(3) shall not apply in relation to the administration of a medicinal product by an extended formulary nurse prescriber or a supplementary prescriber where—
  - (a) that person is acting in accordance with the directions of another person who is an appropriate practitioner, or
  - (b) that administration is exempt from the restriction in section 58(2)(b) (restriction on administration) by virtue of any of the subsequent provisions of this Order.]

### **Textual Amendments**

F37 Arts. 3B, 3C inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 6

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

D 4.	c		provisions	•	1 4 •	4		10 0 1	1 4
Huratian	Λt	cnacial	nrowicione	ın	ralation	ŧΛ	naw	madicinal	nraducte
Dui auvii	VΙ	SDCCIAL	DI 0 41910H9	ш	iciauon	w	11 ( )	miculcinai	DIVUUCIS
	-								

₹.	•	•	٠	٠	٠	٠	٠	٠	•	٠	•	٠	•	•	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	٠	•								
																																								-

#### **Textual Amendments**

F39 1

**F39** Art. 4 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), **11** 

# **Exempt medicinal products**

- 5.—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there—
  - (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or
  - (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.
- (2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.
- (3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.
- (4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use—
  - (a) where a purpose for which it may be used is so specified, for that purpose;
  - (b) where the class of persons in whom it may be used is so specified, in persons of that class  $I^{F40}$

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**

**F40** 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** 

# [F41 Exemption for products consisting of or containing aloxiprin, aspirin or paracetamol

**5A.** A medicinal product falling within article 3(g) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the quantity of that product sold or supplied to a person at any one time does not exceed 100 tablets or capsules.]

## **Textual Amendments**

**F41** Art. 5A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 7

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

Circu	mstances	in whic	h contro	lled dr	ugs and i	nedicinal	products	authorized b	y the
Europ	pean Com	munity	are not	prescri	ption onl	y medicin	ies		

F426																
v.																

#### **Textual Amendments**

**F42** 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 [F43, a supplementary prescriber][F44, a district nurse/health visitor prescriber or an extended formulary nurse prescriber] who by reason of an emergency is unable to furnish a prescription immediately;
    - (b) that the doctor [F45, supplementary prescriber][F46, 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 [<sup>F47</sup>, supplementary prescriber][<sup>F48</sup>, 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 [F49, supplementary prescriber][F50, 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 [F51a 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,

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

- (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**

- **F43** Words in art. 8(2)(a) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(i)
- **F44** 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)
- F45 Words in art. 8(2)(b) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(ii)
- **F46** 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)
- **F47** Words in art. 8(2)(c) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(a)(iii)
- **F48** 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)
- **F49** Words in art. 8(4)(a)(ii) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 8(b)
- **F50** 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)
- F51 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.**—[F52(1)] The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains, any of the substances listed in column 1 of Schedule 1 or 2, only one or more unit preparation of such substances, if—
  - (a) each such unit preparation has been diluted to at least one part in a million (6x), and the person selling, supplying or administering the medicinal product has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required; or
  - (b) each such unit preparation has been diluted to at least one part in a million million (6c).

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

[F53(2)] The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains solely one or more unit preparations of the following substances—

Aconite

Arsenic Trioxide

Belladonna Herb

Ignatia Bean

Nux Vomica Seed,

if each such unit preparation has been diluted to at least one part in a million (6x)]

#### **Textual Amendments**

- F52 Art. 10 renumbered as art. 10(1) (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 9
- F53 Art. 10(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 9

# **Exemptions for certain persons**

- 11.—(1) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply—
  - (a) to the sale or supply by a person listed in column 1 of Part I of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied;
  - (b) to the supply by a person listed in column 1 of Part II of Schedule 5 of the prescription only medicines listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.
- (2) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration by a person listed in column 1 of Part III of Schedule 5 of the prescription only medicines for parenteral administration listed in relation to that person in column 2 of that Part where the conditions specified in the corresponding paragraphs in column 3 of that Part are satisfied.

# [F54Exemption for sale or supply in hospitals

- 12.—(1) Subject to paragraph (3), 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 directions satisfying the conditions specified in paragraph (2).
  - (2) The conditions specified in paragraph (1) are that the directions—
    - (a) are in writing;
    - (b) relate to the particular person to whom the medicine is to be administered; and
    - (c) are given by a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine.
- (3) Such directions may be given by an extended formulary nurse prescriber or a supplementary prescriber only where he complies with any condition as to the cases or circumstances in which he

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

may give a prescription for that medicine specified by virtue of article 3A or 3B, as if the directions are a prescription.

(4) The exemption in paragraph (1) applies notwithstanding that the directions do not satisfy the conditions specified in article 15(2).]

#### **Textual Amendments**

F54 Art. 12 substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 2

# [F55] 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 [F56Strategic Health Authority,] Health Authority or Special Health Authority;
  - (c) an NHS trust [F57 or NHS foundation 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 [F58Strategic Health Authority,] Health Authority or Special Health Authority;
  - (c) an NHS trust [F59 or NHS foundation 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**

- F55 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)
- **F56** Words in art. 12A(1)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, **Sch. 1 para. 73(2)(a)**
- **F57** Words in art. 12A(1)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), **Sch. 2**
- **F58** Words in art. 12A(2)(b) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, **Sch. 1 para. 73(2)(b)**
- **F59** Words in art. 12A(2)(c) inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), **Sch. 2**

# Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist doctors or dentists in providing national health services

- **12B.**—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—
  - (a) the individual supplies or, as the case may be, administers the medicine in order to assist a
    doctor or dentist in the provision of, respectively, NHS primary medical services or NHS
    primary dental services;
  - (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
  - (c) the conditions specified in paragraph (2) are satisfied.
  - (2) The conditions referred to are that—
    - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the doctor or dentist

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

- 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 [F60 or Primary Care Trust]—
    - (a) in the case of the provision of general medical services or general dental services, with which an arrangement has been made for the provision of those services; or
    - (b) in the case of the performance of personal medical services or personal dental services, which is a party to the pilot scheme under which those services are provided;
- (e) the individual referred to in paragraph (1) is designated in writing for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction, by the doctor or dentist in question, or, alternatively, where the Direction also relates to supply or administration in order to assist one or more other doctors or dentists, as referred to in sub-paragraph (a), by one of those other doctors or dentists; and
- (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.
- (3) In this article—
  - (a) a reference to the provision of NHS primary dental services shall be construed as a reference to—
    - (i) in relation to England and Wales, the provision of general dental services under Part II of the National Health Service Act 1977, or the performance of personal 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—
    - [F61(i) in relation to England and Wales, the provision of primary medical services under Part I of the National Health Service Act 1977;]

- (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
- [F62(iii) in relation to Northern Ireland, the provision of primary medical services under Part VI of the Health and Personal Social Services (Northern Ireland) Order 1972;]

#### **Textual Amendments**

- F55 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)
- **F60** Words in art. 12B(2)(d)(ii) inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), regs. 1, 8, **Sch. 5**
- F61 Art. 12B(3)(b)(i) substituted (E.) (1.4.2004) by The General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004 (S.I. 2004/865), art. 1(1), Sch. 1 para. 18(2); and substituted (W.) by The General Medical Services Transitional and Consequential Provisions (Wales) (No. 2) Order 2004 (S.I. 2004/1016), art. 1(1), Sch. 1 para. 18(2)
- F62 Art. 12B(3)(b)(iii) substituted (N.I.) (1.4.2004) by The General Medical Services Transitional and Consequential Provisions (No. 2) (Northern Ireland) Order 2004 (S.R. 2004/156), art. 1(1), Sch. 1 para. 10(2) (with art. 88)

# 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—
  - $I^{F63}(a)$  the medicine is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—
    - (i) a body referred to in article 12A(a) to (d),
    - (ii) an authority or person carrying on the business of an establishment or agency referred to in article 12D(1),
    - (iii) a force or service referred to in article 12E(1)(a)(i) to (iii), or
    - (iv) Her Majesty's Forces,

for the supply or, as the case may be, the administration of prescription only medicines;]

- (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction; and
- (c) the conditions specified in paragraph (2) are satisfied.
- (2) The conditions referred to are that—
  - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine by the person lawfully conducting a retail pharmacy business who supplies or, as the case may be, administers the prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;

- (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
- [F64(c)] the Patient Group Direction is signed—
  - (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
  - (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider and, if there is a relevant manager for the establishment or agency, that manager,
  - (iii) in the case of an arrangement with a prison service, by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that service,
  - (iv) in the case of an arrangement with a police force or the Police Service of Northern Ireland—
    - (a) by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, and
    - (b) a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland, and
  - (v) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces;]
- [ where the prescription only medicine is administered by the person lawfully conducting a retail pharmacy business within the meaning of section 69, the individual who administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is [\*F66\*designated in writing—
  - (i) in the case of an arrangement with a body referred to in article 12A(a) to (d), on behalf of that body,
  - (ii) in the case of an arrangement with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1), by or on behalf of the relevant provider or, if there is a relevant manager for the establishment or agency, that relevant manager,
  - (iii) in the case of an arrangement with a force or service referred to in article 12E(1)(a)
    (i) to (iii), by or on behalf of the person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for that force or service, or
  - (iv) in the case of an arrangement with Her Majesty's Forces, by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order against the entry in column 1 of that Table for Her Majesty's Forces,
  - for the purpose of the administration of prescription only medicines under the Patient Group Direction; and []
  - (d) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

#### **Textual Amendments**

- F55 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)
- F63 Art. 12C(1)(a) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 10(a)
- F64 Art. 12C(2)(c) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 10(b)(i)
- **F65** 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)**
- **F66** Words in art. 12C(2)(cc) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 10(b)(ii)

# [F67]Exemption for the supply and administration of prescription only medicines by independent hospitals, clinics and agencies

- **12D.**—(1) The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine in the course of the business of—
  - (a) in England, Wales or Scotland—
    - (i) an independent hospital,
    - (ii) an independent clinic, or
    - (iii) an independent medical agency; or
  - (b) in Northern Ireland, a nursing home,

where the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, to a particular person in accordance with a Patient Group Direction and where the conditions specified in paragraph (2) are satisfied.

- (2) The conditions referred to are that—
  - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration, by the person who supplies or administers the medicine, of a description or class of prescription only medicine, and the Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
  - (b) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
  - (c) the Patient Group Direction is signed—
    - (i) by or on behalf of the registered provider, and
    - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager;
  - (d) the individual who supplies or, as the case may be, administers the medicine belongs to one of the classes of individual specified in Part III of Schedule 7 to this Order, and is designated in writing—
    - (i) by or on behalf of the registered provider, or
    - (ii) if there is a relevant manager for the independent hospital, clinic or agency, or nursing home, by that manager,

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

- for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
- (e) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.

#### **Textual Amendments**

F67 Arts. 12D, 12E inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 11

# Exemption for health professionals who supply or administer prescription only medicines under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces

- 12E.—(1) The restrictions imposed by section 58(2) (sale, supply and administration) shall not apply to the supply or, as the case may be, the administration of a prescription only medicine by an individual belonging to one of the classes specified in Part III of Schedule 7 to this Order where—
  - (a) the individual supplies or, as the case may be, administers the medicine in order to assist the provision of health care by, on behalf of, or under arrangements made by—
    - (i) a police force in England, Wales or Scotland,
    - (ii) the Police Service of Northern Ireland,
    - (iii) a prison service, or
    - (iv) Her Majesty's Forces;
  - (b) the medicine is supplied for the purpose of being administered, or, as the case may be, is administered, in accordance with a Patient Group Direction; and
  - (c) the conditions specified in paragraph (2) are satisfied.
  - (2) The conditions referred to are that—
    - (a) the Patient Group Direction relates to the supply or, as the case may be, the administration of a description or class of prescription only medicine in order to assist the provision of health care by, or on behalf of, or under arrangements made by the police force or service, the prison service or, as the case may be, Her Majesty's Forces;
    - (b) the Patient Group Direction has effect at the time at which the medicine is supplied or, as the case may be, is administered;
    - (c) the Patient Group Direction contains the particulars specified in Part I of Schedule 7 to this Order (but with the omission of paragraph (c) of that Part in the case of a Direction which relates to administration only);
    - (d) the Patient Group Direction is signed—
      - (i) by or on behalf of a person specified in column 2 of the Table in Part IIA of Schedule 7 to this Order ("the authorising person") against the entry in column 1 of that Table for the police force or service, the prison service or Her Majesty's Forces by whom, or on whose behalf, the health care is provided, or with whom arrangements are made for the provision of such care; and
      - (ii) in the case of a police force or the Police Service of Northern Ireland, by a doctor who is not employed or engaged by, and who does not provide services under arrangements made with, any police force or the Police Service of Northern Ireland;

- (e) the individual referred to in paragraph (1) is designated in writing, by or on behalf of the authorising person, for the purpose of the supply or, as the case may be, the administration of prescription only medicines under the Patient Group Direction; and
- (f) at the time at which the medicine is supplied or, as the case may be, is administered, a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of it.]

#### **Textual Amendments**

F67 Arts. 12D, 12E inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 11

### Exemption in cases involving another's default

13. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person who, having exercised all due diligence, believes on reasonable grounds that the product sold or supplied is not a prescription only medicine.

# [F68 Exemptions relating to prescriptions given by nurses

- **13A.**—[<sup>F69</sup>(1) The restrictions imposed by section 58(2)(a) (restrictions in sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by—
  - (a) another pharmacist,
  - (b) a registered nurse, or
  - (c) a registered midwife,

who is not an appropriate practitioner in relation to that medicine where the pharmacist selling or supplying the medicine, having exercised all due diligence, believes on reasonable grounds that the person is such a practitioner.]

(2) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a prescription given by an extended formulary nurse prescriber [F70] or supplementary prescriber] where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the extended formulary nurse prescriber [F70] or supplementary prescriber] has complied with any condition with which he is required to comply by virtue of [F71] articles 3A(2) and (3) or 3B].]

# **Textual Amendments**

- **F68** Art. 13A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 7
- **F69** Art. 13A(1) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 12(a)
- **F70** Words in art. 13A(2) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **12(b)(i)**
- F71 Words in art. 13A(2) substituted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 12(b)(ii)

### Exemption in the case of a forged prescription

**14.** The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.

# **Prescriptions**

- **15.**—(1) For the purposes of section 58(2)(a) [<sup>F72</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 [F73, a supplementary prescriber], [F74a 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 [<sup>F75</sup>, a supplementary prescriber][<sup>F76</sup>, 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.
- [<sup>F77</sup>(2A) For the purposes of paragraph (1), where a prescription is issued and dispensed in England and the conditions specified in paragraph (2C) are fulfilled, the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (2B).
  - (2B) The conditions referred to are that the prescription shall be—

- (a) created in an electronic form and signed with an electronic signature and transferred to the person by whom it is dispensed as an electronic communication (including where it is so transferred through one or more intermediaries); or
- (b) entered on a document where—
  - (i) the prescription is created electronically and signed with an electronic signature and both the data and the signature are entered on the document in a non-legible manner;
  - (ii) the prescription is created in writing on the document, as referred to in paragraph (2) (b), and is signed with an electronic signature which is entered on the document in a non-legible manner; or
  - (iii) the prescription is created in an electronic form which is entered on the document in a non-legible manner, and is signed as referred to in paragraph (2)(a),

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

- (2C) The conditions referred to are that—
  - (a) the prescription is issued by a doctor—
    - (i) under or by virtue of the National Health Service Act 1997; or
    - (ii) as part of the performance of personal medical services in connection with a pilot scheme under the National Health Service (Primary Care) Act 1977,

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

- (b) the Secretary of State is satisfied that—
  - (i) the use of electronic means in order to create, sign and transfer prescriptions (or whichever of those purposes is applicable) is appropriate for the purposes of a pilot scheme on the use of electronic prescribing, in relation to both the doctor and the person lawfully conducting a retail pharmacy business concerned, and in relation to the premises at which the prescription is dispensed; and
  - (ii) the particular electronic means used by both the doctor and the person lawfully conducting a retail pharmacy business concerned are suitable for the purposes of such a pilot scheme.]
- (3) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to a sale or supply of a prescription only medicine which is not in accordance with a prescription given by an appropriate practitioner by reason only that a condition specified in paragraph (2) [<sup>F78</sup>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.

 $I^{F79}(5)$  In paragraphs (2B) and (2C)—

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

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

"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**

- F72 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)
- F73 Words in art. 15(2)(c)(iii) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 13(a)
- F74 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)
- F75 Words in art. 15(2)(c)(iv) inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 13(b)
- **F76** 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)**
- F77 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)
- F78 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)
- F79 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

Status: Point in time view as at 01/05/2004.

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

Jeff Rooker
Minister of State, Ministry of Agriculture,
Fisheries and Food

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



D. C. Gowdy Permanent Secretary

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



*P. Small* Permanent Secretary

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

#### SCHEDULE 1

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

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 form

[F80 Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F80 Aceclofenac]

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 face (Herpes

labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

31

Status: Point in time view as at 01/05/2004.

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

		from the restri only medicine	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Acrivastine			24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine
Acrosoxacin				
Actinomycin C				
Actinomycin D				
[F81Adapalene	]			
Adenosine				
Adrenaline		(1) By inhaler		
		(2) External [F82(except ophthalmic)]		
Adrenaline Acid		(1) By inhaler		
Tartrate		(2) External		
Adrenaline Hydrochloride	e	(1) By inhaler		
		(2) External		
Adrenocortica Extract	ıl			
Albendazole				
Alclofenac				
Alclometason Dipropionate	e			
Alcuronium Chloride				
Aldesleukin				

Aldosterone

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

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

 $I^{F80}$ Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F83Aloxiprin (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 Column 2 Substance Maximum

Column 3 Route of administration, strength

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F81Altretamine]

Amantadine

Hydrochloride

Ambenonium

Chloride

Ambutonium

Bromide

Amcinonide

Ametazole

Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine

Non-Gentisate ophthalmic

> use Non-

Amethocaine

Hydrochloride

ophthalmic

use

Amikacin

Sulphate

Amiloride Hydrochloride

Aminocaproic

Acid

Aminoglutethimide

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Aminopterin

Sodium

Amiodarone

Hydrochloride

Amiphenazole

Hydrochloride

[F84Amisulpride]

Amitriptyline

Amitriptyline

Embonate

Amitriptyline

Hydrochloride

Amlodipine

Besylate

Ammonium

Bromide

Amodiaquine

Hydrochloride

Amorolfine

Hydrochloride

Amoxapine

Amoxycillin

Amoxycillin

Sodium

Amoxycillin

Trihydrate

Amphomycin

Calcium

Amphotericin

Ampicillin

Ampicillin

Sodium

Ampicillin

Trihydrate

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

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

Amsacrine

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic use

[F80 Anastrozole]

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

Status: Point in time view as at 01/05/2004.

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

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

Column 1 Column 2

Maximum

strength

Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Antimony

Substance

Sulphate

Antimony

Trichloride

Antimony

Trioxide

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F81] Apraclonidine

Hydrochloride]

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

	prescription	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity			
Arsenic Trioxide							
Arsphenami	ne						
[F85Aspirin	[ F86(1) 75mg]	[ F86(1) Non- effervescent tablets and capsules]		[ F86(1) The quantity sold or supplied in one container or package shall not exceed 100 The quantity of non- effervescent tablets, capsules or a combination of both sold or supplied to a person at any one time shall not exceed 100]			
	[ <sup>F87</sup> [ <sup>F88</sup> ( <b>20)</b> ] mg]	[F88(2)]on-effervescent tablets and capsules		[F88(2)]The quantity sold or supplied in one container or package			

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

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	prescription Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
				shall not exceed 32		
		[F88(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		F89	F89	F89		
		F89 F89				
Atenolol						
Atracurium Besylate						
Atropine		<ul><li>(1) Internal</li><li>(a) by inhaler</li></ul>				
		(b) otherwise	(b) 300mcg (MD)			

	•	from the restri	ictions on the sale and supp	oly of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		than by			
		inhaler	1mg (MDD)		
		(2) External (except ophthalmic)	Ting (WDD)		
Atropine	1	(1) Internal			
Methobromic	de	(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		Internal			
Methonitrate		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
Atropine Oxide		(1) Internal			
Hydrochloride		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			

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

		from the restra	ictions on the sale and suppl es	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	,	Column 5 Maximum quantity
Atropine Sulphate		<ul><li>(1) Internal</li><li>(a) by inhaler</li></ul>		
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD)	
		(2) External (except ophthalmic)		
Auranofin				
Azapropazon	e			
Azathioprine				
Azathioprine Sodium				
Azelaic Acid				
Azelastine Hydrochlorid	le	For nasal administration	140mcg per nostril (MD)	Container or package
		For the treatment of seasonal allergic rhinitis [F90 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 [F915 years]		
		As a non-aerosol,		

	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 Treatment l administration, use or pharmaceutical form	imitations	Maximum quantity			
		aqueous form					
Azidocillin Potassium							
Azithromycin							
Azlocillin Sodium							
Aztreonam							
Bacampicillin Hydrochloride							
Bacitracin							
Bacitracin Methylene Disalicylate							
Bacitracin Zinc							
Baclofen							
[ <sup>F84</sup> Balsalazide Sodium]	e						
Bambuterol Hydrochloride	e						
Barium Carbonate							
Barium Chloride							
Barium Sulphide							
Beclamide							
Beclomethaso	ne						
Beclomethaso Dipropionate	ne	For nasal 100mcg per administration (non-aerosol)	nostril (MD)	Container or package containing not more than [F9220,000 mcg] of			

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

	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	
		For the prevention and treatment of allergic rhinitis	200 mcg per nostril (MDD)  [F93For a maximum period of 3 months]	Beclomethasone Dipropionate	
		[F94For use in persons aged 18 years and over]			
Belladonna Herb		(1) Internal	(1) 1mg of the alkaloids (MDD)		
		(2) External			
Belladonna Root		(1) Internal	(1) 1mg of the alkaloids (MDD)		
		(2) External			
Bemegride					
Bemegride Sodium					
Benapryzine Hydrochlorid	e				
Bendrofluazio	de				
Benethamine Penicillin					
Benoxaprofer	1				
Benperidol					
[F84Benserazio	de]				
Benserazide Hydrochlorid	e				
Bentiromide					
Benzathine Penicillin					
Benzbromaro	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 Column 3 C Route of T administration,

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

Status: Point in time view as at 01/05/2004.

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

[F81Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

Fumarate

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

[F84Brimonidine

Tartrate]

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

	Exemptions from the restrictions on the sale and supply of				
Column 1 Substance	prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceuti form	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
Bromvaleton	e				
Brotizolam					
Budesonide		For nasal administration	200mcg per nostril (MD)	Container or package	
		For the prevention or treatment of seasonal allergic rhinitis	[F93For a maximum period of 3 months]	containing not more than 10mg of Budesonide	
		200 mcg per nostril (MDD)			
		[F94For use in persons aged 18 years and over]			
		As a non- aerosol, aqueous form			
Bufexamac					
Bumetanide					
Buphenine Hydrochlorid	۵		6mg (MD)		
-			18mg (MDD)		
Bupivacaine		Any use except ophthalmic use			
Bupivacaine Hydrochlorid	le	Any use except ophthalmic use			
Buserelin Acetate					

Status: Point in time view as at 01/05/2004.

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

[F95Cabergoline]

Calcipotriol

[F81Calcipotriol

Hydrate]

Calcitonin

Calcitriol

Calcium Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium

Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

 $\textbf{I}^{F96} Can desart an$ 

Cilexetil]

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form Candicidin Canrenoic Acid Cantharidin 0.01 per External cent Capreomycin Sulphate Captopril Carbachol Carbamazepine Carbaryl [F84Carbasalate Calcium] Carbenicillin Sodium Carbenoxolone (1) Pellet (1) 5mg (MD) Sodium 25mg (MDD) (2) 2.0 per(2) Gel cent (3) 20mg (MD) (3) (3) 1.0 per (3) Granules for Container cent 80mg (MDD) mouthwash or package in adults containing and children not more not less than than 12 years [F97560mg] Carbenoxolone Sodium Carbidopa Carbimazole Carbocisteine Carbon Tetrachloride

Carboplatin

Status: Point in time view as at 01/05/2004.

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

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

[F84Cefdinir]

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

[F95Cefprozil]

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form Ceftriaxone Sodium Cefuroxime Axetil Cefuroxime Sodium Celiprolol Hydrochloride Cephalexin Cephalexin Sodium Cephaloridine Cephalothin Sodium Cephamandole Nafate Cephazolin Sodium Cephradine Cerium Oxalate Cerivastatin [F84Cerivastatin Sodium] Ceruletide Diethylamine Cetirizine 10mg (MDD) Hydrochloride

Chenodeoxycholic

Acid

Chloral External

Hydrate

Chlorambucil

Chloramphenicol

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

strength

Column 2 Column 3
Maximum Route of

Column 3 Column 4
Route of Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium

Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(15)) 5.0 per

cent

(1) Internal

(2) ExternalProphylaxis

Chloroquine
Chloroquine

of malaria

Chloroquine Sulphate

Prophylaxis of malaria

Chlorothiazide

Chlorotrianisene

Chlorphenoxamine

Hydrochloride

Chlorpromazine

Chlorpromazine

Embonate

Chlorpromazine Hydrochloride

Chlorpropamide

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

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

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

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

relief of heartburn,

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

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

heartburn by a single For a maximum period of

14 days

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

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

dose taken at night

Cimetidine Hydrochloride

Cinchocaine 3.0 per cent Non-

ophthalmic

use

Cinchocaine Equivalent

Nonophthalmic

Hydrochloride f 3.0 per oph cent of use

Cinchocaine

Cinchophen

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[<sup>F81</sup>Citalopram Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin

Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin

Phosphate

			ctions on the sale and sup	ply of
Column 1	prescription Column 2	only medicine Column 3	s Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Maximum quantity
Clioquinol		(1) External (other than treatment of mouth ulcers)		
	(2) 35mg	(2) Treatment of mouth ulcers	(2) 350mg (MDD)	
Clobetasol Propionate				
Clobetasone Butyrate	[F990.05 per cent]	[F99Cream 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)]		[F99Container or package containing not more than 15g of medicinal product]
Clofazimine				
Clofibrate				
Clomiphene Citrate				
Clomipramin	e			
Clomipramin Hydrochlorid				
Clomocyclin	e			

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Clomocycline

Sodium

Clonidine

Clonidine

Hydrochloride

Clopamide

Clopenthixol

Decanoate

Clopenthixol

Hydrochloride

Clorexolone

Clotrimazole

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

Cloxacillin Benzathine

Cloxacillin Sodium

Clozapine

Cocculus Indicus

Co-

dergocrine Mesylate

Colaspase

Colchicine

Colestipol Hydrochloride

Colfosceril Palmitate

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

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

Colistin

Sulphate

Colistin

Sulphomethate

Colistin

Sulphomethate

Sodium

Coniine

Conium

7.0 per cent External

form

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

Status: Point in time view as at 01/05/2004.

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

Cytarabine

Cytarabine

Hydrochloride

Dacarbazine

Dalteparin

Sodium

Danazol

Danthron

Dantrolene

Sodium

Dapsone

Dapsone

Ethane

Ortho

Sulphonate

Daunorubicin

Hydrochloride

Deanol Bitartrate

Debrisoquine

Sulphate

Demecarium

Bromide

Demeclocycline

Demeclocycline

Calcium

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone

Pivalate

Deptropine

Citrate

26mg (MDD)

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form Dequalinium (1) 0.25mg (1) Internal: Chloride throat lozenges or throat pastilles (2) 1.0 per (2) External: paint cent

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Dexamethasone

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

Dexamethasone

Sodium

Phosphate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 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 Diethylammorent External

For local

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

in localised forms of

For maximum period of 7 days

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

	•	from the restri only medicine	ctions on the sale and supp	ply of
-	prescription Column 2	oniy meaicine Column 3	s Column 4	Column 5
Substance I	Maximum strength	Route of administration use or pharmaceutiform soft tissue	Treatment limitations on,	Maximum quantity
		rheumatism		
		For use in adults and children not less than 12 years		
Diclofenac Potassium				
Diclofenac Sodium				
Dicyclomine			10mg (MD)	
Hydrochloride			60mg (MDD)	
[ <sup>F80</sup> Didanosine]				
Dienoestrol				
Diethanolamine Fusidate	e			
Diflucortolone Valerate				
Diflunisal				
Digitalin				
Digitalis Leaf				
Digitalis Prepared				
Digitoxin				
Digoxin				
Dihydralazine Sulphate				
Dihydroergotar Mesylate	mine			
Dihydrostrepto	mycin			
Dihydrostrepto Sulphate	mycin			

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Diloxanide Furoate Diltiazem Hydrochloride Dimercaprol Dimethisoquin Non-Hydrochloride ophthalmic use Dimethisterone Dimethothiazine Mesylate Dimethyl Sulphoxide Dimethyltubocurarine Bromide Dimethyltubocurarine Chloride Dimethyltubocurarine Iodide Dinoprost Dinoprost Trometamol Dinoprostone [F83Diphenhydramine Hydrochloridepreparations except liquid-filled capsules] [F100 Diphenoxy late 2.5 mg]  $I^{F100}$ In  $\text{[}^{\text{F100}}\text{25 mg (MDD)}\text{]}$ [F100]Container Hydrochloride] combination or package with containing

not more

than 20

tablets]

Atropine

Sulphate for

short term

use as an adjunctive therapy to

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceute form		Column 5 Maximum quantity		
		appropriate rehydration in acute diarrhoea				
		For use in persons aged 16 years and over				
		Tablets]		_		
Dipivefrin Hydrochlorid	le					
Dipyridamol	e					
Disodium Etidronate						
Disodium Pamidronate						
Disopyramid	e					
Disopyramid Phosphate	e					
Distigmine Bromide						
Disulfiram						
Dithranol	1.0 per cent					
Dobutamine Hydrochlorid	le					
[ <sup>F100</sup> Dolasetro Mesilate]	on					
Domperidone	e	[F101] For the relief of post- prandial symptoms of excessive fullness, nausea, epigastric	[F10110mg of Domperidone (MD)] [F10140mg of Domperidone (MDD)]	or package		

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

			ctions on the sale and sup	ply of
Column 1	prescription Column 2	only medicine Column 3	s Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutiform	Treatment limitations on,	Maximum quantity
		bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]		
Domperidone Maleate		[F102] For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,]	[F103] 10 mg of Domperidone as Domperidone Maleate (MD)] [F103] 40 mg of Domperidone as Domperidone Maleate (MDD)]	[F102 Container or package containing not more than [F104200mg] of Domperidone as Domperidone Maleate;]
[ <sup>F84</sup> Donepezil Hydrochloride	e]			
Dopamine Hydrochloride	e			
Dopexamine Hydrochloride	e			
[ <sup>F81</sup> Dorzolami Hydrochloride				
Dothiepin				
Dothiepin Hydrochloridd	e			
Doxapram Hydrochloridd	e			

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

Doxazosin

Mesylate

Doxepin

Hydrochloride

Doxorubicin

Doxorubicin

Hydrochloride

Doxycycline

Doxycycline

Calcium Chelate

Doxycycline

Hydrochloride

Droperidol

Dydrogesterone

Dyflos

Econazole

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

Econazole Nitrate

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

Ecothiopate Iodide

Edrophonium Chloride

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

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

Eflornithine Hydrochloride

[<sup>F80</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

	•		ictions on the sale and supply	y of
Column 1 Substance	Prescription Column 2 Maximum strength	only medicine Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Ephedrine Hydrochlorio	de	(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD) Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Ephedrine Sulphate		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD)	
			Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops		
		(3) External		
Epicillin				
Epirubicin				
Epirubicin Hydrochloric	le			
Epithiazide				
Epoetin Alfa				
Epoetin Beta				
Epoprosteno Sodium	1			
Ergometrine Maleate				

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical form

Ergometrine

Tartrate

Ergot,

Prepared

Ergotamine

Tartrate

Erythromycin

Erythromycin

Estolate

Erythromycin

Ethylcarbonate

Erythromycin

Ethyl

Succinate

Erythromycin

Lactobionate

Erythromycin

Phosphate

Erythromycin

Stearate

Erythromycin

Thiocyanate

Esmolol

Hydrochloride

Estramustine

Phosphate

[F105 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 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

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

[F81 Exemestane]

Famciclovir

Famotidine

For the

10mg (MD)

short-term symptomatic

20mg (MDD)

relief of heartburn,

For maximum period of

rtburn, 14 days

dyspepsia, indigestion,

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

	Exemptions from the restrictions on the sale and supply of						
Column 1	prescription only medicines  Column 2 Column 3 Column 4 Column 5						
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Maximum quantity			
Fazadinium Bromide		acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms					
Felbinac	3.17 per cent	External  [F107] 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	For maximum period of 7 days	Container or package containing not more than [F10650g] of medicinal product			
		adults and children not less than 12 years					
Felodipine							
Felodipine Felypressin							
-							

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 [F99External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)]

Feprazone

Ferrous Arsenate

[F81Ferumoxsil]

[F84Fexofenadine Hydrochloride]

Filgrastim

Finasteride

Flavoxate

Hydrochloride

Flecainide

Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone

Acetonide

Flucloxacillin Magnesium

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

		Exemptions from the restrictions on the sale and supply of					
Column 1	prescription Column 2	n only medicine Column 3	es Column 4	Column 5			
			Treatment limitations ion,	Maximum quantity			
Flucloxacilli Sodium	n						
Fluconazole		For oral administration for the treatment of vaginal candidiasis [F108] 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			
		[F109] For use in persons aged 18	[F110For a maximum period of 3 months]				

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Substance	Column 2 Maximum strength	Column 3 Route of administrat use or pharmaceur form years and		Column 5 Maximum quantity			
		over]					
		In the form of a non- pressurised nasal spray					
		F111	F111	F111			
			F111				
		F111					
		F111					
Fluocinolone Acetonide							
Fluocinonide							
Fluocortin Butyl							
Fluocortolone							
Fluocortolone Hexanoate							
Fluocortolone Pivalate							
Fluorescein Dilaurate							
Fluorometholo	ne						
Fluorouracil							
Fluorouracil Trometamol							
Fluoxetine Hydrochloride							
Flupenthixol Decanoate							

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

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

Flupenthixol Hydrochloride

Fluperolone

Acetate

Fluphenazine

Decanoate

Fluphenazine

Enanthate

Fluphenazine

Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen [F1128.75 [F113Throat [F11443.75 mg (MDD)] mg] lozenges]

[FII5Container or package containing not more than 140 mg of Flurbiprofen]

Flurbiprofen

Sodium

Fluspirilene

Flutamide

Fluticasone

Propionate

[F84Flutrimazole]

Fluvastatin

Sodium

Fluvoxamine

Maleate

Folic Acic 500mcg (MDD)

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

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

Formocortal

Foscarnet

Sodium

Fosfestrol

Sodium

Fosfomycin

Trometamol

Fosinopril

Sodium

Framycetin

Sulphate

Frusemide

Furazolidone

Fusafungine

Fusidic

Acid

Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

Ganciclovir

Sodium

Gelsemine 0.1 per cent

Gelsemium 25mg (MD)

77 (17)

75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin

Sulphate

Gestodene

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

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

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Glucagon

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

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride

Griseofulvin

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

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

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

Halofantrine Hydrochloride

Haloperidol

Haloperidol Decanoate

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 (c)

cent

preparations

other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

Hexobarbitone

Sodium

Hexoestrol

Hexoestrol Dipropionate

L-Histidine Dietary

Hydrochloride supplementation

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

0.45mg (MDD)

(2) External (except ophthalmic)

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

		from the restrictions on the sale and su only medicines	pply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form	Column 5 Maximum quantity
Homatropine		0.2mg (MD)	
Hydrobromic	de	0.6mg (MDD)	
Homatropine		2mg (MD)	
Methylbrom	ide	6mg (MDD)	
Hydralazine Hydrochlorio	de		
Hydrargaphe	en	Local application to skin	
Hydrobromio Acid	С		
Hydrochloro	thiazide		
Hydrocortiso	one [F116(1)0.5 per cent]	[F116(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]	(Fon(a))ner or package containing not more than 15g of medicinal product]
	[F117(2)].0 per cent	[F117(2)] External  (a) For  use either alone	(Fon(2))her or package containing not more than 15g

(cream

ointment) or

30ml (spray)

or

### Status: Point in time view as at 01/05/2004.

Changes to 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
-	Maximum strength	Route of Treatment limitations administration, use or pharmaceutical		Maximum quantity
	form or in			of medicinal
		conjun	ction	product

conjunction with Crotamiton in irritant dermatitis, contact allergic dermatitis, insect

bite reactions, mild moderate eczema, and either in combination with Clotrimazole [F118 or Miconazole

Nitrate]

athlete's

foot and

for

candidal

intertrigo

or in

combination

with

lignocaine

for anal

and

perianal

itch

associated

with

haemorrhoids

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

			ctions on the sale and sup	ply of
Column 1		only medicine		Column 5
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
Hydrocortisc	onEquivalent to 1.0 per cent Hydrocortisc	(b) For use in adults and children not less than 10 years (c) Cream ointmen or spray  External  For use	nt le,	Container or package containing not more than 15g of medicinal product In the case of suppositories, container or package containing no more than 12

Status: Point in time view as at 01/05/2004.

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

			ctions on the sale and supp	ply of
Column 1	prescription Column 2	only medicines Column 3	S Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	Maximum quantity
		[F119 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		
Hydrocortiso Butyrate	one			
Hydrocortiso Caprylate	ne			
Hydrocortiso Hydrogen Succinate	ne			
Hydrocortiso Sodium Phosphate	ne			
Hydrocortiso Sodium Succinate	nEquivalent to 2.5mg Hydrocortison	For ne aphthous ulceration of the mouth for adults and children not less than 12 years		Container or package containing not more than equivalent to 50mg of Hydrocortisone
		In the form of pellets		

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

		from the restri	ctions on the sale and suppers	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form		Column 5 Maximum quantity
[ <sup>F83</sup> Hydrocya Acid]	anic			
Hydroflume	thiazide			
Hydroxychlo Sulphate	oroquine	Prophylaxis of malaria		
Hydroxypro	gesterone			
Hydroxyprog Enanthate	gesterone			
Hydroxyprog Hexanoate	gesterone			
Hydroxyurea	a			
Hydroxyzine Embonate	2			
Hydroxyzine Hydrochlorie		(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	73mg (MDD)	(a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride
		(b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis,	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride

Status: Point in time view as at 01/05/2004.

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

	prescription	from the restri	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti form in children not less than 6 years but		Column 5 Maximum quantity
		less than 12 years		
Hyoscine	(1) 0.15 per cent	(1) Internal		
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Butylbromid	Butylbromide			
		(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 supplyes	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		than by inhaler		
		(2) External		
Hyoscine		(1) Internal		
Methonitrate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscyamine	;	(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 1mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Hydrobromid	e	(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine Sulphate	;	(1) Internal		
Sulphate		(a) by inhaler		
		(b) otherwise than by inhaler (2) External	(b) Equivalent of 300mcg of Hyoscyamine (MD) Equivalent of 1mg of Hyoscyamine (MDD)	

Status: Point in time view as at 01/05/2004.

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

		from the restri only medicine	ctions on the sale and suppl es	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceute form	Column 4 Treatment limitations on,	Column 5 Maximum quantity
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		
	[ <sup>F120</sup> (3) 10.0 per cent]	[F120(3) External]	[F120(3) 125 mg (MD) 500 mg (MDD)]	[F120(3) Container or package containing not more than [F12150g] of medicinal product]
[ <sup>F83</sup> Ibuprofen Lysine		Rheumatic and muscular pain, pain of non-serious arthritic	(a) in the case of a prolonged release preparation 600 mg (MD) 1,200 mg (MDD)	

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

	•	from the restri	ctions on the sale and supp	ly of
Column 1 Substance	Column 2 Maximum strength		•	Column 5 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>F80</sup>Imidapril Hydrochloride]

Imipenem Hydrochloride

Imipramine

Imipramine Hydrochloride

Imipramine

Ion

Exchange

Resin

**Bound Salt** 

or Complex

[F95Indapamide]

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 Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Indomethacin

Sodium

Indoprofen

Indoramin

Hydrochloride

Inosine

Pranobex

[F122Insulin]

Iodamide

Iodamide

Meglumine

Iodamide

Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic

Acid

Ipratropium

Bromide

Iprindole

Hydrochloride

Iproniazid

Phosphate

[F84Irbesartan]

Isoaminile

Isoaminile

Citrate

Isocarboxazid

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

	•	from the restri	ictions on the sale and suppl es	ly of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceuti	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
Isoconazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Isoetharine				
Isoetharine Hydrochlorid	e			
Isoetharine Mesylate				
Isoniazid				
Isoprenaline Hydrochlorid	e			
Isoprenaline Sulphate				
Isopropamide Iodide			Equivalent of 2.5mg of Isopropamide ion (MD)	
			Equivalent of 5.0mg of Isopropamide ion (MDD)	
Isotretinoin				
Isradipine				
Itraconazole				
Jaborandi		External		
Kanamycin Acid Sulphate				
Kanamycin Sulphate				
Ketamine Hydrochlorid	e			

Status: Point in time view as at 01/05/2004.

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

	prescription	only medicine	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
Ketoconazole	2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	xtern(a)] Maximum frequency of application of once every 3 days	[F123(a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole
		[F125(b) For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo]		
Ketoprofen	2.5 per cent	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 Hydrocholori	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 [F95Lansoprazole] Latamoxef Disodium [F95]Lercanidipine Hydrochloride] Levallorphan Tartrate Levobunolol Hydrochloride [F83Levocabast 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 [F126 Levocarnitine] [F126For 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 Colum Substance Maxim

Column 2 Column 2 Rou strength adm

Column 3 Column 4
Route of Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Levodopa

[F84Levofloxacin]

Levonorgestre [F127] 0.75mg [F127] 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 Sulphate Lithium (MD)

Equivalent of 15mg of

Lithium (MDD)

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

90

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

		from the restri	ctions on the sale and supplys	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
		jorni	9mg (MDD)	
		(2) External		
Lobeline Hydrochlorid	le	(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lobeline Sulphate		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lodoxamide Trometamol	[F128] equivaler of 0.1 per cent Lodoxamide	treatment of ocular	3,	
Lofepramine				
Lofepramine Hydrochloric				
Lofexidine Hydrochlorid	le			
Lomefloxacii Hydrochloric				
Lomustine				
Loperamide Hydrochlorid	le	Treatment of acute diarrhoea		
Loratidine			10mg (MDD)	F130

. . .

### Status: Point in time view as at 01/05/2004.

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

[F96Lornoxicam]

[F96Losartan

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

		emptions from the restrictions on the sale and supply of escription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform	Column 4 Treatment limitations on,	Column 5 Maximum quantity		
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		[F131] (a) For the symptomatic relief of irritable bowel syndrome	[F131(a) 135 mg (MD) 405 mg (MDD)]			
		(b) For uses other than the symptomatic relief of irritable bowel syndrome]	[F131(b) 100 mg (MD) 300 mg (MDD)]			
Mebeverine Pamoate						
Mebhydrolin						
Mebhydrolin Napadisylate						
Mecamylamine Hydrochloride	;					
Mecillinam						
Meclofenoxate Hydrochloride						
Medigoxin						
Medrogestone						
Medroxyproge: Acetate	sterone					

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 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

[F95Meloxicam]

Melphalan

Melphalan Hydrochloride

Menotrophin

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic use

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

[F84Mercaptamine

Bitartrate]

Mercaptopurine

Mersalyl

Mersalyl

Acid

Mesalazine

Mesna

Mestranol

Metaraminol

Tartrate

Metergoline

Metformin

Hydrochloride

Methacycline

Methacycline

Calcium

Methacycline

Hydrochloride

Methallenoestril

Methicillin

Sodium

Methixene

Methixene

Hydrochloride

Methocarbamol

Methocidin

Throat lozenges and throat pastilles

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine

Hydrochloride

Methotrimeprazine

Maleate

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

Methsuximide

Methyclothiazide

Methyldopa

Methyldopate Hydrochloride

Methylephedrine Hydrochloride

30mg (MD) 60mg (MDD)

Methylprednisolone

Methylprednisolone

Acetate

Methylprednisolone

Sodium Succinate

Methylthiouracil

Methysergide

Maleate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

Metoprolol

Fumarate

Metoprolol Succinate

Metoprolol

Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

Mezlocillin

Sodium

Mianserin

Hydrochloride

Miconazole

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

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

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

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

Mifepristone

Miglitol

Milrinone

Milrinone

Lactate

Minocycline

Minocycline Hydrochloride

Minoxidil

[F132(1) 2.0 per cent]

[F132(1) External

[F132(2) 5.0 per cent

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

[F80Mirtazapine]

Misoprostol

Mitobronitol

Mitomycin

Mitozantrone

Hydrochloride

Mivacurium

Chloride

[F105 Mizolastine]

Moclobemide

[F84Modafinil]

[<sup>F81</sup>Moexipril Hydrochloride] Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

[F80 Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

Status: Point in time view as at 01/05/2004.

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

	Column 2 Maximum strength  (1) 0.05 per	conly medicines Column 3 Route of administration use or pharmaceution form (1) Nasal sprays or nasal	Column 4 Treatment limitations on,	Column 5 Maximum quantity
		(1) Nasal sprays		
Naphazoline (1) 0.05 per Hydrochloridæent		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>F84</sup> Naratriptar Hydrochlorid				
Natamycin				
[ <sup>F96</sup> Nebivolol Hydrochloride	e]			
Nedocromil Sodium	[F1332.0 per cent]	[F133]For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis	1	[F133]Container or package containing not more than 3 ml of medicinal product]
Nefazodone Hydrochloride	e			
Nefopam Hydrochlorid	e			
Neomycin				

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Neomycin

Oleate

Neomycin

Palmitate

Neomycin

Sulphate

Neomycin

Undecanoate

Neostigmine

Bromide

Neostigmine

Methylsulphate

Netilmicin

Sulphate

Nicardipine

Hydrochloride

Nicergoline

[F105Niceritrol]

Nicotinic Any use, 600mg (MDD)

Acid except

for the treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F83Nilutamide]

Nimodipine

Niridazole

[F96Nisoldipine]

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 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 Treatment limitations administration, use or pharmaceutical form		Maximum quantity	

75mg (MD)

[F135150mg (MDD)]

[F136For a maximum

period of 14 days]

Nitrofurazone

Nizatidine

For the prevention [F134] and treatment] of the symptoms of food-related heartburn [F134] and meal-induced indigestion]

For use in adults and children not less than 16 years

Nomifensine

Noradrenaline

Noradrenaline

Acid

Tartrate

Maleate

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 strength administration, quantity use or pharmaceutical form

Noscapine

Hydrochloride

Novobiocin

Calcium

Novobiocin

Sodium

Nux Vomica

Seed

Nystatin

[F1373.0 per cent]

[F137 External

For use in combination with

Hydrocortisone

of

maximum strength 0.5 per cent for intertrigo

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

Octacosactrin

Octreotide

Oestradiol

Oestradiol

Benzoate

Oestradiol

Cypionate

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

[F137]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 Column 3 Column 4
Route of Treatment
administration,

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

[F80Omeprazole

Magnesium]

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

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

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

Oxatomide

Oxedrine Tartrate

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

containing not more than 400mg of

Oxethazaine

Oxitropium Bromide

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Oxybuprocaine Non-Hydrochloride ophthalmic use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

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

Oxytetracycline Oxytetracycline Calcium

Oxytetracycline Dihydrate

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 Oxytetracycline Hydrochloride Oxytocin, natural Oxytocin, synthetic Pancreatin (1) 21,000(1) capsules European Pharmacopoeia units of lipase per capsule (2) 25,000(2) powder European Pharmacopoeia units of lipase per gram Pancuronium Bromide [F95Pantoprazole Sodium] (1) By Papaverine inhaler (2) 50mg (MD) (2) Otherwise 150mg (MDD) than by inhaler Papaverine (1) By Hydrochloride inhaler (2) (2) Equivalent of 50mg of Otherwise Papaverine (MD) than by Equivalent of 150mg of inhaler Papaverine (MDD) [F85Paracetamol (1) [F138250mg]) Non-(1) The effervescent quantity tablets and sold or capsules supplied in

	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	administratio	on,	quantity		
		use or				
		pharmaceuti	cal			
		form				
		[F139wholly		one		
		or mainly]		container or		
		for use		package		
		in children		shall not		
		aged less		exceed 32		
		than 12		The		
		years		quantity		
	(2) 500	-		of		
	(2) 500	( )		non-		
	mg	effervescent		effervescent		
		tablets and		tablets,		
		capsules		capsules		
		[F140wholly		or a		
		or mainly]		combination		
		for use in		of		
		adults and		both		
		children not		sold or		
		less than 12		supplied		
		years		to a		
				person		
				at any		
				one		
				time		
				shall		
				not		
				exceed		
				100		
		(2) 4.11		(2) T1		
		(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		
				1		

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

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

of
both
sold or
supplied
to a
person
at any
one
time
shall
not

exceed 100]

combination

Paraldehyde

Paramethadione

Paramethasone

Acetate

Parathyroid

Gland

Pargyline Hydrochloride

Paroxetine Hydrochloride

Pecilocin

Penamecillin

Penbutolol Sulphate

[F95Penciclovir]

Penicillamine

Penicillamine Hydrochloride

Pentamidine Isethionate

Penthienate 5mg (MD)Bromide 15mg (MDD) Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colum Substance Maxi

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pentolinium

Tartrate

Perfluamine

Pergolide

Mesylate

Perhexiline

Maleate

Pericyazine

Perindopril

Perindopril

Erbumine

Perphenazine

Phenacetin 0.1 per cent

Phenazone External

Phenazone Salicylate

Phenbutrazate

Hydrochloride

Phenelzine

Sulphate

Phenethicillin

Potassium

Phenformin

Hydrochloride

Phenglutarimide

Hydrochloride

Phenindione

[F141Phenolphthalein.]

Phenoxybenzamine

Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

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

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine Hydrochloride

Phentolamine Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine Hydrochloride Internal

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

except 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 Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Physostigmine Salicylate

Physostigmine Sulphate

[F83Phytomenadione

Any use except the prevention or

treatment of haemorrhagic disorders

Picrotoxin

Pilocarpine

Pilocarpine Hydrochloride

Pilocarpine Nitrate

Pimozide

Pindolol

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

Piperacillin Sodium Piperazine Oestrone Sulphate

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

Pipothiazine Palmitate Piracetam

Acetate
Pirbuterol
Hydrochloride

Pirbuterol

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 I<sup>F142</sup>Pirenzepine Dihydrochloride Monohydrate] Pirenzepine Hydrochloride Piretanide Piroxicam For maximum period of 7 0.5 per cent External 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 [F105Piroxicam Betacyclodextrin] **Pituitary** By inhaler Gland (Whole Dried) Pituitary By inhaler Powdered (Posterior Lobe)

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Pivampicillin

Pivampicillin Hydrochloride

Pivmecillinam

Pivmecillinam Hydrochloride

Pizotifen

Pizotifen Malate

Plicamycin

Podophyllotoxin

Podophyllum

Podophyllum

Indian

Podophyllum 20.0 per

Resin cent

External

Ointment or impregnated plaster

Poldine Methylsulphate 2mg (MD)

6mg (MDD)

Polidexide

Polyestradiol Phosphate

Polymyxin B Sulphate

Polythiazide

Poppy Capsule

Potassium 0.0127 per Arsenite cent

Potassium Bromide Potassium

Canrenoate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

[F84Pramipexole

Hydrochloride]

Pravastatin

Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone

Butylacetate

Prednisolone

Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum strength administration, quantity use or pharmaceutical form Prednisolone Steaglate Prednisone Prednisone Acetate Prenalterol Hydrochloride Prenylamine Lactate Prilocaine Non-Hydrochloride ophthalmic use Primidone Probenecid Probucol Procainamide Hydrochloride Procaine Non-Hydrochloride ophthalmic use Procaine Penicillin Procarbazine Hydrochloride Prochlorperazine Prochlorperazine Edisylate Prochlorperazine 3mg [F99Buccal [F9912mg (MDD)] [F99Container Maleate tablets or package for the containing treatment of not more nausea and than 8 vomiting tablets] in cases of previously diagnosed migraine

Status: Point in time view as at 01/05/2004.

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

		from the restriction only medicines	ctions on the sale and sup	ply of
Column 1	Column 2	i oniy meaicines Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration use or pharmaceutic form	Treatment limitations on,	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	;		15mg (MD)	
Bromide			45mg (MDD)	
[ <sup>F96</sup> Propiverin Hydrochlorid	ie e]			
Propofol				
Propranolol Hydrochlorid	e			
Propylthioura	cil			
Proquazone				
Protamine 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)

	•	from the restri	ctions on the sale and supply	vof
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
Prothionamic	de			
Protirelin				
Protriptyline Hydrochloric	le			
Proxymetaca Hydrochloric		Non- ophthalmic use		
Pseudoephed Hydrochloric		Internal	(a) In the case of a prolonged release preparation	
			120mg (MD)	
			240mg (MDD)	
			(b) in any other case 60mg (MD)	
			240mg (MDD)	
Pseudoephed	lrine		60mg (MD)	
Sulphate			180mg (MDD)	
Pyrantel Embonate		(a) For the treatment of enterobiosis, in adults and children not less than 12 years	(a) 750mg MDD (as a single dose)	(a) Container or package containing not more than 750mg of Pyrantel Embonate
		(b) For the treatment of enterobiosis, in children less than 12 years but not less than 6 years	(b) 500mg MDD (as a single dose)	(b) Container or package containing not more than 750mg of Pyrantel Embonate
		(c) For the treatment of enterobiosis in children less than 6	(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 restri	ctions on the sale and sup	ply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceute form		Column 5 Maximum quantity
		years but not less than 2 years		than 750mg of Pyrantel Embonate
Pyrantel Tartrate				
Pyrazinamid	e			
Pyridostigmi Bromide	ine			
Pyrimethami	ine			
[ <sup>F96</sup> Quetiapir Fumarate]	ne			
[ <sup>F81</sup> Quinagol Hydrochlorid				
Quinapril				
[ <sup>F142</sup> Quinapri Hydrochlorid				
Quinestradol	l			
Quinestrol				
Quinethazon	e			
Quinidine				
Quinidine Bisulphate				
Quinidine Polygalactur	onate			
Quinidine Sulphate				

100mg (MD) Quinine

300mg (MDD)

Quinine Equivalent of 100mg of Quinine (MD)

Bisulphate

Equivalent of 300mg of

Quinine (MDD)

Equivalent of 100mg of Quinine

Cinchophen Quinine (MD)

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

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

Status: Point in time view as at 01/05/2004.

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

	prescription	only medicine		-
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform		Column 5 Maximum quantity
			Equivalent of 300mg of Quinine (MDD)	
Quinine Tannate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine in combination with Urea Hydrochloride	<del>)</del>			
Ramipril				
[F80]Ranitidine Bismuth Citrate]				
Ranitidine Hydrochloride		For the short term symptomatic relief of heartburn, dyspepsia,	Equivalent to 75mg of Ranitidine (MD)  Equivalent to 300mg of Ranitidine (MDD)  For a maximum period of	
		indigestion, acid indigestion and hyperacidity [F143 or the prevention of these symptoms when associated with consuming food and drink]	14 days	
Rauwolfia Serpentina				
Rauwolfia Vomitoria				

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

Column 5 Maximum quantity

use or

pharmaceutical

form

Razoxane

[F84Reboxetine

Mesilate]

Remoxipride

Hydrochloride

Reproterol

Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

[F80Rimexolone]

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

[F100]Ropinirole

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

Column 2 Maximum strength

Column 3 Column 4 Route of

Treatment limitations administration,

Column 5 Maximum quantity

use or

pharmaceutical

form

Salmeterol

Substance

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F84Sertindole]

[F80]Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F80Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

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

	prescription	ns from the restrictions on the sale and supply of on only medicines			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administratio use or pharmaceutic form		Column 5 Maximum quantity	
Sodium Arsenite	0.013 per cent				
Sodium Bromide					
Sodium Clodronate					
Sodium Cromoglyca	te	(a) For nasal admistration			
	(b) 2.0 per cent	(b) For the treatment of acute seasonal allergic conjunctivitis [F144 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			

Status: Point in time view as at 01/05/2004.

Changes to 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	• •	only medicine	S		
Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutiform of dental	Column 4 Treatment limitations on,	Column 5 Maximum quantity	
		caries			
		In the form of			
		(a) tablets or drops	(a) 2.2 mg (MDD)		
	(b) 0.2 per cent	(b) mouth rinses other than those for daily use			
	(c) 0.05 per cent	(c) mouth rinses for daily use			
Sodium Fusidate					
Sodium Metrizoate					
Sodium Monofluorop	1.14 per ohæepthate	Dentrifrice			
Sodium Oxidronate					
Sodium Stiboglucona	nte				
Sodium Valproate					
Somatorelin Acetate					
Sotalol Hydrochloric	de				
<sup>F81</sup> Sparfloxa	cin]				
Spectinomyc	ein				
Spectinomyc Hydrochlorio					
Spiramycin					
Spiramycin Adipate					

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

		from the restr n 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 pharmaceut form		Maximum quantity	
Spironolacto	one				
Stannous Fluoride	([ <sup>F145</sup> 1]) 0.62 per cent	([ <sup>F145</sup> 1]) Dentifrice			

[<sup>F145</sup>(2) 0.4 per]

[F145(2) Dental gels for use in the prevention and treatment of dental caries and decalcification of the teeth]

External

Stilboestrol

Stilboestrol Dipropionate

Streptodornase External

Streptokinase Streptomycin

Streptomycin Sulphate

Strychnine

Strychnine Arsenate

Strychnine Hydrochloride

[F83Strychnine Nitrate]

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Sulbenicillin

Sulbenicillin

Sodium

Sulconazole Nitrate

External (except vaginal)

[F83Sulfabenzamide]

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

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

Suxethonium

Bromide

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

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

[<sup>F96</sup>Tacalcitol Monohydrate]

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin Napsylate

Tamoxifen

Tamoxifen

Citrate

[F95Tamsulosin Hydrochloride]

[F80Tazarotene]

Tazobactam Sodium

Teicoplanin

[F84Temocapril Hydrochloride]

Temocillin Sodium

Tenoxicam

Terazosin Hydrochloride

Terbinafine [F146] 1.0 per cent] use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel]

[F148] Container or package containing not more than 30 grams 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)

		from the restr	ictions on the sale and sup	pply of
Column 1 Substance	Prescription Column 2 Maximum strength	Column 3 Route of administratiuse or pharmaceut	Column 4 Treatment limitations ion,	Column 5 Maximum quantity
[ <sup>F149</sup> Terbinafi Hydrochlorid		([F150]]) [F151] Preparat other than spray solutions, for [F149] exter use for the treatment of tinea pedis and tinea cruris]	nal	([F150]]) [F149]Container or package containing not more than 15 g of medicinal product.]
		[F152(2) Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis]		[F152(2) Container containing not more than 30ml of medicinal product]
Terbutaline				
Terbutaline Sulphate				
Terfenadine			F153	F153
Terlipressin				
Terodiline Hydrochloric	le			
[ <sup>F84</sup> Testostero	one]			
Tetrabenazin				
Tetracosactri				
Tetracosactri Acetate	n			
Tetracycline				

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Tetracycline Hydrochloride

Tetracycline

Phosphate Complex

Tetroxoprim

Thallium

Acetate

Thallous

Chloride

Thiabendazole

Thiambutosine

Thiethylperazine

Malate

Thiethylperazine

Maleate

Thiocarlide

Thioguanine

Thiopentone

Sodium

Thiopropazate Hydrochloride

Thioproperazine

Mesylate

Thioridazine

Thioridazine

Hydrochloride

Thiosinamine

Thiotepa

Thiothixene

Thiouracil

Thymoxamine

Hydrochloride

Thyroid

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

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

Thyrotrophin

Thyroxine

Sodium

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

Sodium

[F95Ticlopidine

Hydrochloride]

Tigloidine

Hydrobromide

[F95Tiludronate

Disodium]

Timolol

Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except vaginal)

(2) Vaginal

for treatment of vaginal candidiasis

[<sup>F81</sup>Tizanidine Hydrochloride]

Tobramycin

Tobramycin Sulphate

Tocainide

Hydrochloride

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

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

Tofenacin Hydrochloride

Tolazamide

Tolazoline

External

Hydrochloride

Tolbutamide

Tolbutamide Sodium

Tolfenamic Acid

Tolmetin Sodium

[F80Topiramate]

[F105 Torasemide]

[F95Toremifene]

Tramadol Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolonq<sup>F154</sup>(1)] 0.1 Acetonide per cent [F154(1)] For the treatment of common mouth ulcers

[F154(1)] Container or package containing not more than 5g of

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

		from the restri	ctions on the sale and suppl	y of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administrati use or pharmaceut	Column 4 Treatment limitations on,	Column 5 Maximum quantity
				medicinal product
		[F155(2) In the form of a non-pressurised nasal spray, for the treatment of symptoms of seasonal allergic rhinitis in persons aged 18 years and over]	[F155(2) 110mcg per nostril (MD) 110mcg per nostril (MDD) For a maximum period of 3 months]	[F155]Container or package containing not more than 3.575mg of Triamcinolone Acetonide]
Triamcinolone Diacetate	<b>;</b>	•		
Triamcinolone Hexacetonide	2			
Гriamterene				
Γribavirin				
Triclofos Sodium				
Trientine Dihydrochlori	de			
Trifluoperazin	e			
Trifluoperazin Hydrochloride				
Trifluperidol				
Trifluperidol Hydrochloride	<b>;</b>			
Γrilostane				
Trimeprazine				
Trimeprazine Tartrate				

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

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

Trimetaphan Camsylate

Trimetazidine

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

(1) Oral Tryptophan

Dietary

supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

Tulobuterol Hydrochloride

Tyrothricin Throat

> lozenges or throat pastilles

Uramustine

Urea Stibamine Urethane

Uridine 5'triphosphate

Urofollitrophin

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Urokinase

Ursodeoxychoic

Acid

Vaccine:

Bacillus

Salmonella

Typhi

Vaccine:

Poliomyelitis

(Oral)

[F81 Valaciclovir Hydrochloride]

Valproic

Acid

[F84Valsartan]

Vancomycin

Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

[F81 Venlafaxine Hydrochloride]

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

Veratrum,

White

Vidarabine

Vigabatrin

Viloxazine

Hydrochloride

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form Vinblastine Sulphate Vincristine Sulphate Vindesine Sulphate Viomycin Pantothenate Viomycin Sulphate Vitamin A (1) Internal (1) 7,500iu (2,250mcg Retinol equivalent) (MDD) (2) External Vitamin A (1) Equivalent to 7,500iu (1) Internal Vitamin A (2,250mcg Acetate Retinol equivalent) (MDD) (2) External Vitamin A (1) Internal (1) Equivalent to 7,500iu Palmitate Vitamin A (2,250mcg Retinol equivalent) (MDD) (2) External Warfarin Warfarin Sodium Xamoterol Fumarate Xipamide Yohimbine Hydrochloride [F81Zalcitabine] Zidovudine

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength

Column 3 Column 4 Route of Treatment limitations administration,

Column 5 Maximum quantity

use or pharmaceutical

form

Zimeldine

Hydrochloride

Zolpidem

Tartrate

Zomepirac

Sodium

Zopiclone

Zuclopenthixol

Acetate

Zuclopenthixol

Decanoate

Zuclopenthixol

Hydrochloride]

#### **Textual Amendments**

- F80 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)
- F81 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)
- F82 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)
- Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment F83 (No. 3) Order 1998 (S.I. 1998/2081), art. 1(1), Sch.
- F84 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)
- F85 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
- F86 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)**
- Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment F87 (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(a)
- 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)**
- F89 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)
- 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)
- Words in Sch. 1 substituted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(a)

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

- Word in Sch. 1 substituted (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), **2(b)**
- F93 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)
- F94 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)
- F95 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)
- **F96** 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)
- F97 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)
- F98 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)
- F99 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)
- F100 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)
- F101 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)
- **F102** 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)**
- **F103** 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)**
- F104 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)
- F105 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)
- F106 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)
- **F107** 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)**
- F108 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)
- **F109** 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)**
- **F110** 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)**
- F111 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)
- **F112** 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)**
- **F113** 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)**
- F114 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)
- **F115** 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)**
- F116 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)
- F117 Sch. 1: entries renumbered (22.4.1999) by The Prescription Only Medicines (Human Use) Amendment Order 1999 (S.I. 1999/1044), arts. 1(1), 2(c)

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

- F118 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)
- F119 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)
- F120 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)
- **F121** 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)
- F122 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)
- F123 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)
- **F124** 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)**
- F125 Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(g)(iii)
- **F126** 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)**
- F127 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
- **F128** 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)
- **F129** 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)
- **F130** 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)
- F131 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)
- **F132** 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)**
- F133 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)
- **F134** Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(i)**
- F135 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)
- F136 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)
- F137 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)
- **F138** 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)
- **F139** 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)
- **F140** 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)
- **F141** 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)**
- **F142** 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)**
- **F143** Words in Sch. 1 added (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, 3(c)

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

- F144 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)
- F145 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)
- F146 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)
- F147 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)
- F148 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)
- **F149** 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)**
- F150 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)
- F151 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)
- F152 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)
- F153 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)
- F154 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)
- F155 Sch. 1 entries inserted (16.11.2000) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000 (S.I. 2000/2899), arts. 1(1), 4(g)

### SCHEDULE 2

Articles 6(1) and 10

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

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

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

#### SCHEDULE 3

Article 2(b)

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

[F156Co-danthramer Capsules NPF]

[F156Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F156Co-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

[F157Water for Injections]

#### **Textual Amendments**

F156 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

F157 Words in Sch. 3 inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 14

## [F158SCHEDULE 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**

F158 Sch. 3A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 9

(3.1. 2002/347), arts. 1(1), 7	
Column 1 Substance	Column 2 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
[F159]Amitriptyline hydrochloride	Oral]
Amorolfine hydrochloride	External use
Amoxycillin trihydrate	Oral
Aspirin	Oral
Azelaic acid	External use
Azelastine hydrochloride	Ophthalmic use or nasal
[F159Azithromycin dihydrate	Oral]

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

[F159] CarbamazepineOral or rectal]CarbarylExternal useCarbenoxolone sodiumMouthwash

Cetirizine hydrochloride Oral

Chloramphenicol Ophthalmic use

Cimetidine Oral

Cinchocaine hydrochloride External use

Ethinylestradiol

## Status: Point in time view as at 01/05/2004.

Changes to 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
[F159Clavulanic acid	Oral]
Clindamycin phosphate	External use
Clobetasone butyrate	External use
Clotrimazole	External use
[F160]Codeine Phosphate	Oral]
[F159Conjugated oestrogens (equine)	External use]
[F160]Co-Phenotrope	Oral]
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
[ <sup>F160</sup> Diazepam	Oral, parenteral or rectal administration in palliative care]
Diclofenac diethylammonium	External use
[F159Diclofenac potassium	Oral]
[F159Diclofenac sodium	Oral or rectal]
[F160]Dihydrocodeine Tartrate	Oral]
Domperidone	Oral or rectal administration in palliative care
Domperidone maleate	Oral administration in palliative care
Doxycycline [F161 hyclate]	Oral
[F162]Doxycycline monohydrate	Oral]
Econazole nitrate	External use
[F162Emedastine	Ophthalmic use]
Erythromycin	External use [ <sup>F163</sup> or oral]
[F159 Erythromycin ethyl succinate	Oral]
[F159 Erythromycin stearate	Oral]
[F159Estradiol	External use]
[F159Estriol	External use]

Oral

Status: Point in time view as at 01/05/2004.

Changes to 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 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
[F159Etonogestrel	Implant]
Etynodiol diacetate (ethynodiol diacetate)	Oral
Famotidine	Oral
Felbinac	External use
Fenticonazole nitrate	External use
Fexofenadine hydrochloride	Oral
[F162Flucloxacillin magnesium	Oral]
Flucloxacillin sodium	Oral
Fluconazole	Oral
Fludroxycortide (Flurandrenolone)	External use
[ <sup>F159</sup> Flumazenil	Parenteral]
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	[F164External Use]
[F159Gabapentin	Oral]
Gentamicin sulphate	Aural
Gestodene	Oral
[F159Glucagon hydrochloride	Parenteral]
[F159Glucose	Parenteral]
Hydrocortisone	External use
Hydrocortisone acetate	External use
Hydrocortisone butyrate	External use
Hydrocortisone sodium succinate	Lozenges
Hyoscine butylbromide	Parenteral [F165] or transdermal] administration in palliative care
Hyoscine hydrobromide	[F166 Oral or parenteral administration in palliative care]

Changes to 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

Ibuprofen External use or oral

Ibuprofen lysineOral[F159]Imipramine hydrochlorideOral]Ipratropium bromideNasal

Isotretinoin External use
Ketoconazole External use
Ketoprofen External 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

[F159]Lignocaine hydrochloride External use or parenteral]

Lithium succinate External use

Lodoxamide trometamol Ophthalmic use

Loratadine Oral

Oral

I<sup>F160</sup>Lorazepam Oral or parenteral administration in palliative

care

[F159]Lymecycline Oral]
Mebendazole Oral

Medroxyprogesterone acetate Parenteral
Mestranol Oral

Metoclopramide hydrochloride Oral or parenteral administration in palliative

care

Metronidazole [F167 External use, oral or rectal]

Metronidazole benzoate Oral

Miconazole Dental lacquer
Miconazole nitrate External use

[F160] Midazolam Parenteral administration in palliative care]

Minocycline Oral

[F162]Mizolastine Oral

[F162]Minocycline hydrochloride 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
Mometasone furoate	External use or nasal
Nedocromil sodium	Ophthalmic use
Nefopam hydrochloride	Oral
Neomycin sulphate	Aural
Neomycin undecenoate	Aural
Nitrofurantoin	Oral
Nizatidine	Oral
Norethisterone 9	Oral
Norethisterone acetate	Oral
Norethisterone enanthate	Parenteral
Norgestimate	Oral
Norgestrel	Oral
F159Nortriptyline hydrochloride	Oral]
Vystatin	External use
Oxytetracycline dihydrate	Oral
Paracetamol	Oral
Penciclovir	External use
Piroxicam	External use
F159Prednisolone	Oral]
Prednisolone hexanoate	External use
Prednisolone sodium phosphate	Aural [ <sup>F168</sup> or oral]
Ranitidine hydrochloride	Oral
<sup>F159</sup> Salbutamol sulphate	Inhalation]
Silver sulphadiazine	External use
Sodium cromoglycate	Ophthalmic use
F159 Sodium fusidate	External use]
Streptodornase	External use
Streptokinase	External use
Sulconazole nitrate	External use
Terbinafine hydrochloride	External use
F159Terbutaline sulphate	Inhalation]

External use or oral

Tetracycline hydrochloride

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

Column 1 Substance	Column 2 Requirements as to use, route of administration, or pharmaceutical form
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
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
F169	F169
Vaccine, Poliomyelitis, Live (Oral)	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
Vaccine, Rubella, Live	Parenteral
Vaccine, Tetanus, Adsorbed	Parenteral
Vaccine, Typhoid, Live Attenuated (Oral)	Oral
Vaccine, Typhoid, Polysaccharide	Parenteral
[F162Water for Injections	Parenteral]]

#### **Textual Amendments**

- F159 Sch. 3A entries inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(g)
- F160 Words in Sch. 3A inserted (10.12.2003) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2003 (S.I. 2003/2915), arts. 1(1), 3
- **F161** Words in Sch. 3A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), **15(a)**
- F162 Words in Sch. 3A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 15(c)
- F163 Words in Sch. 3A inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(a)
- F164 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(b)
- F165 Words in Sch. 3A inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(c)
- F166 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(d)
- F167 Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 3(e)
- **F168** Words in Sch. 3A substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), **3(f)**
- **F169** Words in Sch. 3A omitted (4.4.2003) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 15(b)

# [F170]SCHEDULE 3B

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

#### PARTICULARS FOR CLINICAL MANAGEMENT PLANS

#### **Textual Amendments**

F170 Sch. 3B inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 16

A clinical management plan shall contain the following particulars—

- (a) the name of the patient to whom the plan relates;
- (b) the illnesses or conditions which may be treated by the supplementary prescriber;

Document Generated: 2024-07-20

Status: Point in time view as at 01/05/2004.

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

- (c) the date on which the plan is to take effect and when it is to be reviewed by the doctor or dentist who is a party to the plan;
- (d) reference to the class or description of medicinal product which may be prescribed or administered under the plan;
- (e) any restrictions or limitations as to the strength or dose of any product which may be prescribed or administered under the plan, and any period of administration or use of any medicinal product which may be prescribed or administered under the plan;
- (f) relevant warnings about the known sensitivities of the patient to, or known difficulties of the patient with, particular medicinal products;
- (g) the arrangements for notification of—
  - (i) suspected or known adverse reactions to any medicinal product which may be prescribed or administered under the plan, and
  - (ii) suspected or known adverse reactions to any other medicinal product taken at the same time as any medicinal product prescribed or administered under the plan; and
- (h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.]

#### SCHEDULE 4

Article 8(4)(c)

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

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone Sodium

Hydrobromic Acid

Meclofenoxate Hydrochloride

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

# SCHEDULE 5

Article 11(1)(a)

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

# PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

	lumn 3			
Coi	Conditions			
1.	The: be- (a)	subjection of the concept of definition of the spectimes (i)  (iii)  (iii)  (iii)	ect to the entation of rder signed he principal he institution herned with eation or earch or the opriate head epartment harge of a lified course of earch stating—the name of the institution for which the prescription only medicine is required, the purpose for which the prescription only medicine is required, and the total quantity required, and the purposes he education esearch which the tution is remed.	
	1.	be— (a)	be— (a) subjection pressure an original pressure and o	

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

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

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

prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(18), the National Health Service (Scotland) Act 1978(19) and the Health and Personal Social

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

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

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

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

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

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

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

#### Status: Point in time view as at 01/05/2004. Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

Column I Persons exempted	Pre to v	umn 2 scription only medicines which the exemption vlies	Column 3 Condition	S
Services (Northern Ireland)				medicine required,
Order 1972( <b>20</b> ), or under any			4.5	and
subordinate legislation made			(b)	for the purposes of
under those Acts or that Order.				a scheme referred
				to in column 1 in
				this paragraph.
4. Registered midwives.	4.	Prescription only medicines containing	be only in	or supply shall the course of their
		any of the following	profession	al practice and in the

- substances-

Chloral hydrate Ergometrine maleate Pentazocine hydrochloride [F171Phytomenadione] Triclofos sodium.

professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.

- 5. Persons lawfully conducting 5. a retail pharmacy business within the meaning of section 69.
- Prescription only medicines which are not for parenteral administration and which-
- (a) are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol,
- (b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol,
- are prescription only medicines by reason only that they contain any

5. The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.

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

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

#### Status: Point in time view as at 01/05/2004. Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

C-1 1	C-1 2	C-1 2		
Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions		
		or determining the standards for such containers.		
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	8. The sale or supply shall be only—  (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and  (c) of no greater quantity than is reasonably necessary for that purpose.		
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain	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.		

l<sup>F172</sup>10. F173... registered chiropodists who hold a prescription only medicines—certificate of competence in competence in tablets: the use of the medicines specified in Column 2 issued by or with the approval of the

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)

following

- (a) Co-dydramol 10/500 tablets;
- (b) Amorolfine hydrochloride cream where the

**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

Order 1976(22).

<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 medicing to which the exemption applies	nes Conditions
Chiropodists Board [F174 or the Health Professions Council].	maximum stren of the Amorolfi the cream does exceed 0.25 per by weight in we	ne in treatment to a maximum of 24 tablets.]
	(c) Amorolfine hydrochloride lacquer where the maximum stren of the Amorolfi the lacquer does exceed 5 per cer weight in volum and	gth ne in s not nt by
	(d) Topical hydrocortisone where the maxin strength of the hydrocortisone medicinal produ does not exceed per cent by weight.	in the act

# **Textual Amendments**

- **F171** 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)
- F172 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.
- F173 Word in Sch. 5 Pt. 1 para. 10 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(a)(i)
- F174 Words in Sch. 5 Pt. 1 para. 10 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(a)(ii)

Article 11(1)(b)

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

# PART II EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

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

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

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

Article 11(2)

PART III
EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1	Pre	lumn 2 escription only medicines which the exemption plies	Column 3
Persons exempted	to 1		Conditions
1. F175 registered chiropodists who hold a certificate of competence in the use of analgesics issued by or with the approval of the Chiropodists Board [F176] or the Health Professions Council].	1.	Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than one of the following substances—  [F177] Bupivacaine hydrochloride	1. The administration shall be only in the course of their professional practice.

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

Column 1	Column 2		Column 3	
Persons exempted	to v	escription only medicines which the exemption plies	Conditions	
		Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride Lignocaine hydrochloride Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride  [F178 Mepivacaine hydrochloride] Prilocaine hydrochloride]		
2. Registered midwives.	2.	Prescription only medicines for parenteral	2. The administration shall be only in the course of their	

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

[F179Diamorphine] Ergometrine maleate Lignocaine Lignocaine hydrochloride [F179 Morphine] Naloxone hydrochloride Oxytocins, natural and synthetic Pentazocine lactate Pethidine hydrochloride Phytomenadione

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

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

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

Status: Point in time view as at 01/05/2004.

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

Column 1 Persons exempted	_	ion only medicines the exemption	Column 3 Conditions
			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 [F180] or persons who are [F181] registered] paramedics].	preso med	following cription only icines for parenteral inistration—Diazepam 5 mg per ml emulsion for injection; Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion; [F182] medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient] prescription only medicines containing one or more of the following substances, but no active ingredient—	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines	Conditions
•	to which the exemption	
	applies	
	Adrenaline	
	Acid Tartrate	
	Anhydrous	
	Glucose	
	[F183Benzylpe	nicillin]
	[ <sup>F184</sup> Bretylium	1
	Tosylate]	
	Compound	
	Sodium	
	Lactate	
	Intravenous	
	Infusion	
	(Hartmann's	
	Solution)	
	Ergometrine	
	Maleate	
	[ <sup>F183</sup> Frusemid	e]
	Glucose	
	Heparin	
	Sodium	
	Lignocaine	
	Hydrochlorid	
	[F183]Metoclop	
	[F183]Morphine	
	Sulphate	
	Nalbuphine	
	Hydrochlorid	e
	Naloxone	
	Hydrochlorid	e
	Polygeline Sodium	
	Bicarbonate	
	Sodium	
	Chloride	
	[ <sup>F183</sup> Streptokii	nasal
	[ Sueptokii	nasej

# **Textual Amendments**

- F175 Word in Sch. 5 Pt. 3 para. 1 omitted (9.7.2003) by virtue of The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(i)(aa)
- F176 Words in Sch. 5 Pt. 3 para. 1 inserted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(i)(bb)
- F177 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)
- **F178** 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)

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

- F179 Words in Sch. 5 Pt. 3 para. 2 inserted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 4
- **F180** 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)
- F181 Word in Sch. 5 Pt. 3 para. 9 substituted for words (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(3)(b)(ii)
- **F182** 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)**
- **F183** 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)**
- **F184** Words in Sch. 5 Pt. 3 para. 9 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), 3

# SCHEDULE 6

Article 16(1)

#### ORDERS REVOKED

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Order 1983	S.I. 1983/1212
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1984	S.I. 1984/756
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1986	S.I. 1986/586
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1987	S.I. 1987/674
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1987	S.I. 1987/1250
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1988	S.I. 1988/2017
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1991	S.I. 1991/962
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1992	S.I. 1992/1534
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1992	S.I. 1992/2937

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

Column 1	Column 2
Orders	References
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1993	S.I. 1993/1890
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993	S.I. 1993/3256
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1994	S.I. 1994/558
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994	S.I. 1994/3016
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 3) Order 1994	S.I. 1994/3050
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1995	S.I. 1995/1384
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995	S.I. 1995/3174
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1996	S.I. 1996/1514
The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1996	S.I. 1996/3193

# [F185SCHEDULE 7

Articles 12A to 12C

# **Textual Amendments**

F185 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;

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

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

# **PART II**

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

Column 1	Column 2
Class of person by whom a prescription only	Person on whose behalf the Direction must be
medicine is supplied or administered	signed
Common Services Agency	The Agency
[F186Strategic Health Authority]	[F186The Strategic Health Authority]
Health Authority	The Health Authority
Special Health Authority	The Special Health Authority
NHS trust [F187 or NHS foundation 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	The Common Services Agency, where the arrangement has been made with the Agency; or the Health Authority, Special Health Authority, NHS trust [F189] or NHS foundation

Changes to 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
Class of person by whom a prescription only	Person on whose behalf the Direction must be
medicine is supplied or administered	signed
Authority, an NHS trust, [F188, an NHS	trust] or Primary Care Trust with which the
foundation trust] or a Primary Care Trust	arrangement has been made]

#### **Textual Amendments**

- **F186** Words in Sch. 7 Pt. 2 inserted (1.10.2002) by The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc. Provisions) Regulations 2002 (S.I. 2002/2469), reg. 1, Sch. 1 para. 73(4)
- F187 Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(2), Sch. 2
- **F188** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(4), **Sch. 4**
- **F189** Words in Sch. 7 Pt. 2 inserted (1.4.2004) by The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004 (S.I. 2004/696), arts. 1(1)(b), 3(3), **Sch. 3**

# [F190PART IIA

PERSONS BY WHOM OR ON WHOSE BEHALF A PATIENT GROUP DIRECTION USED IN THE PROVISION OF HEALTH CARE BY OR ON BEHALF OF THE POLICE, THE PRISON SERVICES OR THE ARMED FORCES MUST BE SIGNED

## **Textual Amendments**

F190 Sch. 7 Pt. 2A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 17

Column 1	Column 2
Force or service by whom or on whose behalf the health care is provided	Person by whom or on whose behalf the Direction must be signed
A police force in England or Wales	The chief officer of police for that police force (within the meaning of the Police Act 1996)
A police force in Scotland	The chief constable of that police force (within the meaning of the Police (Scotland) Act 1997)
The Police Service of Northern Ireland	The Chief Constable of the Police Service of Northern Ireland
The prison service in England and Wales	The governor of the prison in relation to which the health care in question is being provided

Column 1	Column 2
Force or service by whom or on whose behalf the health care is provided	Person by whom or on whose behalf the Direction must be signed
The prison service in Scotland	The Scottish Prison Service Management Board
The prison service in Northern Ireland	The Northern Ireland Prison Service Management Board
Her Majesty's Forces	<ul><li>(i) the Surgeon General,</li><li>(ii) a Medical Director General, or</li></ul>
	(iii) a chief executive of an executive agency of the Ministry of Defence]

# **PART III**

# CLASSES OF INDIVIDUAL [F191BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### **Textual Amendments**

**F191** 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)** 

[F192]Registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.]

Pharmacists.

Registered health visitors.

Registered midwives.

Registered nurses.

Registered ophthalmic opticians.

[F193]Registered] chiropodists.

[F194]Registered orthoptists.

Registered physiotherapists.

Registered radiographers.]]

### **Textual Amendments**

- F192 Words in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(a)
- F193 Word in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(b)
- F194 Words in Sch. 7 Pt. 3 substituted (9.7.2003) by The Health Professions Order 2001 (Consequential Amendments) Order 2003 (S.I. 2003/1590), art. 1, Sch. para. 21(4)(c)

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

#### **EXPLANATORY NOTE**

(This note is not part of the Order)

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

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

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

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

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

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

# **Status:**

Point in time view as at 01/05/2004.

# **Changes to legislation:**

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