#### 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;

[F1"additional supply optometrist" means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register;]

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

<sup>(1) 1968</sup> c. 67. Section 58 has been amended by the Prescription by Nurses Etc. Act 1992 (c. 28), section 1. The expression "the appropriate Ministers" is defined in section 1(2) of the Medicines Act 1968.

<sup>(2)</sup> In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Secretary of State concerned with Agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

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

[F2" 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,
- (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;]

[F3"clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003;]

F4

[F5"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;]

[F5:-Community marketing authorization" means a marketing authorization granted by the European Community under Council Regulation (EEC) No. 2309/93[F6 or Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency];]

[F7" community practitioner nurse prescriber" means a person—

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for Community Practitioners in the current edition of the British National Formulary;

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

"cyanogenetic substances" means preparations which-

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

[F8" dental hygienist" means a person whose name is registered under the title of dental hygienist in the dental care professionals register;

"dental therapist" means a person whose name is registered under the title of dental therapist in the dental care professionals register;

"dental care professionals register" means the dental care professionals register established under section 36B of the Dentists Act 1984;]

F9...

"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;

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

F10 ...

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

F12 ...

### [F5":Health Authority"—

- (a) F13
- (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;]

[F1444] health 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 [F15, supplementary prescriber], [F16a community practitioner nurse prescriber, a nurse independent prescriber or a pharmacist independent 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);

[F17. health record" has the meaning given by section 68(2) of the Data Protection Act 1998(6);]

[F5"homoeopathic certificate of registration" means a certificate of registration for the purposes of the Medicines (Homoeopathic Medicinal Products For Human Use) Regulations 1994;]

[F18" 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 [F192001, and];]
- (c) [F20 in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

[F18" 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—

<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.

- (i) an independent hospital, or
- (ii) a private psychiatric hospital,

as defined by section 77(1) of the Regulation of Care (Scotland) Act [F212001, and]]

(c) [F22 in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

[F18" 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
- (b) in relation to Scotland, has the meaning given by section 77(1) of the Regulation of Care (Scotland) Act [F23 2001, and]]
- (c) [F24in relation to Northern Ireland, has the meaning given by article 2(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;]

"inhaler" does not include an aerosol;

[F25:"IRME practitioner" means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000(4);]

[F26"Local Health Board" has the same meaning as in the National Health Service Act 1977;]

[F5"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;

[F27" medical exposure" has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;]

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

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

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

"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 F28...

"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);

IF5"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;]

[F29" nurse independent prescriber" means a person—

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber;

[F30ccNHS foundation trust" has the same meaning as in section 1(1) of the Health and Social Care (Community Health and Standards) Act 2003;]

[F31"nursing home" has the meaning given by article 16 [F32 article 11 of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003];]

"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); [F33" operator"—
- (a) in relation to an aircraft, means the person for the time being having management of the aircraft, and
- (b) for the purposes of article 7B, has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;]

[F34" optometrist independent prescriber" means a person—

- (a) who is a registered optometrist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

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

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

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

<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.

# [F5."Patient Group Direction" means—

- (a) in connection with the [F35sale or] supply of a prescription only medicine as referred to in article 12A(2), [F3612B, 12C, 12D or 12E], a written direction relating to the [F37sale or 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 [F38 sale or] supply and administration, or to administration, to persons generally (subject to any exclusions which may be set out in the Direction);]

[F39" pharmacist independent prescriber" means a person—

- (a) who is a pharmacist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"prescription only medicine" means a medicinal product of a description or falling within a class specified in article 3 of this Order;

[F5:cPrimary Care Trust" has the same meaning as in the National Health Service Act 1977;]

[F40" 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);]

[F41" professional register" means the register maintained by the Nursing and Midwifery Council [F42 under article 5 of] 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;

[F43" radioactive medicinal product" means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilize the radiation emitted therefrom;

[F44" 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;];

[F45" registered dietitian" means a person who is registered in Part 4 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[F46" registered midwife" means a person registered in the Midwives' Part of the professional register;]

[F47" registered nurse" means a person registered in the Nurses' Part [F48 or Specialist Community Public Health Nurses' Part] of the professional register;]

[F45" registered occupational therapist" means a person who is registered in Part 6 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[<sup>F49</sup> "registered optometrist" means a person whose name is registered in the register of optometrists maintained under section 7(a) of the Opticians Act 1989, or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act;]

[F44"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;];

[F45" registered orthotist and prosthetist" means a person who is registered in Part 10 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

[F44" 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;]

[F44"registered 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;]

[F50" 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
  - (iiii) [F51 in relation to Northern Ireland, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment or agency, and]
- (b) [F52in relation to a nursing home, the person registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the person carrying on the establishment;]]

[F44"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;]

[F45" registered speech and language therapist" means a person who is registered in Part 12 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001;]

I<sup>F50</sup> "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
- (iii) [F53in relation to Northern Ireland—
  - (aa) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 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, and
- (b) [F54in relation to a nursing home—
  - (i) a person who is registered under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 as the manager of the establishment or agency, but who is not the registered provider for that establishment or agency, or
  - (ii) if there is no such person, but the registered provider has appointed a person to manage the establishment or agency, that appointed person;

[F50" relevant register" means—

- (a) in relation to a [F55 registered] nurse [F56 or registered midwife], the professional register, F57 ...
- (b) in relation to a pharmacist, [F58Part 1 of the register maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007] or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976; F59...
- (c) [F60 in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers diagnostic or therapeutic

that register [F61; and]

- (d) [F62in relation to a registered optometrist, the register of optometrists maintained under section 7(a) of the Opticians Act 1989;]]
- "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;

[F5"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;]

F63 ...

[F64"Strategic Health Authority" means a Strategic Health Authority established under section 8 of the National Health Service Act 1977;]

[F65" supplementary prescriber" means—

- (a) a [<sup>F66</sup>registered] nurse, <sup>F67</sup>...
- (b) a pharmacist, F68 F69...
- (c) a registered midwife,]<sup>F70</sup>...
- (d) [F71a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
  - (i) chiropodists and podiatrists;
  - (ii) physiotherapists; or
  - (iii) radiographers diagnostic or therapeutic [F72 or]]
- (e) [F73a registered optometrist, ]

against whose name is recorded in the relevant register an annotation [F74 or entry] signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber [F75 or, in the case of a nurse or midwife, as a nurse independent/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.

[F56] 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 [F76] or an authorization granted by the licensing authority in accordance with Article 126a of Directive 2001/83/EC]).]

- (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 [F77Schedules 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.
- <sup>F78</sup>(7) In articles 12 to [F79</sup>12E], 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 [<sup>F80</sup>sale,] supply or adminstration of prescription only medicines includes a reference to an arrangement which covers such [<sup>F81</sup>sale,] supply or administration and other matters.
- (9) In Schedule 7, Part I, a reference to treatment of a clinical situation includes a reference to any form of management of that situation.]]

#### **Textual Amendments**

- Words in art. 1(2) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 3(a)
- F2 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)
- F3 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)
- **F4** 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)**
- 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)**
- **F6** Words in art. 1(2) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), **Sch. para. 5(a)**
- F7 Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(a)

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

- Words in art. 1(2) inserted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), 3(2)
- F9 Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(b)
- **F10** Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(c)
- F11 Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(d)
- F12 Words in art. 1(2) omitted (1.5.2006) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(e)
- F13 Words in art. 1(2) repealed (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 2
- 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)(d)
- F15 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)
- F16 Words in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(f)
- F17 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)
- 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)(g)
- F19 Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(a)(i)
- **F20** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(a)(ii)
- **F21** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(b)(i)**
- **F22** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(b)(ii)
- **F23** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(c)(i)**
- **F24** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(c)(ii)**
- F25 Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 2(a)
- **F26** Words in art. 1(2) inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), 2
- **F27** Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(b)**
- **F28** Words in art. 1(2) omitted (17.11.2006) by virtue of The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(c)**
- **F29** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(g)
- **F30** 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**
- **F31** 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)
- **F32** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(d)
- **F33** Words in art. 1(2) substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(d)**

- Words in art. 1(2) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 2
- F35 Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(e)(i)(aa)
- **F36** 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
- F37 Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(e)(i)(bb)
- **F38** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(e)(ii)
- **F39** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(h)
- **F40** 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)**
- **F41** 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)
- F42 Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(iv)
- **F43** Words in art. 1(2) inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **2(e)**
- **F44** 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)**
- F45 Words in art. 1(2) inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 2
- **F46** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(v)
- **F47** Words in art. 1(2) substituted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(vi)**
- **F48** Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **2(i)**
- **F49** Words in art. 1(2) substituted (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **197**
- F50 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)
- **F51** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(f)(i)
- **F52** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(f)(ii)
- **F53** Words in art. 1(2) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 2(2)(g)(i)
- **F54** Words in art. 1(2) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(2)(g)(ii)**
- F55 Word in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(j)
- **F56** Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(vii)
- **F57** Word in art. 1(2) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(a)(i)**
- F58 Words in art. 1(2) substituted (coming into force in accordance with art. 1(2)(3) of the amending S.I.) by The Pharmacists and Pharmacy Technicians Order 2007 (S.I. 2007/289), Sch. 1 para. 20
- **F59** Word in art. 1(b) omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(i)**

- **F60** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(a)(iii)**
- **F61** Word in art. 1(c) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(ii)**
- **F62** Words inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **3(b)(iii)**
- **F63** 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)**
- F64 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
- F65 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)
- **F66** Word in art. 1(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(k)(i)
- **F67** Word in art. 1(2) omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), **Sch. para. 39(a)(viii)**
- **F68** Word in art. 1(2) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(b)(i)**
- **F69** Words in art. 1(2) inserted (1.8.2004) by The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(a)(viii)
- F70 Word in art. 1(2)(c) omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 3(c)(i)
- **F71** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(b)(iii)**
- F72 Word in art. 1(2)(d) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 3(c)(ii)
- F73 Art. 1(2)(e) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 3(c)(iii)
- **F74** Words in art. 1(2) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **3(c)**
- F75 Words in art. 1(2) inserted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 2(k)(ii)
- F76 Words in art. 1(2) inserted (20.11.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(b), Sch. para. 5(b)
- F77 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)
- F78 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)
- **F79** 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)**
- **F80** Word in art. 1(8) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(3)(a)**
- Word in art. 1(8) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **2(3)(b)**

#### Appropriate practitioners

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

- (a) in relation to the descriptions and classes of medicinal products specified in article 3, doctors, dentists [F82, supplementary prescribers], [F83 nurse independent prescribers, pharmacist independent prescribers,] veterinary surgeons and veterinary practitioners;
- [F84(b)] in relation to the descriptions and classes of medicinal products specified in Schedule 3, [F85community practitioner nurse prescribers];
- $^{F86}$ (c)  $\cdots$
- [F87(c)] in relation to the descriptions and classes of medicinal products specified in article 3, other than medicinal products that are controlled drugs or for parenteral administration or both , optometrist independent prescribers.]
- F86(d) .....

- F82 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
- F83 Words in art. 2(a) added (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 2(a)
- F84 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
- F85 Words in art. 2(b) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 3(a)
- F86 Art. 2(c)(d) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 2(b)
- F87 Art. 2(c) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 3

## [F88 Medicinal 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.
  - [F89(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.]
  - [F90(h) medicinal products in respect of which a marketing authorization has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all

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

pharmaceutical forms which in the marketing authorization are classified as being pharmacy only medicines.]

#### **Textual Amendments**

F913 A

- F88 Art. 3 substituted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 4
- F89 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
- **F90** Art. 3(h) inserted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 3

### Prescribing and administration by nurse independent prescribers

| <b>J</b> 1 | •   |
|------------|---|
|            |   |
|            |   |
| Textu      | al Amendments   |
| F91        | Art. 3A omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment |

# [F92Prescribing and administration by supplementary prescribers

Order 2008 (S.I. 2008/464), arts. 1(1), 4

- **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).

- [<sup>F93</sup>(2) Paragraph (1) does not apply if the supplementary prescriber is a community practitioner nurse 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.]
  - (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;

| <sup>F94</sup> (b) |
|--------------------|
|--------------------|

(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.

- F92 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
- F93 Art. 3B(2) substituted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 5
- F94 Art. 3B(3)(b) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), 4

# Exemptions from conditions in respect of the cases or circumstances in which a <sup>F95</sup>... supplementary prescriber may administer a medicinal product

- **3C.** The conditions specified by virtue of <sup>F96</sup>... article 3B(3) shall not apply in relation to the administration of a medicinal product by <sup>F97</sup>... 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**

- F92 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
- **F95** Words in art. 3C heading omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 6(a)
- **F96** Words in art. 3C omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 6(b)(i)
- F97 Words in art. 3C omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 6(b)(ii)

# Duration of special provisions in relation to new medicinal products

| т,    |   |
|-------|---|
|       |   |
| Textu | al Amendments   |
| F98   | Art. 4 revoked (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 |
|       | (S.I. 2002/549), arts. 1(1), <b>11</b>  |

### **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  $I^{F99}$ ,

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**

**F99** 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** 

# [F100] 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**

**F100** Art. 5A inserted (4.4.2003) by The Prescription Only Medicines (Human Use) Amendment Order 2003 (S.I. 2003/696), arts. 1(1), 7

# [F101] Exemption for products consisting of or containing pseudoephedrine salts or ephedrine base or salts

- **5B.**—(1) A medicinal product falling within article 3(h) shall be exempt from the restrictions imposed by section 58(2) (restrictions on sale, supply and administration) if the conditions in paragraph (2) are satisfied—
  - (2) The conditions referred to in this paragraph are that—
    - (a) the medicinal product sold or supplied to a person must not be sold or supplied at the same time as another medicinal product that consists of or contains—
      - (i) in the case of pseudoephedrine salts, ephedrine base or salts;
      - (ii) in the case of ephedrine base or salts, pseudoephedrine salts; and
    - (b) the medicinal product or products sold or supplied to a person at any one time must not in total contain more than—
      - (i) in the case of pseudoephedrine salts, 720mg pseudoephedrine salts;
      - (ii) in the case of ephedrine base or salts, 180mg ephedrine base or salts. ]

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

#### **Textual Amendments**

**F101** Art. 5B inserted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 7

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

#### **Textual Amendments**

**F102** 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

[F103 Atropine sulphate and obidoxime chloride injection]

[F103 Atropine sulphate and pralidoxime chloride injection]

[F103] Atropine sulphate, pralidoxime mesilate and avizafone injection]

[F104Chlorphenamine Injection]

[F105Dicobalt Edetate Injection]

F106

F106

Glucagon Injection

[F107Glucose Injection 50%]

Hydrocortisone Injection

[F108] Naloxone Hydrochloride

[F103Pralidoxime chloride injection]

[F103Pralidoxime mesilate 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.

- F103 Words in art. 7 inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), 3
- **F104** Words in art. 7 substituted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 4(a)
- **F105** Words in art. 7 substituted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 4(b)
- **F106** Words in art. 7 omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 4(c)
- **F107** Words in art. 7 inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 4(d)
- **F108** Words in art. 7 substituted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 4(e)

# [F109 Exemptions for administration of smallpox vaccine

- **7A.**—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of smallpox vaccine where the conditions specified in paragraph (2) or (3) are satisfied.
  - (2) The conditions referred to in this paragraph are—
    - (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by—
      - (i) the Secretary of State,
      - (ii) the Scottish Ministers,
      - (iii) the National Assembly for Wales,
      - (iv) the Department of Health, Social Services and Public Safety,
      - (v) an NHS body; and
    - (b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom.
  - (3) The conditions referred to in this paragraph are—
    - (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by Her Majesty's Forces;
    - (b) the vaccine is administered for the purpose of providing protection against smallpox virus to—
      - (i) members of Her Majesty's Forces; or
      - (ii) other persons employed or engaged by those Forces.
  - (4) For the purposes of this regulation, "NHS body" means—
    - (a) the Common Services Agency,
    - (b) a Strategic Health Authority, Health Authority or Special Health Authority,
    - (c) a Primary Care Trust,
    - (d) a Local Health Board, or
    - (e) an NHS trust or NHS foundation trust

F109 Art. 7A inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), 4

# [F110 Exemption for administration by operators

- **7B.**—(1) The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to—
  - (a) a radioactive medicinal product, administration of which results in a medical exposure; or
  - (b) any other prescription only medicine if it is being administered in connection with a medical exposure,

where the conditions specified in paragraph (2) are satisfied.

- (2) The conditions referred to in paragraph (1) are that—
  - (a) the radioactive medicinal product or other prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000 which apply to the exposure referred to in paragraph (1);
  - (b) that medical exposure has been authorised by an IRME practitioner or, where it is not practicable for an IRME practitioner to authorise the exposure, by an operator acting in accordance with written guidelines issued by an IRME practitioner;
  - (c) the IRME practitioner is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(5);
  - (d) the radioactive medicinal product or other prescription only medicine is not a controlled drug; and
  - (e) in the case of a prescription only medicine which is not a radioactive medicinal product, it is specified in the protocols referred to in sub-paragraph (a).]

#### **Textual Amendments**

**F110** Art. 7B inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **3** 

#### **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 [FIII], a supplementary prescriber][FII2] a community practitioner nurse prescriber, a nurse independent prescriber [FII3], an optometrist independent prescriber][FII4], dentist] or a pharmacist independent prescriber] who by reason of an emergency is unable to furnish a prescription immediately;

- (b) that the doctor [F115, supplementary prescriber], [F116 community practitioner nurse prescriber, nurse independent prescriber [F117, optometrist independent prescriber][F114, dentist] or pharmacist independent 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 [F118, supplementary prescriber], [F119 community practitioner nurse prescriber, nurse independent prescriber [F120, optometrist independent prescriber][F114, dentist] or pharmacist independent 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(12) 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) [F121] subject to paragraph (6)] 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 [F122, supplementary prescriber], [F123 community practitioner nurse prescriber, nurse independent prescriber [F124, optometrist independent prescriber][F125, dentist] or pharmacist independent 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 [F126 in the case of a controlled drug or 30 days in any other case] is sold or supplied except that where the prescription only medicine—
      - (i) is [F127a 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;

Changes to 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) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;
- (e) that the container or package of the prescription only medicine is labelled so as to show-
  - (i) the date on which the prescription only medicine is sold or supplied,
  - (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,
  - (iii) the name of the person requesting the prescription only medicine,
  - (iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and
  - (v) the words "Emergency Supply".
- (5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.
- [F128(6) Paragraph (4)(a) does not apply in relation to the sale or supply of a prescription only medicine where—
  - (a) the sale or supply is made—
    - (i) whilst a disease is, or
    - (ii) in anticipation of a disease being imminently,
    - pandemic and a serious risk, or potentially a serious risk, to human health; and
  - (b) the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has satisfied himself—
    - (i) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber or pharmacist independent prescriber for the person to be treated with it; and
    - (ii) as to the dose which in the circumstances it would be appropriate for that person to take.]

# **Textual Amendments**

- F111 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)
- **F112** Words in art. 8(2)(a) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(a)(i)**
- F113 Words in art. 8(2)(a) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 4(a)(i)
- **F114** Word in art. 8(2) inserted (8.5.2009) by The Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, **3(a)**
- F115 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)

- F116 Words in art. 8(2)(b) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 7(a)(ii)
- F117 Words in art. 8(2)(b) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 4(a)(ii)
- F118 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)
- F119 Words in art. 8(2)(c) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 7(a)(iii)
- **F120** Words in art. 8(2)(c) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 4(a)(iii)
- F121 Words in art. 8(4)(a) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 3(b)(i)
- **F122** 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)
- **F123** Words in art. 8(4)(a)(ii) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **7(b)**
- **F124** Words in art. 8(4)(a)(ii) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), 4(b)
- F125 Word in art. 8(4)(a)(ii) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 3(b)(ii)
- F126 Words in art. 8(4)(b) inserted (8.5.2009) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 3(c)
- **F127** 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
- **F128** Art. 8(6) inserted (8.5.2009) by The Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 3(d)

### 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.**—[F129(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 [F130 or in Schedule 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).
- [F131](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

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

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**

- F129 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
- **F130** Words in art. 10(1) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 8
- F131 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.

### [F132 Exemption 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 <sup>F133</sup>... a supplementary prescriber only where he complies with any condition as to the cases or circumstances in which he may give a prescription for that medicine specified by virtue of article <sup>F134</sup>... 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).]

- F132 Art. 12 substituted (31.1.2004) by The Prescription Only Medicines (Human Use) Amendment Order 2004 (S.I. 2004/2), arts. 1(1), 2
- F133 Words in art. 12(3) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), 8(a)
- **F134** Words in art. 12(3) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **8(b)**

# [F135] 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 [F136Strategic Health Authority,] Health Authority or Special Health Authority;
  - (c) an NHS trust [F137 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 [F138Strategic Health Authority,] Health Authority or Special Health Authority;
  - (c) an NHS trust  $[^{F139}$  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);

Changes to 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 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**

- **F135** 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)**
- **F136** 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)**
- F137 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
- **F138** 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)**
- **F139** 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

- 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
  - [F140(ii) on behalf of the Primary Care Trust, Local Health Board, Health Board or Health and Social Services Board that is responsible for the arrangements under which the 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—
    - [F141(i) in relation to England and Wales, the provision of primary dental services under Part 1 of the National Health Service Act 1977;]
      - (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—
    - [F142(i) in relation to England and Wales, the provision of primary medical services under Part I of the National Health Service Act 1977;]
    - [F143(ii) in relation to Scotland, the provision of primary medical services under Part I of the National Health Service (Scotland) Act 1978; and
    - [F144(iii) in relation to Northern Ireland, the provision of primary medical services under Article 15B or Part VI of the Health and Personal Social Services (Northern Ireland) Order 1972.]

- **F135** 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)
- **F140** Art. 12B(2)(d)(ii) substituted (1.4.2006) by The General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006 (S.I. 2006/562), art. 1(1), Sch. 1 para. 6(2)(a)
- **F141** Art. 12B(3)(a)(i) substituted (1.4.2006) by The General Dental Services, Personal Dental Services and Abolition of the Dental Practice Board Transitional and Consequential Provisions Order 2006 (S.I. 2006/562), art. 1(1), **Sch. 1 para. 6(2)(b)**
- F142 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)
- F143 Art. 12B(3)(b)(ii) substituted (1.10.2004) by The Primary Medical Services (Scotland) Act 2004 (Consequential Amendments) Order 2004 (S.I. 2004/2261), art. 1(1), Sch. para. 2
- F144 Art. 12B(3)(b)(iii) substituted (18.11.2004) by The Primary Medical Services (Northern Ireland) Order 2004 (Consequential Amendments) Order 2004 (S.I. 2004/3038), art. 1(1), Sch. para. 3

# 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 [<sup>F145</sup>sale or] 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—

### [F146(a) the medicine—

- (i) is supplied, or as the case may be, is administered by such a person pursuant to an arrangement made with—
  - (aa) a body referred to in article 12A(a) to (d),
  - (bb) a force or service referred to in article 12E(1)(a)(i) to (iii), or
  - (cc) Her Majesty's Forces,

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

- (ii) is sold or supplied or, as the case may be, is administered by such a person pursuant to an arrangement made with an authority or person carrying on the business of an establishment or agency referred to in article 12D(1) for the sale or supply or, as the case may be, the administration of prescription only medicines;]
- (b) the medicine is [F147 sold or] 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 [F148 sale or] 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 [F149 sells or] 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 [F150] sold or] 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);
- [F151(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 [F153] 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 [F154 sold or] 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**

- **F135** 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)**
- F145 Words in art. 12C(1) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 3(a)(i)
- F146 Art. 12C(1)(a) substituted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 3(a)(ii)
- **F147** Words in art. 12C(1)(b) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(a)(iii)**
- **F148** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(aa)**
- **F149** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(bb)**
- **F150** Words in art. 12C(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(i)(cc)**
- F151 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)
- **F152** 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)**
- F153 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)
- **F154** Words in art. 12C(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), **3(b)(ii)**

# [F155] 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 [F156sale or] supply or, as the case may be, the administration of a prescription only medicine in the course of the business of—
  - [F157(a) an independent hospital,
    - (b) an independent clinic,
    - (c) an independent medical agency, or
    - (d) in Northern Ireland, a nursing home,

where the medicine is [F158 sold or] 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 [F159] sale or] supply or, as the case may be, the administration, by the person who [F160] sells or] 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 [F161] sold or] 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 [F162 sells or] 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,
  - for the purpose of the [F163 sale or] 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 [F164] sold or] 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.

- F155 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
- F156 Words in art. 12D(1) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(a)(i)
- F157 Art. 12D(1)(a)-(d) substituted for art. 12D(1)(a)(b) (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(a)(ii)
- F158 Words in art. 12D(1) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(a)(iii)
- **F159** Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(i)(aa)
- **F160** Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(i)(bb)
- F161 Words in art. 12D(2)(a) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(i)(cc)
- F162 Words in art. 12D(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(ii)(aa)
- F163 Words in art. 12D(2)(d) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(ii)(bb)
- **F164** Words in art. 12D(2)(e) inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 4(b)(iii)

# 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**

F155 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

# $[^{\rm F165}{\rm Exemption}$ for the supply of prescription only medicines in the event or anticipation of pandemic disease

- **12F.** 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 an individual where that supply is—
  - (a) made—
    - (i) whilst a disease is, or
    - (ii) in anticipation of a disease being imminently,

pandemic and a serious risk, or potentially a serious risk, to human health; and

- (b) in accordance with a protocol which—
  - (i) is approved by—
    - (aa) the Ministers;
    - (bb) an NHS body (within the meaning of article 7A(4)); or
    - (cc) the Health Protection Agency established under section 1 of the Health Protection Agency Act 2004; and
  - (ii) contains criteria as to—
    - (aa) symptoms of, and treatment for, that disease;
    - (bb) the recording of the name of the person who supplies the prescription only medicine to the person to be treated (or to a person acting on that person's behalf) and of the evidence that the medicine was supplied to the person to be treated (or to a person acting on that person's behalf).]

#### **Textual Amendments**

F165 Art. 12F inserted (8.5.2009) by The Medicines for Human Use (Prescribing)(Miscellaneous Amendments) Order 2009 (S.I. 2009/1165), arts. 1, 4

#### 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.

# [F166 Exemptions relating to prescriptions given by [F167 certain health professionals]

- **13A.**—[F168(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, F169...
  - (c) a registered midwife, F170...
  - [F171(d)] a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
    - (i) chiropodists and podiatrists;

Changes to 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) physiotherapists; or
- (iii) radiographers: diagnostic or therapeutic, [F172 or]]

[F173(e) a registered optometrist,]

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 a F174... [F175 supplementary prescriber] where the pharmacist, having exercised all due diligence, believes on reasonable grounds that [F176 the F174...][F175 supplementary prescriber] has complied with any condition with which he is required to comply by virtue of [F177 F178 article] 3B].]

#### **Textual Amendments**

- F166 Art. 13A inserted (1.4.2002) by The Prescription Only Medicines (Human Use) Amendment Order 2002 (S.I. 2002/549), arts. 1(1), 7
- **F167** Words in art. 13A heading substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **10(a)**
- F168 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)
- **F169** Word in art. 13A(1)(b) omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **5(a)**
- F170 Word in art. 13A(1)(c) omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 5(a)
- **F171** Art. 13A(1)(d) inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **5(c)**
- **F172** Word in art. 13A(d) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **5(b)**
- F173 Art. 13A(e) inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 5(c)
- **F174** Words in art. 13A(2) omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **9(a)**
- F175 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)
- **F176** Words in art. 13A(2) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **10(b)(ii)**
- F177 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)
- **F178** Word in art. 13A(2) substituted (1.4.2008) by The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **9(b)**

# 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**

- [F17915.—(1) For the purposes of section 58(2)(a), and subject to paragraph (3), 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, a supplementary prescriber, [F180] a community practitioner nurse prescriber, a nurse independent prescriber[F181], an optometrist independent prescriber], a pharmacist independent prescriber], a veterinary surgeon or a veterinary practitioner,
      - (iv) where the appropriate practitioner giving it is a doctor, dentist, a supplementary prescriber, [F182] a community practitioner nurse prescriber, a nurse independent prescriber[F183], an optometrist independent prescriber] or a pharmacist independent 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 the address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care;
    - (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
    - (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.
- (3) For the purposes of paragraph (1) the prescription may, as an alternative to fulfilling the conditions specified in paragraph (2)(a) and (b), fulfil instead the conditions specified in paragraph (4), unless the prescription is a health prescription for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations or is given by a veterinary surgeon or a veterinary practitioner.
- (4) The conditions referred to in paragraph (3) are that the prescription shall be created in electronic form and signed with an advanced 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).
- (5) The prohibition on sale or supply imposed by section 58(2)(a) shall not apply where a prescription only medicine is sold or supplied other than in accordance with a prescription given by an appropriate practitioner and –

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

- (a) the reason the sale or supply is not in accordance with such a prescription is that a condition specified in paragraph (2) or (4) is not fulfilled; and
- (b) the person selling or supplying the prescription only medicine has exercised all due diligence and believes on reasonable grounds that the condition is fulfilled.
- (6) In paragraph (2) "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 the 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.

(7) In this Article—

"advanced electronic signature" means an electronic signature which is—

- (a) uniquely linked to the signatory,
- (b) capable of identifying the signatory,
- (c) created using means that the signatory can maintain under his sole control, and
- (d) which is linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"electronic communication" means a communication transmitted (whether from one person to another, from one device to another or from a person to a device or vice versa)—

- (a) by means of a telecommunication system (within the meaning of the Telecommunications Act 1984, or
- (b) by other means but while in an electronic form; and

## **Textual Amendments**

- **F179** Art. 15 substituted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), 6
- **F180** Words in art. 15(2)(c)(iii) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **11(a)**
- **F181** Words in art. 15(2)(c)(iii) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **5(a)**
- **F182** Words in art. 15(2)(c)(iv) substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **11(b)**
- **F183** Words in art. 15(2)(c)(iv) inserted (4.6.2008) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2008 (S.I. 2008/1161), arts. 1(1), **5(b)**

### Revocations

- **16.**—(1) The Orders specified in Schedule 6 are revoked.
- (2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(13) articles 2 to 6 and Schedules 1 and 2 are revoked.

<sup>&</sup>quot;signatory" means the appropriate practitioner giving the prescription.]

Status: Point in time view as at 01/06/2010.

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

Signed by authority of the Secretary of State for Health

Baroness Jay
Minister of State,
Department of Health

Win Griffiths
Parliamentary Under Secretary of State, Welsh
Office

Sam Galbraith
Parliamentary Under Secretary of State, The
Scottish Office

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

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



D. C. Gowdy
Permanent Secretary

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

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



*P. Small* Permanent Secretary

#### SCHEDULE 1

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

Container or package

containing

not more

than 2g of

medicinal

product

# SUBSTANCES WHICH IF INCLUDED IN MEDICINAL PRODUCTS MAKE THOSE PRODUCTS PRESCRIPTION ONLY MEDICINES AND EXEMPTIONS FROM RESTRICTIONS ON THE SALE AND SUPPLY OF PRESCRIPTION ONLY MEDICINES

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

[F184] Acamprosate]

Acarbose

Acebutolol

Hydrochloride

[F184] 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

infections of the lips and face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite 1.3 per cent External

40

Aldosterone

Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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<br>Substance        | Column 2<br>Maximum<br>strength  | Column 3 Route of administration use or pharmaceutiform |             | Column 5<br>Maximum<br>quantity                                    |  |
| Acrivastine                  |  |   | 24 mg (MDD) | Container or package containing not more than 240mg of Acrivastine |  |
| Acrosoxacin                  |  |   |             |  |  |
| Actinomycin<br>C             |  |   |             |  |  |
| Actinomycin<br>D             |  |   |             |  |  |
| [ <sup>F185</sup> Adapalene  | e]   |   |             |  |  |
| Adenosine                    |  |   |             |  |  |
| Adrenaline                   |  | (1) By inhaler  |             |  |  |
|                              |  | (2) External [F186(except ophthalmic)]                  |             |  |  |
| Adrenaline<br>Acid           |  | (1) By inhaler  |             |  |  |
| Tartrate                     |  | (2) External  |             |  |  |
| Adrenaline<br>Hydrochloride  | e  | (1) By inhaler  |             |  |  |
|                              |  | (2) External  |             |  |  |
| Adrenocortica<br>Extract     | ıl   |   |             |  |  |
| Albendazole                  |  |   |             |  |  |
| Alclofenac                   |  |   |             |  |  |
| Alclometason<br>Dipropionate | e  |   |             |  |  |
| Alcuronium<br>Chloride       |  |   |             |  |  |
| Aldesleukin                  |  |   |             |  |  |
|                              |  |   |             |  |  |

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

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

 $[^{F184}$ Alendronate

Sodium]

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

[F187 Aloxiprin (1) 620 mg

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

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

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

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength

Column 3 Column 4 Route of

Column 5 Treatment limitations Maximum quantity

use or

pharmaceutical

administration,

form

Alphadolone

Acetate

Alphaxalone

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

[F185Altretamine]

Amantadine

Hydrochloride

Ambenonium

Chloride

Ambutonium

Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine Non-

ophthalmic

use

Amethocaine

Non-Gentisate ophthalmic

use

Non-

Amethocaine

Hydrochloride ophthalmic

use

Amikacin

Sulphate

Amiloride

Hydrochloride

Aminocaproic

Acid

Aminoglutethimide

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Aminopterin

Sodium

Amiodarone

Hydrochloride

Amiphenazole Hydrochloride

[F188 Amisulpride]

Amitriptyline

Amitriptyline Embonate

Amitriptyline Hydrochloride

Amlodipine Besylate

Ammonium Bromide

Amodiaquine Hydrochloride

Amorolfine Hydrochloride

Amoxapine

Amoxycillin

Amoxycillin Sodium

Amoxycillin Trihydrate

Amphomycin Calcium

Amphotericin

Ampicillin

Ampicillin

Sodium

Ampicillin Trihydrate Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Amsacrine

Substance

Amygdalin

Amyl Nitrite

Amylocaine Hydrochloride Nonophthalmic use

[F184 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

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

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

Antimony

Sulphate

Antimony

Trichloride

Antimony

Trioxide

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

[F185] Apraclonidine

Hydrochloride]

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

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

```
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
Arsenic
Trioxide
Arsphenamine
[F189 Aspirin
              <sup>F190</sup>(1) 75mg]<sup>F190</sup>(1) Non-
                                                                              The
                            effervescent
                                                                      quantity
                            tablets and
                                                                      sold
                                                                                or
                            capsules]
                                                                      supplied
                                                                      one
                                                                      container or
                                                                      package
                                                                      shall
                                                                               not
                                                                      exceed 100
                                                                           The
                                                                           quantity
                                                                           of
                                                                           non-
                                                                           effervescent
                                                                           tablets,
                                                                           capsules
                                                                           or a
                                                                           combination
                                                                           of
                                                                           both
                                                                           sold or
                                                                           supplied
                                                                           to a
                                                                           person
                                                                           at any
                                                                           one
                                                                           time
                                                                           shall
                                                                           not
                                                                           exceed
                                                                           100]
                                                                         [F192(2]]he
                                                                      quantity
                            effervescent
             mg]
                            tablets and
                                                                      sold
                            capsules
                                                                      supplied
                                                                      one
                                                                      container or
                                                                      package
```

Status: Point in time view as at 01/06/2010.

Changes to 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   |                 | pply of  |
|------------------------|---------------------------------|---|-----------------|--|
| Column 1<br>Substance  | Column 2<br>Maximum<br>strength | Column 3 Route of administrati use or pharmaceut form                     |                 | Column 5<br>Maximum<br>quantity  |
|                        |                                 |   |                 | shall not exceed 32  |
|                        |                                 | [F192(3)]All preparations other than non-effervescent tablets or capsules | ı               | 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             |                                 | F193  | F193            | F193   |
|                        |                                 | F193  |                 | • • •  |
|                        |                                 | F193  |                 |  |
|                        |                                 | • • •   |                 |  |
| Atenolol               |                                 |   |                 |  |
| Atracurium<br>Besylate |                                 |   |                 |  |
| Atropine               |                                 | (1) Internal  |                 |  |
|                        |                                 | (a) by inhaler  |                 |  |
|                        |                                 | (b)   | (b) 300mcg (MD) |  |

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

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

Status: Point in time view as at 01/06/2010.

Changes to 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            | ly of   |
|-----------------------------|---------------------------|---|--|---|
| Column 1<br>Substance       | Column 2 Maximum strength | Column 3 Route of administrati use or pharmaceut form                                 | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>quantity                               |
| Atropine<br>Sulphate        |                           | (1) Internal (a) by inhaler   | (h) 260mag (MD)                          |   |
|                             |                           | (b)<br>otherwise<br>than by<br>inhaler  | (b) 360mcg (MD)                          |   |
|                             |                           | (2) External (except ophthalmic)  | 1.2mg (MDD)                              |   |
| Auranofin                   |                           |   |  |   |
| Azapropazone                | e                         |   |  |   |
| Azathioprine                |                           |   |  |   |
| Azathioprine<br>Sodium      |                           |   |  |   |
| Azelaic<br>Acid             |                           |   |  |   |
| Azelastine<br>Hydrochloride | e                         | For nasal administration  | 140mcg per nostril (MD)                  | Container or package  |
|                             |                           | For the treatment of seasonal allergic rhinitis [F194 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 [F1955 years]                            |  |   |
|                             |                           | As a non-aerosol,   |  |   |

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form aqueous form Azidocillin Potassium Azithromycin Azlocillin Sodium Aztreonam Bacampicillin Hydrochloride Bacitracin Bacitracin Methylene Disalicylate Bacitracin Zinc Baclofen [F188Balsalazide Sodium] Bambuterol Hydrochloride Barium Carbonate Barium Chloride Barium Sulphide Beclamide Beclomethasone Beclomethasone 100mcg per nostril (MD) Container For nasal Dipropionate administration or package (noncontaining aerosol) not more

than [F19620,000 mcg] of

Status: Point in time view as at 01/06/2010.

Changes to 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<br>n only medicine                           | ly of                                     |                                 |
|-----------------------------|---------------------------|---|---|---------------------------------|
| Column 1<br>Substance       | Column 2 Maximum strength | Column 3 Route of administrati use or pharmaceut            | Column 4<br>Treatment limitations<br>ion, | Column 5<br>Maximum<br>quantity |
|                             |                           | For the prevention  | 200 mcg per nostril (MDD)                 | Beclomethasone<br>Dipropionate  |
|                             |                           | and<br>treatment<br>of allergic<br>rhinitis                 | [F197For a maximum period of 3 months]    |                                 |
|                             |                           | [F198For use<br>in persons<br>aged 18<br>years and<br>over] |   |                                 |
| Belladonna<br>Herb          |                           | (1) Internal  | (1) 1mg of the alkaloids (MDD)            |                                 |
|                             |                           | (2) External  |   |                                 |
| Belladonna<br>Root          |                           | (1) Internal  | (1) 1mg of the alkaloids (MDD)            |                                 |
|                             |                           | (2) External  |   |                                 |
| Bemegride                   |                           |   |   |                                 |
| Bemegride<br>Sodium         |                           |   |   |                                 |
| Benapryzine<br>Hydrochloric | le                        |   |   |                                 |
| Bendrofluazi                | de                        |   |   |                                 |
| Benethamine<br>Penicillin   |                           |   |   |                                 |
| Benoxaprofe                 | n                         |   |   |                                 |
| Benperidol                  |                           |   |   |                                 |
| [F188Benseraz               | ide]                      |   |   |                                 |
| Benserazide<br>Hydrochlorid |                           |   |   |                                 |
| Bentiromide                 |                           |   |   |                                 |
| Benzathine<br>Penicillin    |                           |   |   |                                 |
| Benzbromaro                 | one                       |   |   |                                 |
|                             |                           |   |   |                                 |

Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Benzhexol Hydrochloride

Benzilonium Bromide

Benzocaine

Any use except ophthalmic use

Benzoctamine Hydrochloride

Benzoyl 10.0 per

External

Peroxide cent

N-Benzoyl Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine Hydrochloride

Betamethasone

Betamethasone Adamantoate

Betamethasone Benzoate

53

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

[F185Bicalutamide]

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

Fumarate

Bleomycin

Bleomycin

Sulphate

Bretylium

Tosylate

 $[^{F188}$ Brimonidine

Tartrate]

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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<br>Substance       | Column 2<br>Maximum<br>strength  | Column 3 Route of administrati use or pharmaceut              | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>quantity             |  |
| Bromvaleton                 | e  |   |  |   |  |
| Brotizolam                  |  |   |  |   |  |
| Budesonide                  |  | For nasal administration                                      | 200mcg per nostril (MD)                  | Container or package                        |  |
|                             |  | For the prevention or treatment of seasonal allergic rhinitis | [F197For a maximum period of 3 months]   | containing not more than 10mg of Budesonide |  |
|                             |  | 200 mcg<br>per nostril<br>(MDD)                               |  |   |  |
|                             |  | [F198For use<br>in persons<br>aged 18<br>years and<br>over]   |  |   |  |
|                             |  | As a non-<br>aerosol,<br>aqueous<br>form                      |  |   |  |
| Bufexamac                   |  |   |  |   |  |
| Bumetanide                  |  |   |  |   |  |
| Buphenine                   | la.  |   | 6mg (MD)                                 |   |  |
| Hydrochloric                | ic .   |   | 18mg (MDD)                               |   |  |
| Bupivacaine                 |  | Any use except ophthalmic use                                 |  |   |  |
| Bupivacaine<br>Hydrochloric | le   | Any use except ophthalmic use                                 |  |   |  |
| Buserelin<br>Acetate        |  |   |  |   |  |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colum Substance Maxin

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

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

[F199Cabergoline]

Calcipotriol

[F185 Calcipotriol

Hydrate]

Calcitonin

Calcitriol

Calcium

Amphomycin

Calcium

Benzamidosalicylate

Calcium

Bromide

Calcium

Bromidolactobionate

Calcium

Carbimide

Calcium

Folinate

Calcium

Metrizoate

Calcium

Sulphaloxate

[F200 Candesartan

Cilexetil]

Carbocisteine

Carbon Tetrachloride Carboplatin Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 [F188Carbasalate Calcium] Carbenicillin Sodium Carbenoxolone (1) Pellet (1) 5mg (MD) Sodium 25mg (MDD) (2) 2.0 per(2) Gel cent (3) 20mg (MD) (3) (3) 1.0 per (3) Granules for cent Container 80mg (MDD) mouthwash or package in adults containing and children not more not less than than [F201560mg] 12 years Carbenoxolone Sodium Carbidopa Carbimazole

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

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

[F188 Cefdinir]

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

[F199Cefprozil]

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

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

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

Ceftriaxone

Sodium

Cefuroxime

Axetil

Cefuroxime

Sodium

Celiprolol

Hydrochloride

Cephalexin

Cephalexin

Sodium

Cephaloridine

Cephalothin

Sodium

Cephamandole

Nafate

Cephazolin

Sodium

Cephradine

Cerium

Oxalate

Cerivastatin

[F188]Cerivastatin

Sodium]

Ceruletide Diethylamine

Cetirizine 10mg (MDD)

Hydrochloride

Chenodeoxycholic

Acid

Chloral External

Hydrate

Chlorambucil

Chloramphenicol

F202

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

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium

Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(14)) 5.0 per

cent

(1) Internal

(2) External

of malaria

Chloroquine Prophylaxis
Phosphate of malaria
Chloroquine Prophylaxis

Chlorothiazide

Sulphate

Chlorotrianisene

Chlorphenoxamine

Hydrochloride

Chlorpromazine

Chlorpromazine

**Embonate** 

Chlorpromazine Hydrochloride

Chlorpropamide

 $<sup>\</sup>textbf{(14)} \;\; \textit{See} S.I. \; 1979/382 \; amended \; by \; S.I. \; 1980/263 \; and \; S.I. \; 1989/1124.$ 

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Column 2 Substance Maximum

Column 3 Route of strength administration,

Column 4 Treatment limitations Column 5 Maximum quantity

use or

pharmaceutical

form

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

(a) For the short-term

(a) 200mg (MD)

800mg (MDD) symptomatic

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 Non-

Cinchocaine Equivalent

Hydrochloride f 3.0 per ophthalmic

cent of use Cinchocaine

Cinchophen

Cinoxacin

Ciprofibrate

Ciprofloxacin

Ciprofloxacin

Hydrochloride

Cisapride

Cisplatin

[F185Citalopram

Hydrobromide]

Clarithromycin

Clavulanic

Acid

Clidinium

Bromide

Clindamycin

Clindamycin

Hydrochloride

Clindamycin

Palmitate

Hydrochloride

Clindamycin

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)

|                             |                          |  | ctions on the sale and sup   | ply of   |
|-----------------------------|--------------------------|--|------------------------------|--|
| Column 1                    | prescription<br>Column 2 | only medicine<br>Column 3  | s<br>Column 4                | Column 5   |
| Substance                   | Maximum<br>strength      | Route of administration use or pharmaceutiform   | Treatment limitations<br>on, | Maximum<br>quantity  |
| Clioquinol                  |                          | (1) External<br>(other than<br>treatment<br>of mouth<br>ulcers)  |                              |  |
|                             | (2) 35mg                 | (2)<br>Treatment<br>of mouth<br>ulcers   | (2) 350mg (MDD)              |  |
| Clobetasol<br>Propionate    |                          |  |                              |  |
| Clobetasone<br>Butyrate     | [F203] 0.05 per cent]    | [F203] Cream for use in adults and in children aged 12 years and over, for external use for the short term symptomatic treatment and control of patches of eczema and dermatitis (excluding seborrhoeic dermatitis)] |                              | [F203] Container or package containing not more than 15g of medicinal product] |
| Clofazimine                 |                          |  |                              |  |
| Clofibrate                  |                          |  |                              |  |
| Clomiphene<br>Citrate       |                          |  |                              |  |
| Clomipramin                 | e                        |  |                              |  |
| Clomipramin<br>Hydrochlorid |                          |  |                              |  |
| Clomocyclin                 | e                        |  |                              |  |
|                             |                          |  |                              |  |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

pharmaceutical

form

Clomocycline

Sodium

Clonidine

Clonidine

Hydrochloride

Clopamide

Clopenthixol

Decanoate

Clopenthixol

Hydrochloride

Clorexolone

Clotrimazole

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

Cloxacillin Benzathine

Cloxacillin Sodium

Clozapine

Cocculus Indicus

Co-

dergocrine

Mesylate

Colaspase

Colchicine

Colestipol Hydrochloride

Colfosceril Palmitate Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Colistin

Sulphate

Colistin

Sulphomethate

Colistin

Sulphomethate

Sodium

Coniine

Conium

7.0 per cent External

Leaf

Corticotrophin

Cortisone

Cortisone

Acetate

Co-

tetroxazine

Co-

trimoxazole

Cropropamide

Crotethamide

Croton Oil

Croton Seed

Curare

Cyclofenil

Cyclopenthiazide

Cyclopentolate

Hydrochloride

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cyproterone

Acetate

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

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

Column 1 Substance Column 2 Maximum strength

Column 3 C Route of T administration,

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Cytarabine Hydrochloride

Cytarabine

Dacarbazine

Dalteparin Sodium

Danazol

Danthron

Dantrolene Sodium

Dapsone

Dapsone Ethane Ortho Sulphonate

Daunorubicin

Hydrochloride

Deanol 26mg (MDD)

Bitartrate

Debrisoquine Sulphate

Demecarium Bromide

Demeclocycline

Demeclocycline

Calcium

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone Pivalate

Deptropine Citrate

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

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

or throat pastilles

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

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Dexamethasone

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

Dexamethasone

Sodium

Phosphate

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

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)

(MDD)

(b) in any other case: equivalent of 15mg of Dextromethorphan (MD)

equivalent of 75mg of Dextromethorphan (MDD)

Dextrothyroxine Sodium

Diazoxide

Dibenzepin Hydrochloride

Dichloralphenazone

Dichlorphenamide

Diclofenac 1.16 per Diethylammoreinn External

For maximum period of 7 days

For local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of Container or package containing not more than 30g of medicinal product

Sulphate

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form soft tissue rheumatism For use in adults and children not less than 12 years Diclofenac Potassium Diclofenac Sodium Dicyclomine 10mg (MD) Hydrochloride 60mg (MDD) [F184Didanosine] Dienoestrol Diethanolamine Fusidate Diflucortolone Valerate Diflunisal Digitalin **Digitalis** Leaf Digitalis Prepared Digitoxin Digoxin Dihydralazine Sulphate Dihydroergotamine Mesylate Dihydrostreptomycin Dihydrostreptomycin

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

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

Diloxanide

Furoate

Diltiazem Hydrochloride

Dimercaprol

Dimethisoquin Hydrochloride Nonophthalmic

use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost Trometamol

Dinoprostone

[F187] Diphenhya Humine Hydrochloride preparations

except liquid-filled capsules]

[F204Diphenoxylat2.5 mg] Hydrochloride]

combination
with
Atropine
Sulphate for
short term
use as an
adjunctive
therapy to

 $I^{F204}In$ 

 $[^{F204}25 \text{ mg (MDD)}]$ 

[F204]Container or package containing not more than 20 tablets]

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

|   |                           | from the restri<br>only medicine   | ctions on the sale and supply                                      | v of   |
|---|---------------------------|--|--|--|
| Column 1<br>Substance                     | Column 2 Maximum strength | Column 3 Route of administration use or pharmaceutiform  | Column 4<br>Treatment limitations<br>on,                           | Column 5<br>Maximum<br>quantity  |
|   |                           | appropriate<br>rehydration<br>in acute<br>diarrhoea  |  |  |
|   |                           | For use in persons aged 16 years and over  |  |  |
| D   |                           | Tablets]   |  |  |
| Dipivefrin<br>Hydrochloride               | e                         |  |  |  |
| Dipyridamole                              |                           |  |  |  |
| Disodium<br>Etidronate                    |                           |  |  |  |
| Disodium<br>Pamidronate                   |                           |  |  |  |
| Disopyramide                              |                           |  |  |  |
| Disopyramide<br>Phosphate                 |                           |  |  |  |
| Distigmine<br>Bromide                     |                           |  |  |  |
| Disulfiram                                |                           |  |  |  |
| Dithranol                                 | 1.0 per cent              |  |  |  |
| Dobutamine<br>Hydrochloride               | e                         |  |  |  |
| [ <sup>F204</sup> Dolasetro:<br>Mesilate] | n                         |  |  |  |
| Domperidone                               |                           | [F205] For<br>the relief<br>of post-<br>prandial<br>symptoms<br>of excessive<br>fullness,<br>nausea,<br>epigastric | [F205] 10mg of Domperidone (MD)] [F205] 40mg of Domperidone (MDD)] | [F205] Container or package containing not more than 200mg of Domperidone] |

Status: Point in time view as at 01/06/2010.

Changes to 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  | pply of  |
|--|---|--|---|--|
| Column 1<br>Substance                        | prescriptior<br>Column 2<br>Maximum<br>strength | only medicine Column 3 Route of administrati use or pharmaceuti  | Column 4 Treatment limitations on,  | Column 5<br>Maximum<br>quantity  |
|  |   | bloating and belching, occasionally accompanied by epigastric discomfort and heartburn]  |   |  |
| Domperidone<br>Maleate                       |   | [F206For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn,] | [F20710 mg of Domperidone as Domperidone Maleate (MD)]  [F20740 mg of Domperidone as Domperidone Maleate (MDD)] | [F206] Container or package containing not more than [F208] 200mg] of Domperidone as Domperidone Maleate;] |
| [ <sup>F188</sup> Donepezil<br>Hydrochloride | 1   |  |   |  |
| Dopamine<br>Hydrochloride                    |   |  |   |  |
| Dopexamine<br>Hydrochloride                  |   |  |   |  |
| [ <sup>F185</sup> Dorzolami<br>Hydrochloride |   |  |   |  |
| Dothiepin                                    |   |  |   |  |
| Dothiepin<br>Hydrochloride                   |   |  |   |  |
| Doxapram<br>Hydrochloride                    |   |  |   |  |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or pharmaceutical

form

Doxazosin

Mesylate

Doxepin

Hydrochloride

Doxorubicin

Doxorubicin

Hydrochloride

Doxycycline

Doxycycline

Calcium Chelate

Doxycycline

Hydrochloride

Droperidol

Dydrogesterone

Dyflos

Econazole

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

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

Ecothiopate Iodide

Edrophonium Chloride

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

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

Eflornithine Hydrochloride

 $[^{F184} \hbox{Eformoterol}$ 

Fumarate]

Embutramide

Emepronium

Bromide

Emetine 1.0 per cent

Emetine Bismuth Iodide

Emetine Equivalent Hydrochloride f 1.0 per

cent of Emetine

Enalapril Maleate

Encephalitis Virus, Tickborne, Cent

Eur

Enoxacin

Enoxaparin Sodium

Enoximone

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

(other than nasal sprays or nasal drops)

60mg (MDD)

(2) 2.0 per cent

(2) Nasal sprays or nasal drops

(3) External

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

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

Column 3 Route of administration,

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

[F209 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 C
Substance M

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Ethamivan

Ethamsylate

Ethiazide

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol Diacetate

21000000

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

[F185 Exemestane]

Famciclovir

Famotidine

For the short-term

10mg (MD)

symptomatic 20mg (MDD)

relief of heartburn,

For maximum period of

artburn, 14 days

dyspepsia, indigestion,

|                                       | prescription                    | from the restriction   | ctions on the sale and suppl<br>s | y of  |
|---------------------------------------|---------------------------------|--|-----------------------------------|---|
| Column 1<br>Substance                 | Column 2<br>Maximum<br>strength | Column 3 Route of administration use or pharmaceutiform  |                                   | Column 5<br>Maximum<br>quantity   |
|                                       |                                 | acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms  |                                   |   |
| Fazadinium<br>Bromide                 |                                 |  |                                   |   |
| Felbinac                              | 3.17 per cent                   | External  [F211] For the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions]  For use in adults and children not less than 12 | For maximum period of 7 days      | Container or package containing not more than [F210 50g] of medicinal product |
|                                       |                                 |  |                                   |   |
| Felodipine                            |                                 | years  |                                   |   |
| Felodipine<br>Felypressin<br>Fenbufen |                                 |  |                                   |   |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Fenfluramine Hydrochloride

Fenofibrate

Fenoprofen

Fenoprofen Calcium

Fenoterol Hydrobromide

Fenticonazole Nitrate [F203 External use (but in the case of vaginal use, only for the treatment of vaginal candidiasis)]

Feprazone

Ferrous Arsenate

[F185 Ferumoxsil]

[F188Fexofenadine Hydrochloride]

Filgrastim

Finasteride

Flavoxate Hydrochloride

Flecainide Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone Acetonide

Flucloxacillin Magnesium

|                          |  | Exemptions from the restrictions on the sale and supply of prescription only medicines  |  |   |  |  |  |
|--------------------------|--|---|--|---|--|--|--|
| Column 1<br>Substance    | prescription Column 2 Maximum strength | Column 3 Route of administrati use or pharmaceut  | Column 4 Treatment limitations ion,                          | Column 5<br>Maximum<br>quantity   |  |  |  |
|                          |  | form  |  |   |  |  |  |
| Flucloxacilli<br>Sodium  | n                                      |   |  |   |  |  |  |
| Fluconazole              |  | For oral administration for the treatment of vaginal candidiasis [F212] or associated candidal balanitis] in persons aged not less than 16 but less than 60 years | 150mg (MD)<br>on   | Container or package containing not more than 150mg of Fluconazole        |  |  |  |
| Flucytosine              |  | J   |  |   |  |  |  |
| Fludrocortise<br>Acetate | one                                    |   |  |   |  |  |  |
| Flufenamic<br>Acid       |  |   |  |   |  |  |  |
| Flumazenil               |  |   |  |   |  |  |  |
| Flumethasor              | ne                                     |   |  |   |  |  |  |
| Flumethasor<br>Pivalate  | ne                                     |   |  |   |  |  |  |
| Flunisolide              | 0.025 per cent                         | (a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever   | (a) 50mcg per nostril<br>(MD)<br>100mcg per nostril<br>(MDD) | (a) Container or package containing not more than 6,000mcg of Flunisolide |  |  |  |
|                          |  | [F213For use in persons aged 18   | [F214For a maximum period of 3 months]                       |   |  |  |  |

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

|                             | Exemptions from the restrictions on the sale and supply of prescription only medicines |  |       |                                 |  |  |  |
|-----------------------------|--|--|-------|---------------------------------|--|--|--|
| Column 1<br>Substance       | Column 2<br>Maximum<br>strength  | Column 3 Route of administrati use or pharmaceut form years and over |       | Column 5<br>Maximum<br>quantity |  |  |  |
|                             |  | In the form<br>of a non-<br>pressurised<br>nasal spray               |       |                                 |  |  |  |
|                             |  | F215   | F215  | F215                            |  |  |  |
|                             |  |  |       |                                 |  |  |  |
|                             |  |  | F215  |                                 |  |  |  |
|                             |  | F215   | • • • |                                 |  |  |  |
|                             |  |  |       |                                 |  |  |  |
|                             |  | F215   |       | <del></del>                     |  |  |  |
|                             |  |  |       |                                 |  |  |  |
| Fluocinolone<br>Acetonide   |  |  |       |                                 |  |  |  |
| Fluocinonide                |  |  |       |                                 |  |  |  |
| Fluocortin<br>Butyl         |  |  |       |                                 |  |  |  |
| Fluocortolone               |  |  |       |                                 |  |  |  |
| Fluocortolone<br>Hexanoate  |  |  |       |                                 |  |  |  |
| Fluocortolone<br>Pivalate   |  |  |       |                                 |  |  |  |
| Fluorescein<br>Dilaurate    |  |  |       |                                 |  |  |  |
| Fluorometholo               | one  |  |       |                                 |  |  |  |
| Fluorouracil                |  |  |       |                                 |  |  |  |
| Fluorouracil<br>Trometamol  |  |  |       |                                 |  |  |  |
| Fluoxetine<br>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 Maximum Substance Maximum Route of Treatment limitations administration, strength quantity use or pharmaceutical form

Flupenthixol Hydrochloride

Fluperolone

Acetate

Fluphenazine Decanoate

Fluphenazine

Enanthate

Fluphenazine Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol Sodium

Sourain

Flurandrenolone

Flurbiprofen [F2168.75 [F217Throat [F21843.75 mg (MDD)] [F219Container mg] lozenges] [F21843.75 mg (MDD)] [F219Container or package containing not more

containing not more than 140 mg of Flurbiprofen]

Flurbiprofen Sodium

Fluspirilene

Flutamide

Fluticasone Propionate

[F188Flutrimazole]

Fluvastatin Sodium

Fluvoxamine Maleate

Folic Acic 500mcg (MDD)

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

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

Formestane

Formocortal

Foscarnet

Sodium

Fosfestrol

Sodium

Fosfomycin

Trometamol

Fosinopril

Sodium

Framycetin

Sulphate

Frusemide

Furazolidone

Fusafungine

Fusidic

Acid

Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

Ganciclovir

Sodium

Gelsemine

0.1 per cent

Gelsemium

25mg (MD) 75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin

Sulphate

Gestodene

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

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

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Glucagon

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

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride

Griseofulvin

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

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

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

Halofantrine

Hydrochloride

Haloperidol

Haloperidol Decanoate

Heparin External External

Calcium

Heparin Sodium

Hexachlorophane External

(a) 2.0 per cent

(a) Soaps

(b) 0.1 per

(b) Aerosols

cent

(c) 0.75 per

cent

(c) preparations

other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

Hexobarbitone

Sodium

Hexoestrol

Hexoestrol Dipropionate

L-Histidine Dietary

Hydrochloride supplementation

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

0.45mg (MDD)

(2) External (except ophthalmic)

|                             |                                   | from the restrictions on the sale and supply of a only medicines  |   |  |  |
|-----------------------------|-----------------------------------|---|---|--|--|
| Column 1<br>Substance       | Column 2<br>Maximum<br>strength   | Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form   | Column 5<br>Maximum<br>quantity   |  |  |
| Homatropine                 |                                   | 0.2mg (MD)  |   |  |  |
| Hydrobromio                 | de                                | 0.6mg (MDD)   |   |  |  |
| Homatropine                 |                                   | 2mg (MD)  |   |  |  |
| Methylbrom                  | iae                               | 6mg (MDD)   |   |  |  |
| Hydralazine<br>Hydrochlorio | de                                |   |   |  |  |
| Hydrargaphe                 | en                                | Local application to skin   |   |  |  |
| Hydrobromio<br>Acid         | С                                 |   |   |  |  |
| Hydrochloro                 | thiazide                          |   |   |  |  |
| nyarocortisc                | one [F220(1)0.5 per cent]         | [F220(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] | (Edf(a))ner or package containing not more than 15g of medicinal product] |  |  |
|                             | [ <sup>F221</sup> (2)].0 per cent | [F221(2)] External  (a) For  use  either  alone   | (Föh(a)))er<br>or package<br>containing<br>not more<br>than 15g           |  |  |

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 5 Column 1 Column 2 Column 3 Column 4 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form of medicinal or in conjunction product (cream with or Crotamiton ointment) or 30ml (spray) in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild

> combination with

moderate eczema, and either in

Clotrimazole

[F222or

Miconazole

Nitrate]

for

athlete's

foot

and

candidal

intertrigo

or in

combination

with

lignocaine

for

anal

and

perianal

itch

associated with

haemorrhoids

|              |                       |                          | rictions on the sale and sup | ply of                |
|--------------|-----------------------|--------------------------|------------------------------|-----------------------|
| Column 1     | Column 2              | only medicin<br>Column 3 | es<br>Column 4               | Column 5              |
| Substance    | Maximum strength      | Route of administrat     | Treatment limitations        | Maximum<br>quantity   |
|              |                       | use or                   |                              |                       |
|              |                       | pharmaceur               | tical                        |                       |
|              |                       | form Form                |                              |                       |
|              |                       | (b) For use in           |                              |                       |
|              |                       | adults                   |                              |                       |
|              |                       | and                      |                              |                       |
|              |                       | childre                  | en                           |                       |
|              |                       | not                      |                              |                       |
|              |                       | less                     |                              |                       |
|              |                       | than                     |                              |                       |
|              |                       | 10                       |                              |                       |
|              |                       | years (a) Crosm          |                              |                       |
|              |                       | (c) Cream ointme         |                              |                       |
|              |                       | or                       | ····                         |                       |
|              |                       | spray                    |                              |                       |
| Hydrocortiso | on <b>E</b> quivalent | External                 |                              |                       |
| -            | to 1.0                | For use                  |                              | Container             |
|              | per cent              |                          |                              | or package            |
|              | Hydrocortiso          | one<br>dermatitis,       |                              | containing            |
|              |                       | contact                  |                              | not more              |
|              |                       | allergic                 |                              | than 15g of           |
|              |                       | dermatitis,              |                              | medicinal             |
|              |                       | insect bite              |                              | product               |
|              |                       | reactions, mild to       |                              | In the                |
|              |                       | moderate                 |                              | case of               |
|              |                       | eczema,                  |                              | suppositories,        |
|              |                       | and in                   |                              | container             |
|              |                       | combination              | 1                            | or package containing |
|              |                       | with one or              |                              | no more               |
|              |                       | more of the              |                              | than 12               |
|              |                       | following:               |                              |                       |
|              |                       | Benzyl<br>Benzoate,      |                              |                       |
|              |                       | Bismuth                  |                              |                       |
|              |                       | Oxide,                   |                              |                       |
|              |                       | Bismuth                  |                              |                       |
|              |                       | Subgallate,              |                              |                       |
|              |                       | Peru                     |                              |                       |
|              |                       | Balsam,                  |                              |                       |
|              |                       | Pramoxine                | 1.                           |                       |
|              |                       | Hydrochlori<br>Zinc      | ae,                          |                       |
|              |                       | Oxide, for               |                              |                       |
|              |                       | haemorrhoid              | ls.                          |                       |
|              |                       | 114011101111010          | 00                           |                       |

Changes to 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<br>Column 2                  | only medicines<br>Column 3   | S<br>Column 4                | Column 5   |
| Substance                             | Maximum<br>strength                       | Route of administration use or pharmaceutic form                                       | Treatment limitations<br>on, | Maximum<br>quantity  |
|                                       |   | combination with Miconazole Nitrate, for athlete's foot and candidal intertrigo]       |                              |  |
|                                       |   | For use in<br>adults and<br>children not<br>less than 10<br>years                      |                              |  |
|                                       |   | Cream,<br>ointment or<br>suppositories   |                              |  |
| Hydrocortiso<br>Butyrate              | one                                       |  |                              |  |
| Hydrocortiso<br>Caprylate             | one                                       |  |                              |  |
| Hydrocortiso<br>Hydrogen<br>Succinate | one                                       |  |                              |  |
| Hydrocortisc<br>Sodium<br>Phosphate   | one                                       |  |                              |  |
| Hydrocortiso<br>Sodium<br>Succinate   | onEquivalent<br>to 2.5mg<br>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   |                              |  |

|                             |                                 | from the restri  | ctions on the sale and sup   | ply of   |
|-----------------------------|---------------------------------|--|------------------------------|--|
| Column 1<br>Substance       | Column 2<br>Maximum<br>strength | Column 3 Route of administration use or pharmaceutiform  | ,                            | Column 5<br>Maximum<br>quantity  |
| [F187Hydrocy<br>Acid]       | anic                            |  |                              |  |
| Hydroflumet                 | hiazide                         |  |                              |  |
| Hydroxychlo<br>Sulphate     | oroquine                        | Prophylaxis of malaria   |                              |  |
| Hydroxyprog                 | gesterone                       |  |                              |  |
| Hydroxyprog<br>Enanthate    | gesterone                       |  |                              |  |
| Hydroxyprog<br>Hexanoate    | gesterone                       |  |                              |  |
| Hydroxyurea                 | ı                               |  |                              |  |
| Hydroxyzine<br>Embonate     | ;                               |  |                              |  |
| Hydroxyzine<br>Hydrochlorid |                                 | (a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years | (a) 25mg (MD)<br>75mg (MDD)  | (a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride |
|                             |                                 | (b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis,  | (b) 25 mg (MD)<br>50mg (MDD) | (b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride |

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

|                          | •   | Exemptions from the restrictions on the sale and supply of prescription only medicines |  |                                 |  |  |
|--------------------------|---|--|--|---------------------------------|--|--|
| Column 1<br>Substance    | Prescription<br>Column 2<br>Maximum<br>strength | Column 3 Route of administrati use or pharmaceut form than by                          | Column 4<br>Treatment limitations<br>ion,    | Column 5<br>Maximum<br>quantity |  |  |
|                          |   | inhaler  |  |                                 |  |  |
|                          |   | (2) External   |  |                                 |  |  |
| Hyoscine<br>Methonitrate |   | (1) Internal   |  |                                 |  |  |
| Wiemomtrate              |   | (a) by inhaler   |  |                                 |  |  |
|                          |   | (b)  | (b) 2.5mg (MD)                               |                                 |  |  |
|                          |   | otherwise<br>than by<br>inhaler  | 7.5mg (MDD)                                  |                                 |  |  |
|                          |   | (2) External   |  |                                 |  |  |
| Hyoscyamine              | ;   | (1) Internal   |  |                                 |  |  |
|                          |   | (a) by inhaler   |  |                                 |  |  |
|                          |   | (b)<br>otherwise<br>than by<br>inhaler   | (b) 300mcg (MD)                              |                                 |  |  |
|                          |   |  | 1mg (MDD)                                    |                                 |  |  |
|                          |   | (2) External   |  |                                 |  |  |
| Hyoscyamine              |   | (1) Internal   |  |                                 |  |  |
| Hydrobromid              | le  | (a) by inhaler   |  |                                 |  |  |
|                          |   | (b) otherwise  | (b) Equivalent of 300mcg of Hyoscyamine (MD) |                                 |  |  |
|                          |   | than by<br>inhaler   | Equivalent of 1mg of Hyoscyamine (MDD)       |                                 |  |  |
|                          |   | (2) External   |  |                                 |  |  |
| Hyoscyamine              | •   | (1) Internal   |  |                                 |  |  |
| Sulphate                 |   | (a) by inhaler   |  |                                 |  |  |
|                          |   | (b) otherwise  | (b) Equivalent of 300mcg of Hyoscyamine (MD) |                                 |  |  |
|                          |   | than by<br>inhaler   | Equivalent of 1mg of Hyoscyamine (MDD)       |                                 |  |  |
|                          |   | (2) External   |  |                                 |  |  |

|                                      |                         |  | ctions on the sale and suppl   | y of  |
|--------------------------------------|-------------------------|--|--|---|
| Column 1<br>Substance                | Column 2<br>Maximum     | only medicine<br>Column 3<br>Route of  | Column 4<br>Treatment limitations  | Column 5<br>Maximum   |
|                                      | strength                | administrati<br>use or<br>pharmaceuti<br>form  |  | 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 |  |   |
|                                      |                         | (1) Internal   | (1)(a) In the case of<br>a prolonged release<br>preparation 600mg (MD)                 |   |
|                                      |                         |  | 1,200mg (MDD)  |   |
|                                      |                         |  | (b) in any other case 400mg (MD)   |   |
|                                      |                         |  | 1,200mg (MDD)  |   |
|                                      | (2) 5.0 per cent        | (2) External   |  |   |
|                                      | [F224(3) 10.0 per cent] | [F224(3)<br>External]  | [F224(3) 125 mg (MD) 500 mg (MDD)]   | [F224(3) Container or package containing not more than [F225 50g] of medicinal product] |
| [ <sup>F187</sup> Ibuprofe<br>Lysine | n                       | Rheumatic<br>and<br>muscular<br>pain, pain of<br>non-serious<br>arthritic  | (a) in the case of a<br>prolonged release<br>preparation 600 mg (MD)<br>1,200 mg (MDD) |   |

|   |                           | from the restri<br>nonly medicine   | ctions on the sale and supp                             | ly of                           |  |
|---|---------------------------|---|---|---------------------------------|--|
| Column 1<br>Substance                               | Column 2 Maximum strength | Column 3 Route of administrati use or pharmaceuti form  | Column 4<br>Treatment limitations<br>on,                | Column 5<br>Maximum<br>quantity |  |
|   |                           | conditions,<br>backache,<br>neuralgia,<br>migraine,<br>headache,<br>dental pain,<br>dysmenorrho<br>feverishness,<br>symptoms<br>of colds and<br>influenza |   |                                 |  |
|   |                           | Internal  | (b) in any other case<br>400 mg (MD) 1,200 mg<br>(MDD)] |                                 |  |
| Idarubicin<br>Hydrochlorid                          | de                        |   |   |                                 |  |
| Idoxuridine   |                           |   |   |                                 |  |
| Ifosfamide  |                           |   |   |                                 |  |
| Ignatius<br>Bean                                    |                           |   |   |                                 |  |
| [ <sup>F184</sup> Imidapri<br>Hydrochlorid          |                           |   |   |                                 |  |
| Imipenem<br>Hydrochlorid                            | le                        |   |   |                                 |  |
| Imipramine  |                           |   |   |                                 |  |
| Imipramine<br>Hydrochlorio                          | le                        |   |   |                                 |  |
| Imipramine Ion Exchange Resin Bound Salt or Complex |                           |   |   |                                 |  |
| [ <sup>F199</sup> Indapam                           | ide]                      |   |   |                                 |  |
| T 1 '1  |                           |   |   |                                 |  |

Indapamide Hemihydrate

Indomethacin

Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

Column 4
Treatment limitations

Column 5 Maximum quantity

use or pharmaceutical

form

Indomethacin

Sodium

Indoprofen

Indoramin

Hydrochloride

Inosine

Pranobex

[F226 Insulin]

Iodamide

Iodamide

Meglumine

Iodamide

Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic

Acid

Ipratropium

Bromide

Iprindole

Hydrochloride

Iproniazid

Phosphate

 $[^{F188}$ Irbesartan]

Isoaminile

Isoaminile

Citrate

Isocarboxazid

|                               | Exemptions from the restrictions on the sale and supply of prescription only medicines |  |   |                                 |  |
|-------------------------------|--|--|---|---------------------------------|--|
| Column 1<br>Substance         | Column 2<br>Maximum<br>strength  | Column 3 Route of administrati use or pharmaceuti  | Column 4<br>Treatment limitations<br>on,      | Column 5<br>Maximum<br>quantity |  |
| Isoconazole<br>Nitrate        |  | External but<br>in the case<br>of vaginal<br>use only<br>external<br>use for the<br>treatment<br>of vaginal<br>candidiasis |   |                                 |  |
| Isoetharine                   |  |  |   |                                 |  |
| Isoetharine<br>Hydrochlorid   | e  |  |   |                                 |  |
| Isoetharine<br>Mesylate       |  |  |   |                                 |  |
| Isoniazid                     |  |  |   |                                 |  |
| Isoprenaline<br>Hydrochlorid  | e  |  |   |                                 |  |
| Isoprenaline<br>Sulphate      |  |  |   |                                 |  |
| Isopropamide<br>Iodide        |  |  | Equivalent of 2.5mg of Isopropamide ion (MD)  |                                 |  |
|                               |  |  | Equivalent of 5.0mg of Isopropamide ion (MDD) |                                 |  |
| Isotretinoin                  |  |  |   |                                 |  |
| Isradipine                    |  |  |   |                                 |  |
| Itraconazole                  |  |  |   |                                 |  |
| Jaborandi                     |  | External   |   |                                 |  |
| Kanamycin<br>Acid<br>Sulphate |  |  |   |                                 |  |
| Kanamycin<br>Sulphate         |  |  |   |                                 |  |
| Ketamine<br>Hydrochlorid      | e  |  |   |                                 |  |

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

|                            |   |   | ctions on the sale and suppl                                   | y of  |
|----------------------------|---|---|--|---|
| Column 1<br>Substance      | prescription<br>Column 2<br>Maximum<br>strength | only medicine. Column 3 Route of administration use or pharmaceuti form   | Column 4<br>Treatment limitations<br>on,                       | Column 5<br>Maximum<br>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                   | sternal] Maximum frequency of application of once every 3 days | [F227(a)] Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole |
|                            |   | [F229(b)] For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo] |  |   |
| Ketoprofen                 | 2.5 per cent                                    | External  For rheumatic and muscular pain in adults and children not less than 12   | For maximum period of 7 days                                   | Container or package containing not more than 30g of medicinal product  |
| Ketorolac<br>Trometamol    |   |   |  |   |
| Ketotifen<br>Fumarate      |   |   |  |   |
| Labetalol<br>Hydrocholoric | 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 [F199Lansoprazole] Latamoxef Disodium [F199]Lercanidipine Hydrochloride] Levallorphan Tartrate Levobunolol Hydrochloride [F187]Levocabastiqueivalent (1) Nasal (1) Hydrochloride of 0.05 Container sprays per cent or package Levocabastine symptomatic containing not more treatment than 10 ml of seasonal allergic

[F230 Levocarnitine]

[F230For dietary

rhinitis

(2) Aqueous

symptomatic

eye drops

treatment

allergic

of seasonal

conjunctivitis

For the

supplementation]

of medicinal product

(2) Container or package containing not more than 4 ml 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 Column 2

Substance Maximum

Maximum Route of T strength administration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or

Column 3

pharmaceutical

form

Levodopa

[F188]Levofloxacin]

Levonorgestre[F2310.75mg] [F231for

use as an emergency contraceptive in women aged 16 years and over]

Lidoflazine

Lignocaine Non-

ophthalmic

use

Lignocaine Hydrochloride Nonophthalmic

use

Lincomycin

Lincomycin Hydrochloride

Liothyronine Sodium

Lisinopril

Lithium Equivalent of 5mg of

Carbonate 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)

|                             |   | Exemptions from the restrictions on the sale and supply of prescription only medicines |  |                                 |  |  |  |
|-----------------------------|---|--|--|---------------------------------|--|--|--|
| Column 1<br>Substance       | Column 2 Maximum strength                             | Column 3 Route of administration use or pharmaceuti                                    | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>quantity |  |  |  |
|                             |   | form   | 9mg (MDD)                                |                                 |  |  |  |
|                             |   | (2) External   | )g (22)                                  |                                 |  |  |  |
| Lobeline<br>Hydrochlorid    | le  | (1) Internal   | (1) Equivalent of 3mg of Lobeline (MD)   |                                 |  |  |  |
|                             |   |  | Equivalent of 9mg of Lobeline (MDD)      |                                 |  |  |  |
|                             |   | (2) External   |  |                                 |  |  |  |
| Lobeline<br>Sulphate        |   | (1) Internal   | (1) Equivalent of 3mg of Lobeline (MD)   |                                 |  |  |  |
|                             |   |  | Equivalent of 9mg of Lobeline (MDD)      |                                 |  |  |  |
|                             |   | (2) External   |  |                                 |  |  |  |
| Lodoxamide<br>Trometamol    | [F232] equivaler<br>of 0.1<br>per cent<br>Lodoxamide] | treatment of ocular  | 3,                                       |                                 |  |  |  |
| Lofepramine                 |   |  |  |                                 |  |  |  |
| Lofepramine<br>Hydrochloric |   |  |  |                                 |  |  |  |
| Lofexidine<br>Hydrochlorid  | le  |  |  |                                 |  |  |  |
| Lomefloxaci<br>Hydrochloric |   |  |  |                                 |  |  |  |
| Lomustine                   |   |  |  |                                 |  |  |  |
| Loperamide<br>Hydrochloric  | le  | Treatment of acute diarrhoea   |  |                                 |  |  |  |
| Loratidine                  |   |  | 10mg (MDD)                               | F234                            |  |  |  |

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

. . .

[F200 Lornoxicam]

[F200]Losartan

Potassium]

Loxapine

Succinate

Lung

Surfactant

Porcine

Luteinising

Hormone

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Maleate

Mafenide

Mafenide

Acetate

Mafenide

Hydrochloride

Mafenide

5.0 per cent Eye drops

Propionate

Magnesium

Fluoride

Magnesium

Metrizoate

Mandragora

Autumnalis

Mannomustine

Hydrochloride

Maprotiline

Hydrochloride

Mebanazine

|                                | •   | •   | ctions on the sale and supp              | ly of  |
|--------------------------------|---|---|--|--|
| Column 1 Column 1 Substance    | orescription<br>Column 2<br>Maximum<br>strength | conly medicine Column 3 Route of administration use or pharmaceuti form                       | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>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<br>Hydrochloride    |   | [F235(a)For<br>the<br>symptomatic<br>relief of<br>irritable<br>bowel<br>syndrome              | [F235(a) 135 mg (MD)<br>405 mg (MDD)]    |  |
|                                |   | (b) For uses other than the symptomatic relief of irritable bowel syndrome]                   | [F235(b) 100 mg (MD)<br>300 mg (MDD)]    |  |
| Mebeverine<br>Pamoate          |   |   |  |  |
| Mebhydrolin                    |   |   |  |  |
| Mebhydrolin<br>Napadisylate    |   |   |  |  |
| Mecamylamine<br>Hydrochloride  |   |   |  |  |
| Mecillinam                     |   |   |  |  |
| Meclofenoxate<br>Hydrochloride |   |   |  |  |
| Medigoxin                      |   |   |  |  |
| Medrogestone                   |   |   |  |  |
| Medroxyproges<br>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

[F199Meloxicam]

Melphalan

Melphalan Hydrochloride

Menotrophin

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic use

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

 $[^{F188}{\rm Mercaptamine}$ 

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 C Substance M

Column 2 Maximum strength Route of Tadministration,

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

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

candidiasis

Mifepristone

Miglitol

Milrinone

Milrinone

Lactate

Minocycline

Minocycline Hydrochloride

Minoxidil

[F236(1) 2.0] $[F^{236}(1)]$ per cent]

External

 $[^{\text{F236}}(2) 5.0]$ per cent

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

[F184Mirtazapine]

Misoprostol

Mitobronitol

Mitomycin

Mitozantrone

Hydrochloride

Mivacurium

Chloride

[F209 Mizolastine]

Moclobemide

[F188 Modafinil]

[F185]Moexipril Hydrochloride]

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

Hydrochloride

Morazone

Hydrochloride

[F184Moxonidine]

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic

Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

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)

|  |                           | from the restric   | ctions on the sale and sup               | ply of   |
|--|---------------------------|--|--|--|
| Column 1<br>Substance                        | Column 2 Maximum strength | Column 3 Route of administration use or pharmaceutic   | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>quantity  |
| Naphazoline<br>Hydrochlorid                  |                           | (1) Nasal<br>sprays<br>or nasal<br>drops not<br>containing<br>liquid<br>paraffin as a<br>vehicle |  |  |
|  | (2) 0.015<br>per cent     | (2) Eye drops  |  |  |
| Naphazoline<br>Nitrate                       | 0.05 per<br>cent          | Nasal sprays<br>or nasal<br>drops not<br>containing<br>liquid<br>paraffin as a<br>vehicle        |  |  |
| Naproxen                                     |                           |  |  |  |
| Naproxen<br>Sodium                           |                           |  |  |  |
| [ <sup>F188</sup> Naratripta<br>Hydrochlorid |                           |  |  |  |
| Natamycin                                    |                           |  |  |  |
| [ <sup>F200</sup> Nebivolo<br>Hydrochlorid   |                           |  |  |  |
| Nedocromil<br>Sodium                         | [F2372.0 per cent]        | [F237]For the prevention, relief and treatment of seasonal and perennial allergic conjunctivitis | ]  | [F237]Container or package containing not more than 3 ml of medicinal product] |
| Nefazodone<br>Hydrochlorid                   | le                        |  |  |  |
| Nefopam<br>Hydrochlorid                      | le                        |  |  |  |
| Neomycin                                     |                           |  |  |  |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

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

[F209 Niceritrol]

Nicotinic Any use, 600mg (MDD) Acid except

except for the treatment of hyperlipidaemia

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

[F187Nilutamide]

Nimodipine

Niridazole

[F200 Nisoldipine]

Nitrendipine

Nitrofurantoin

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

|           |                     | from the restr                          | ictions on the sale and sup <sub>l</sub> es | ply of              |
|-----------|---------------------|---|---|---------------------|
| Column 1  | Column 2            | 001111111111111111111111111111111111111 | Column 4                                    | Column 5            |
| Substance | Maximum<br>strength | Route of administratuse or pharmaceut   |   | Maximum<br>quantity |
|           |                     | form                                    |   |                     |

Nitrofurazone

Nizatidine

For the prevention [F238 and treatment] of the symptoms of food-related heartburn [F238 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

[F239150mg (MDD)]

75mg (MD)

[F240 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 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

[F2413.0 per cent]

[F241 External

For use in combination with

Hydrocortisone

of ma

maximum strength 0.5 per cent for intertrigo

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

Octacosactrin

Octreotide

Oestradiol

Oestradiol

Benzoate

Oestradiol

Cypionate

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

[F241] Container or package containing not more than 15g of medicinal product]

Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Oestradiol

Phenylpropionate

Oestradiol

Undecanoate

Oestradiol

Valerate

Oestriol

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

[F184Omeprazole

Magnesium]

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian

Gland Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

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

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

Oxatomide

Oxedrine Tartrate

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

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

114

Changes to 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<br>nonly medicine                        | ctions on the sale and supplys            | y of                                |                 |
|---------------------------------------|---|--|---|-------------------------------------|-----------------|
| Column 1<br>Substance                 | Column 2<br>Maximum<br>strength   | Column 3 Route of administration use or pharmaceute form |   | Column<br>Maximu<br>quantity        | m               |
| Oxytetracyc<br>Hydrochlori            |   |  |   |                                     |                 |
| Oxytocin, natural                     |   |  |   |                                     |                 |
| Oxytocin, synthetic                   |   |  |   |                                     |                 |
| Pancreatin                            | (1) 21,000<br>European<br>Pharmacopo<br>units of<br>lipase per<br>capsule | (1) capsules   |   |                                     |                 |
|                                       | (2) 25,000<br>European<br>Pharmacopo<br>units of<br>lipase per<br>gram    | (2) powder<br>eia  |   |                                     |                 |
| Pancuronium<br>Bromide                | m   |  |   |                                     |                 |
| [ <sup>F199</sup> Pantopra<br>Sodium] | azole   |  |   |                                     |                 |
| Papaverine                            |   | (1) By inhaler   |   |                                     |                 |
|                                       |   | (2)  | (2) 50mg (MD)                             |                                     |                 |
|                                       |   | Otherwise than by inhaler                                | 150mg (MDD)                               |                                     |                 |
| Papaverine<br>Hydrochlori             | de  | (1) By inhaler   |   |                                     |                 |
|                                       |   | (2)<br>Otherwise   | (2) Equivalent of 50mg of Papaverine (MD) |                                     |                 |
|                                       |   | than by<br>inhaler                                       | Equivalent of 150mg of Papaverine (MDD)   |                                     |                 |
| [F189Paraceta                         | amol (1) [F2422   | 50mg]) Non-<br>effervescent<br>tablets and<br>capsules   |   | (1)<br>quantity<br>sold<br>supplied | The<br>or<br>in |

|           |                             |                          | ctions on the sale and sup | ply 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                     |                            |              |  |  |
|           |                             | [F243wholly              |                            | 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     |  |  |
|           |                             | [ <sup>F244</sup> wholly |                            | 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)                      |                            |              |  |  |
|           |                             | (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 Substance Maximum Route of Treatment limitations Maximum 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

[F199Penciclovir]

Penicillamine

Penicillamine

Hydrochloride

Pentamidine Isethionate

Penthienate Bromide 5mg (MD)

15mg (MDD)

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 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

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

[F245Phenolphthalein.]

Phenoxybenzamine

Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine

Hydrochloride

Phentolamine

Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine Hydrochloride Internal

(1) all preparations

(1) 25mg (MD) 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

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5
Maximum
quantity

use or pharmaceutical

form

Physostigmine Salicylate

Physostigmine Sulphate

[F187Phytomenadione

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 Hydrochloride

50mg (MD)

150mg (MDD)

Pipothiazine Palmitate

Pirbuterol Acetate

Piracetam

Pirbuterol Hydrochloride

Dried)
Pituitary

Powdered (Posterior Lobe)

Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 I<sup>F246</sup>Pirenzepine Dihydrochloride Monohydrate] Pirenzepine Hydrochloride Piretanide Piroxicam 0.5 per cent External For maximum period of 7 Container days or package For the containing relief of not more rheumatic than 30g of pain, pain of medicinal non-serious product arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries For use in adults and children not less than 12 years [F209Piroxicam Betacyclodextrin] **Pituitary** By inhaler Gland (Whole

By inhaler

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Colum Substance Maxin

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

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

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 Column 3 C Route of T administration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Potassium

Clavulanate

Potassium

Perchlorate

Practolol

Pralidoxime

Chloride

Pralidoxime

Iodide

Pralidoxime

Mesylate

[F188Pramipexole

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 Substance Maximum

Maximum Route of T strength administration,

Column 3 Column 4
Route of Treatment limitations

Column 5 t limitations Maximum quantity

use or

pharmaceutical

form

Prednisolone

Steaglate

Prednisone

Prednisone

Acetate

Prenalterol Hydrochloride

Prenylamine Lactate

Prilocaine Hydrochloride Nonophthalmic

use

Primidone

Probenecid

Probucol

Procainamide Hydrochloride

Procaine Hydrochloride Nonophthalmic

use

Procaine Penicillin

Procarbazine Hydrochloride

Prochlorperazine

Prochlorperazine

Edisylate

Prochlorperazine 3mg]

Maleate

[F203Buccal F20312mg (MDD)] tablets

for the treatment of nausea and vomiting in cases of previously diagnosed migraine [F203 Container or package containing not more than 8 tablets]

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

|   |                          |  | ctions on the sale and sup   | ply of              |
|---|--------------------------|--|------------------------------|---------------------|
| Column 1                                    | prescription<br>Column 2 | only medicines<br>Column 3                                       | S<br>Column 4                | Column 5            |
| Substance                                   | Maximum<br>strength      | Route of administration use or pharmaceution form                | Treatment limitations<br>on, | Maximum<br>quantity |
|   |                          | only. For<br>use in<br>persons<br>aged 18<br>years and<br>over.] |                              |                     |
| Prochlorpera:<br>Mesylate                   | zine                     |  |                              |                     |
| Procyclidine<br>Hydrochlorid                | le                       |  |                              |                     |
| Progesterone                                |                          |  |                              |                     |
| Prolactin                                   |                          |  |                              |                     |
| Proligestone                                |                          |  |                              |                     |
| Prolintane<br>Hydrochlorid                  | le                       |  |                              |                     |
| Promazine<br>Embonate                       |                          |  |                              |                     |
| Promazine<br>Hydrochlorid                   | le                       |  |                              |                     |
| Propafenone                                 |                          |  |                              |                     |
| Propafenone<br>Hydrochlorid                 | le                       |  |                              |                     |
| Propanidid                                  |                          |  |                              |                     |
| Propantheline<br>Bromide                    | е                        |  | 15mg (MD)<br>45mg (MDD)      |                     |
| [ <sup>F200</sup> Propiveri<br>Hydrochlorid |                          |  |                              |                     |
| Propofol                                    |                          |  |                              |                     |
| Propranolol<br>Hydrochlorid                 | le                       |  |                              |                     |
| Propylthioura                               | acil                     |  |                              |                     |
| Proquazone                                  |                          |  |                              |                     |
| Protamine<br>Sulphate                       |                          |  |                              |                     |

Status: Point in time view as at 01/06/2010.

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

|                               | prescription                    | n only medicine   | ections on the sale and supply                     |  |
|-------------------------------|---------------------------------|---|--|--|
| Column 1<br>Substance         | Column 2<br>Maximum<br>strength | Column 3 Route of administrati use or pharmaceut  | •  | Column 5<br>Maximum<br>quantity  |
| Prothionami                   | de                              |   |  |  |
| Protirelin                    |                                 |   |  |  |
| Protriptyline<br>Hydrochlorid |                                 |   |  |  |
| Proxymetaca<br>Hydrochlorid   |                                 | Non-<br>ophthalmic<br>use   |  |  |
| Pseudoephed<br>Hydrochlorid   |                                 | Internal  | (a) In the case of a prolonged release preparation |  |
|                               |                                 |   | 120mg (MD)   |  |
|                               |                                 |   | 240mg (MDD)  |  |
|                               |                                 |   | (b) in any other case 60mg (MD)                    |  |
|                               |                                 |   | 240mg (MDD)  |  |
| Pseudoephed                   | drine                           |   | 60mg (MD)  |  |
| Sulphate                      |                                 |   | 180mg (MDD)  |  |
| Pyrantel<br>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 restra  | ictions on the sale and suppers | ply of              |
|-----------|---------------------|--|---------------------------------|---------------------|
| Column 1  | Column 2            | Column 3   | Column 4                        | Column 5            |
| Substance | Maximum<br>strength | Route of Treatment limitations administration, use or pharmaceutical |                                 | Maximum<br>quantity |
|           |                     | form   |                                 |                     |
|           |                     | years but  |                                 | than 750mg          |
|           |                     | not less than  |                                 | of Pyrantel         |
|           |                     | 2 years  |                                 | Embonate            |

Pyrantel Tartrate

Pyrazinamide

Pyridostigmine

Bromide

Pyrimethamine

[F200 Quetiapine Fumarate]

[<sup>F185</sup>Quinagolide Hydrochloride]

Quinapril

[F246Quinapril Hydrochloride]

Quinestradol

Quinestrol

Quinethazone

Quinidine

Quinidine Bisulphate

Quinidine

Polygalacturonate

Quinidine Sulphate

Quinine 100mg (MD)

300mg (MDD)

Quinine Equivalent of 100mg of

Bisulphate Quinine (MD)

Equivalent of 300mg of

Quinine (MDD)

Quinine Equivalent of 100mg of

Cinchophen Quinine (MD)

Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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<br>Substance  | Column 2<br>Maximum<br>strength | Column 3 Route of administrati use or pharmaceut form | ,                                    | Column 5<br>Maximum<br>quantity |
|  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Dihydrochlo   | ride                            |   | Equivalent of 100mg of Quinine (MD)  |                                 |
|  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Ethyl   |                                 |   | Equivalent of 100mg of Quinine (MD)  |                                 |
| Carbonate  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Glycerophos   | phate                           |   | Equivalent of 100mg of Quinine (MD)  |                                 |
|  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Hydrobromi  | de                              |   | Equivalent of 100mg of Quinine (MD)  |                                 |
|  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Hydrochlorio  | de                              |   | Equivalent of 100mg of Quinine (MD)  |                                 |
| J  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Iodobismuth   | ate                             |   | Equivalent of 100mg of Quinine (MD)  |                                 |
|  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Phosphate   |                                 |   | Equivalent of 100mg of Quinine (MD)  |                                 |
| 1  |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Salicylate  |                                 |   | Equivalent of 100mg of Quinine (MD)  |                                 |
| <i>y</i>   |                                 |   | Equivalent of 300mg of Quinine (MDD) |                                 |
| Quinine<br>Sulphate  |                                 |   | Equivalent of 100mg of Quinine (MD)  |                                 |

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

|   | Exemptions from the restrictions on the sale and supply of prescription only medicines |   |   |                                 |  |  |
|---|--|---|---|---------------------------------|--|--|
| Column 1<br>Substance                               | Column 2<br>Maximum<br>strength  | Column 3 Route of administration use or pharmaceuti form  |   | Column 5<br>Maximum<br>quantity |  |  |
| Quinine   |  |   | Equivalent of 300mg of<br>Quinine (MDD)<br>Equivalent of 100mg of |                                 |  |  |
| Tannate   |  |   | Quinine (MD)  |                                 |  |  |
|   |  |   | Equivalent of 300mg of Quinine (MDD)                              |                                 |  |  |
| Quinine in combination with Urea Hydrochloride      | e  |   |   |                                 |  |  |
| Ramipril  |  |   |   |                                 |  |  |
| [ <sup>F184</sup> Ranitidine<br>Bismuth<br>Citrate] | <b>;</b>   |   |   |                                 |  |  |
| Ranitidine<br>Hydrochloride                         | <del>)</del>   | For the short term  | Equivalent to 75mg of Ranitidine (MD)                             |                                 |  |  |
|   |  | symptomatic relief of   | Equivalent to 300mg of Ranitidine (MDD)                           |                                 |  |  |
|   |  | heartburn,<br>dyspepsia,  | For a maximum period of   |                                 |  |  |
|   |  | indigestion, acid indigestion and hyperacidity [F247 or the prevention of these symptoms when associated with consuming food and drink] | 14 days   |                                 |  |  |
| Rauwolfia<br>Serpentina                             |  |   |   |                                 |  |  |
| Rauwolfia<br>Vomitoria                              |  |   |   |                                 |  |  |

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

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

pharmaceutical

use or

form

Column 4
Treatment limitations

Column 5 Maximum quantity

Razoxane

[F188]Reboxetine

Mesilate]

Remoxipride

Hydrochloride

Reproterol Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

[F184Rimexolone]

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

[F204Ropinirole

Hydrochloride]

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 Substance Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Salmeterol

Xinafoate

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

[F188Sertindole]

[F184]Sertraline

Hydrochloride]

Serum

Gonadotrophin

[F184Sevoflurane]

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake

Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

Status: Point in time view as at 01/06/2010.

Changes to 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   | ections on the sale and sup<br>es | ply of  |
|-----------------------|---------------------------------|---|-----------------------------------|---|
| Column 1<br>Substance | Column 2<br>Maximum<br>strength | Column 3 Route of administrati use or pharmaceute form  | ,                                 | Column 5<br>Maximum<br>quantity   |
| Sodium<br>Arsenite    | 0.013 per cent                  |   |                                   |   |
| Sodium<br>Bromide     |                                 |   |                                   |   |
| Sodium<br>Clodronate  |                                 |   |                                   |   |
| Sodium<br>Cromoglyca  | te                              | (a) For nasal admistration  |                                   |   |
|                       | (b) 2.0 per cent                | (b) For the treatment of acute seasonal allergic conjunctivitis [F248 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   | s                                 | (c) Container or package containing not more than 5g of                     |
|                       |                                 | In the form of an eye ointment  |                                   | medicinal<br>product  |
| Sodium<br>Ethacrynate |                                 | -   |                                   |   |
| Sodium<br>Fluoride    | (1) 0.33 per cent               | (1)<br>Dentifrices  |                                   |   |
|                       |                                 | (2) Other preparations for use in the prevention  |                                   |   |

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

|                             | Exemptions from the restrictions on the sale and supply of prescription only medicines |   |                  |                                 |  |  |
|-----------------------------|--|---|------------------|---------------------------------|--|--|
| Column 1<br>Substance       | Column 2<br>Maximum<br>strength  | Column 3 Route of administration use or pharmaceutiform of dental |                  | Column 5<br>Maximum<br>quantity |  |  |
|                             |  | caries  |                  |                                 |  |  |
|                             |  | In the form of  |                  |                                 |  |  |
|                             |  | (a) tablets or drops  | (a) 2.2 mg (MDD) |                                 |  |  |
|                             | (b) 0.2 per cent   | (b) mouth<br>rinses other<br>than those<br>for daily use          |                  |                                 |  |  |
|                             | (c) 0.05 per cent  | (c) mouth rinses for daily use                                    |                  |                                 |  |  |
| Sodium<br>Fusidate          |  |   |                  |                                 |  |  |
| Sodium<br>Metrizoate        |  |   |                  |                                 |  |  |
| Sodium<br>Monofluorop       | 1.14 per<br>phæspthate   | Dentrifrice   |                  |                                 |  |  |
| Sodium<br>Oxidronate        |  |   |                  |                                 |  |  |
| Sodium<br>Stiboglucona      | ate  |   |                  |                                 |  |  |
| Sodium<br>Valproate         |  |   |                  |                                 |  |  |
| Somatorelin<br>Acetate      |  |   |                  |                                 |  |  |
| Sotalol<br>Hydrochlorid     | de   |   |                  |                                 |  |  |
| F185Sparflox                | acin]  |   |                  |                                 |  |  |
| Spectinomy                  | ein  |   |                  |                                 |  |  |
| Spectinomyo<br>Hydrochlorio |  |   |                  |                                 |  |  |
| Spiramycin                  |  |   |                  |                                 |  |  |
| Spiramycin<br>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)

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 Spironolactone  $([^{F249}1])$ Stannous  $([^{F249}1])$ Fluoride 0.62 per Dentifrice cent  $I^{F249}(2)$ [F249(2) 0.4 Dental per] gels for use in the prevention and treatment of dental caries and decalcification of the teeth] Stilboestrol Stilboestrol Dipropionate Streptodornase External Streptokinase External Streptomycin Streptomycin Sulphate Strychnine Strychnine Arsenate Strychnine Hydrochloride [F187Strychnine Nitrate] Styramate

Succinylsulphathiazole

Sucralfate Sulbactam Sodium Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

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

Exemptions from the restrictions on the sale and supply of

prescription only medicines

Column 1 C
Substance M

Column 2 Maximum strength Route of Tadministration,

Column 4
Treatment limitations

Column 5 Maximum quantity

use or

pharmaceutical

form

Sulbenicillin

Sulbenicillin

Sodium

Sulconazole Nitrate External (except

vaginal)

[F187Sulfabenzamide]

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

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

[F200 Tacalcitol Monohydrate]

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin

Napsylate

Tamoxifen

Tamoxifen

Citrate

[F199 Tamsulosin Hydrochloride]

[F184Tazarotene]

Tazobactam

Sodium

Teicoplanin

[F188 Temocapril Hydrochloride]

Temocillin

Sodium

Tenoxicam

Terazosin Hydrochloride

Terbinafine [F2501.0 per

cent]

[F251] External use for the treatment of tinea pedis, tinea cruris and tinea corporis. In the form of a gel]

[F252] Container or package containing not more than 30 grams of medicinal product]

Status: Point in time view as at 01/06/2010.

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

|   |                                 | from the restriction only medicine   | ctions on the sale and sup<br>s          | ply of   |  |
|---|---------------------------------|--|--|--|--|
| Column 1<br>Substance   | Column 2<br>Maximum<br>strength | Column 3 Route of administration use or pharmaceutiform  | Column 4<br>Treatment limitations<br>on, | Column 5<br>Maximum<br>quantity  |  |
| [ <sup>F253</sup> Terbinafin∉ <sup>F253</sup> 1.0 per<br>Hydrochloridedent] |                                 | ([F254]]) [F255] Preparation other than spray solutions, for [F253] externuse for the treatment of tinea pedis and tinea cruris] |  | ([F2541])<br>[F253]Container<br>or package<br>containing<br>not more<br>than 15 g of<br>medicinal<br>product.] |  |
|   |                                 | [F256(2)] Spray solutions for external use for the treatment of tinea corporis, tinea cruris and tinea pedis]                    |  | [F256(2)<br>Container<br>containing<br>not more<br>than 30ml<br>of medicinal<br>product]                       |  |
| Terbutaline   |                                 |  |  |  |  |
| Terbutaline<br>Sulphate   |                                 |  |  |  |  |
| Terfenadine   |                                 |  | F257                                     | F257   |  |
| Terlipressin  |                                 |  | •••                                      |  |  |
| Terodiline<br>Hydrochloric  | de                              |  |  |  |  |
| [F188 Testoster   | one]                            |  |  |  |  |
| Tetrabenazin  | e                               |  |  |  |  |
| Tetracosactri   | n                               |  |  |  |  |
| Tetracosactri<br>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

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

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

Thyrotrophin

Thyroxine

Sodium

Tiamulin

Fumarate

Tiaprofenic

Acid

Tibolone

Ticarcillin

Sodium

[F199Ticlopidine

Hydrochloride]

Tigloidine

Hydrobromide

[F199Tiludronate

Disodium]

Timolol

Maleate

Tinidazole

Tinzaparin

Tioconazole (1) 2.0 per

cent

(1) External (except vaginal)

(2) Vaginal

for

treatment of vaginal candidiasis

[F185Tizanidine Hydrochloride]

Tobramycin

Tobramycin

Sulphate

Tocainide

Hydrochloride

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

Exemptions from the restrictions on the sale and supply of prescription only medicines Column 1 Column 2 Column 3 Column 4 Column 5 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

[F184Topiramate]

[F209 Torasemide]

[F199 Toremifene]

Tramadol Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolonq<sup>F258</sup>(1)] 0.1 Acetonide per cent [F258(1)] For the treatment of common mouth ulcers

[F258(1)] Container or package containing not more than 5g of

Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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<br>Substance           | Column 2<br>Maximum<br>strength  | Column 3 Column 4 Route of Treatment limitations administration, use or pharmaceutical form   |   | Column 5<br>Maximum<br>quantity   |
|                                 |  |   |   | medicinal product   |
|                                 |  | [F259] (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] | [F259(2) 110mcg per nostril (MD) 110mcg per nostril (MDD) For a maximum period of 3 months] | [F259]Container or package containing not more than 3.575mg of Triamcinolone Acetonide] |
| Triamcinolone<br>Diacetate      | <b>;</b>   |   |   |   |
| Triamcinolone<br>Hexacetonide   | <b>)</b>   |   |   |   |
| Triamterene                     |  |   |   |   |
| Tribavirin                      |  |   |   |   |
| Triclofos<br>Sodium             |  |   |   |   |
| Trientine<br>Dihydrochlori      | de   |   |   |   |
| Trifluoperazin                  | e  |   |   |   |
| Trifluoperazin<br>Hydrochloride |  |   |   |   |
| Trifluperidol                   |  |   |   |   |
| Trifluperidol<br>Hydrochloride  | ;  |   |   |   |
| Trilostane                      |  |   |   |   |
| Trimeprazine                    |  |   |   |   |
| Trimeprazine<br>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 Substance Maximum Route of Treatment limitations Maximum administration, strength quantity use or pharmaceutical form

Trimetaphan Camsylate

Trimetazidine

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

L- (1) Oral

Tryptophan Dietary

supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

Tulobuterol Hydrochloride

Tyrothricin Throat

lozenges or throat pastilles

Uramustine

Urea Stibamine

Urethane

Uridine 5'triphosphate

Urofollitrophin

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

[F185 Valaciclovir Hydrochloride]

Valproic

Acid

[F188 Valsartan]

Vancomycin

Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

[F185 Venlafaxine

Hydrochloride]

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

Veratrum,

White

Vidarabine

Vigabatrin

Viloxazine

Hydrochloride

Zidovudine

Status: Point in time view as at 01/06/2010.

Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (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 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) Internal (1) Equivalent to 7,500iu 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 [F185Zalcitabine]

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

Zimeldine

Hydrochloride

Zolpidem

Tartrate

Zomepirac

Sodium

Zopiclone

Zuclopenthixol

Acetate

Zuclopenthixol

Decanoate

Zuclopenthixol

Hydrochloride]

#### **Textual Amendments**

- F184 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)
- **F185** 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)
- F186 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)
- **F187** Words in Sch. 1 inserted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), art. 1(1), **Sch.**
- F188 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)
- F189 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
- **F190** 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)**
- F191 Words in Sch. 1 substituted (16.9.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 1998 (S.I. 1998/2081), arts. 1(1), 3(a)
- F192 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)
- F193 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)
- **F194** 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)
- **F195** 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)

- F196 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)
- **F197** 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)
- F198 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)
- **F199** 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)
- F200 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)
- **F201** 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)**
- **F202** 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)**
- F203 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)
- **F204** 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)**
- **F205** 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)
- **F206** 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)**
- **F207** 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)
- **F208** 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)
- **F209** 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)
- **F210** 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)
- **F211** 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)**
- F212 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)
- **F213** 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)**
- **F214** 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)**
- F215 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)
- **F216** 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)**
- **F217** 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)**
- **F218** 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)**
- **F219** 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)**
- F220 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)
- F221 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)

- F222 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)
- **F223** 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)
- F224 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)
- **F225** 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)
- F226 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)
- F227 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)
- **F228** 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)
- **F229** 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)
- **F230** 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)**
- F231 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
- **F232** 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)
- **F233** 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)
- **F234** 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)**
- **F235** 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)**
- F236 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)
- **F237** 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)**
- **F238** 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)
- F239 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)
- **F240** 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)
- F241 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)
- **F242** 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)
- **F243** 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)
- **F244** 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)
- **F245** 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)**
- **F246** 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)**
- F247 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)

- **F248** 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)
- F249 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)
- **F250** 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)
- F251 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)
- F252 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)
- F253 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)
- F254 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)
- F255 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)
- **F256** 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)
- F257 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)
- **F258** 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)
- **F259** 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)

#### [F260SCHEDULE 2

Article 10(1)

### SUBSTANCES WHICH MAY BE EXCLUDED FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES AT HIGH DILUTION

#### **Textual Amendments**

**F260** Sch. 2 substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), 12

Codeine and its salts

Dihydrocodeine and its salts

Ethylmorphine and its salts

Morphine and its salts

Medicinal Opium

Pholcodine and its salts]

#### SCHEDULE 3

Article 2(b)

### DESCRIPTIONS AND CLASSES OF PRESCRIPTION ONLY MEDICINES IN RELATION TO WHICH [F261 community practitioner nurse prescribers] ARE APPROPRIATE PRACTITIONERS

#### **Textual Amendments**

**F261** Words in Sch. 3 heading substituted (1.5.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (S.I. 2006/915), arts. 1(1), **13** 

[F262Co-danthramer Capsules NPF]

[F262Co-danthramer Capsules, Strong NPF]

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[F262Co-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

[F263Water for Injections]

#### **Textual Amendments**

**F262** 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

**F263** 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

#### F264SCHEDULE 3A

Article 3A

# CONTROLLED DRUGS WHICH MAY BE PRESCRIBED, ADMINISTERED OR DIRECTED FOR ADMINISTRATION BY NURSE INDEPENDENT PRESCRIBERS AND CONDITIONS FOR SUCH PRESCRIPTION OR ADMINISTRATION

#### **Textual Amendments**

**F264** Sch. 3A omitted (1.4.2008) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 2008 (S.I. 2008/464), arts. 1(1), **10** 

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

#### [F265SCHEDULE 3B

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

#### PARTICULARS FOR CLINICAL MANAGEMENT PLANS

#### **Textual Amendments**

F265 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;
- (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 MEDICINE 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

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

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

#### SCHEDULE 5

Article 11(1)(a)

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

# PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

| Column 1<br>Persons exempted | Column 2 Prescription only medicines to which the exemption applies  1. All prescription only medicines |    | lumn 3<br>nditions | ï  |   |
|------------------------------|---|----|--------------------|--|---|
|                              |   | 1. | be— (a)            | subjection characteristics subjection characteri | r supply shall ect to the entation of rder signed he principal e institution erned with ation or arch or the opriate head epartment harge of a lifted course of arch stating—the name of the institution for which the prescription only medicine is required, the purpose for which the prescription only medicine only medicine only medicine |
|                              | 152   |    |                    |  | ,   |

| Column 1 Column 2 Persons exempted Prescription only medicing to which the exemption applies |                         | Prescription only medicines to which the exemption  | Column 3<br>Conditions              |  |   |
|--|-------------------------|---|-------------------------------------|--|---|
|  |                         |   |                                     | (b)  | is required,<br>and (iii) the total<br>quantity<br>required, and<br>for the purposes<br>of the education<br>or research<br>with which the<br>institution is<br>concerned.   |
| 2.   | supponly the factor (1) | sons selling or olying prescription medicines to any of following— a public analyst appointed under section 27 of the Food Safety Act 1990(15) or article 36 of the Food (Northern Ireland) Order 1989(16), an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990, | 2. All prescription only medicines. | subject to<br>an order s<br>of any per<br>1 of this p<br>status of t<br>and the ar<br>only medi<br>shall be or<br>with the e | the presentation of igned by or on behalf son listed in column baragraph stating the he person signing it mount of prescription to incident required, and only in connection exercise by those of their statutory |
|  | (3)                     | a sampling officer<br>within the meaning<br>of article 38(1) of<br>the Food (Northern<br>Ireland) Order<br>1989,  |                                     |  |   |
|  | (4)                     | a person duly<br>authorized by<br>an enforcement<br>authority under<br>sections 111 and<br>112,   |                                     |  |   |
|  | (5)                     | a sampling officer within the meaning of Schedule 3 to the Act.   |                                     |  |   |

<sup>(15) 1990</sup> c. 16. (16) S.I. 1989/846 (N.I. 6).

| Column 1  | Column 2   | Column 3   |  |
|---|--|--|--|
| Persons exempted  | Prescription only medicines to which the exemption applies   | Conditions   |  |
| 3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(17), the National Health Service (Scotland) Act 1978(18) and the Health and Personal Social Services (Northern Ireland) Order 1972(19), or under any subordinate legislation made under those Acts or that Order. | 3. All prescription only medicines.  | 3. The sale or supply shall be—  (a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only medicine required, and  (b) for the purposes of a scheme referred to in column 1 in this paragraph. |  |
| 4. Registered midwives.   | 4. [F266Prescription only medicines containing any of the following substances— Diclofenac Ergometrine maleate Hydrocortizone Acetate Lidocaine Lidocaine Hydrochloride Miconazole Nystatin Phytomenadione.] | 4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.   |  |
| 5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.   | 5. Prescription only medicines which are not for parenteral administration and which—  (a) are eyes drops and are prescription only medicines by reason only that they contain not more than                 | 5. The sale or supply shall be subject to the presentation of an order signed by a [F271 registered optometrist].  |  |

<sup>(17) 1977</sup> c. 49. (18) 1978 c. 29. (19) S.I. 1972/1265 (N.I. 14).

| Column 1  | Column 2  |   | Column  | 3                               |
|---|---|---|---|---------------------------------|
| Persons exempted  | Prescription only medicines   |   | Conditio  |                                 |
| •   | to which the exemption  |   |   |                                 |
|   | applies   |   |   |                                 |
|   | 0.5 per<br>Chlora<br>or   | cent<br>mphenicol,  |   |                                 |
|   | and are only m by reas that the not mo 1.0 per  |   |   |                                 |
|   | (c) are predonly moreason they conform for the following substant for the following | scription edicines by only that ontain any following nces: 267 267 267 Cyclopentolate ydrochloride F <sup>268</sup> Fusidic acid] 269 269 269 269 269 269 269 269 269 269 269 269 270 269 270 269 270 |   |                                 |
| 6. [F272Registered optometrists]                              | 6. Prescription onl listed in column 2 5.   | y medicines   |   | their professional practice and |
| [F273 <b>6A</b> Persons lawfully conducting a retail pharmacy | Homotropine hydrobromide  Ketotifen   |   | The sale or supply shall be subject to the presentation of an order signed by an additional supply optometrist. |                                 |
| business within the meaning of section 69.                    |   |   |   |                                 |
| Section 07.   | Levocabastine   |   | 11 5 1  |                                 |
|   | Lodoxamide  |   |   |                                 |

Status: Point in time view as at 01/06/2010.

Changes to 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<br>Persons exempted  | Column 2 Prescription only medicines to which the exemption applies           |              | umn 3<br>aditions   |   |
|---|---|--------------|---|---|
|   | Nedocromil sodium   |              |   |   |
|   | Olopatadine   |              |   |   |
|   | Pilocarpine hydrochloride   |              |   |   |
|   | [F274Pilocarpine nitrate]   |              |   |   |
|   | Polymyxin B/bacitracin  |              |   |   |
|   | Polymyxin B/trimethoprim  |              |   |   |
|   | Sodium cromoglycate.  |              |   |   |
| <b>6B</b> Additional supply optometrists.   | Prescription only medicines specified in column 2 of paragraph 6A.            | The only (a) | in the co   | urse of their onal practice, and ergency.]  |
| 7. Persons selling or supplying prescription only medicines to the British Standards Institution. | 7. All prescription only medicines.   | 7.           | be— (a) sub pre an on Bri Ins the per and the onl required to onl pur cor sta | or supply shall  oject to the esentation of order signed behalf of the itish Standards stitution stating e status of the eson signing it d the amount of exprescription ly medicine quired, and ly for the expose of testing ntainers of edicinal products determining the ndards for such intainers. |
| 8. Holders of marketing authorizations, product licences or manufacturer's licences.              | 8. Prescription only medicines referred to in the authorizations or licences. | 8.           | be only— (a) to a (b) so that to j ent  | or supply shall a pharmacist, as to enable at pharmacist prepare an ary relating to prescription  |

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

| Column 1  | Column 2   | Column 3  |  |
|---|--|---|--|
| Persons exempted  | Prescription only medicines to which the exemption applies | Conditions  |  |
|   |  | only medicine in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose. |  |
| 9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act | 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.                                   |  |

[F275]F27610. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2.]

Order 1976(21).

1972(20) 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)

- ed 10. The following whose prescription only medicines—
  - (a) Co-dydramol 10/500 tablets;
  - (b) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;
  - (c) Amorolfine
    hydrochloride
    lacquer where the
    maximum strength
    of the Amorolfine in
    the lacquer does not

10. The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days' treatment to a maximum of 24 tablets.]

<sup>(20) 1972</sup> c. 66.

<sup>(21)</sup> S.I. 1976/1214 (N.I. 23).

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

| Column 1         | Column               | 2   | Column 3   |
|------------------|----------------------|---|------------|
| Persons exempted | •                    | tion only medicines<br>the exemption  | Conditions |
|                  |                      | exceed 5 per cent by weight in volume;  |            |
|                  | (d)                  | Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight [F278 in weight; and] |            |
|                  | F <sup>279</sup> (e) | Amoxicillin;  |            |
|                  | (f)                  | Erythromycin;   |            |
|                  | (g)                  | Flucoxacillin;  |            |
|                  | (h)                  | Tioconazole 28%; and  |            |
|                  | (i)                  | Silver Sulfadiazine.]   |            |

#### **Textual Amendments**

- **F266** Words in Sch. 5 Pt. 1 para. 4 substituted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), 3(3)(a)
- **F267** Words in Sch. 5 Pt. 1 para. 5 omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), 8(a)
- **F268** Words in Sch. 5 Pt. 1 para. 5 inserted (7.4.2005) by The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), **8(b)**
- **F269** Words in Sch. 5 Pt. 1 omitted (7.4.2005) by virtue of The Medicines for Human Use (Prescribing) Order 2005 (S.I. 2005/765), arts. 1(1), 8(c)
- **F270** Words in Sch. 5 Pt. 1 para. 5 omitted (30.6.2005) by virtue of The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 7(1)(a)
- F271 Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), Sch. 1 para. 27(b)
- F272 Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), Sch. 1 para. 27(b)
- F273 Sch. 5 Pt. 1 paras. 6A, 6B inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), 7(1)(b)
- **F274** Words in Sch. 5 Pt. 1 Table inserted (6.1.2006) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) (No. 2) Order 2005 (S.I. 2005/3324), arts. 1(1), **3**
- **F275** Words in Sch. 5 Pt. 1 para. 10 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), **4(2)(a)**
- **F276** 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.**

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

- **F277** Word in Sch. 5 Pt. 1 para. 10 omitted (17.11.2006) by virtue of The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(2)(b)(i)
- F278 Words in Sch. 5 Pt. 1 para. 10 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(2)(b)(ii)
- **F279** Words in Sch. 5 Pt. 1 para. 10 added (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(2)(b)(iii)

Article 11(1)(b)

## PART II EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

| Column 1  | Column 2  | Column 3   |
|---|---|--|
| Persons exempted  | Prescription only medicines to which the exemption applies                                    | Conditions   |
| 1. Royal National Lifeboat<br>Institution and certified first<br>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.  |
| [F280]3A. Persons employed or engaged in the provision of lawful drug treatment services.   | 3A. Ampoules of sterile water for injection containing not more than 2 ml of sterile water.   | 3A. The supply shall be only in the course of provision of lawful drug treatment services.]  |
| 4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees. | 4. Such prescription only medicines as may be specified in the relevant enactment.            | 4. The supply shall be—  (a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and  (b) subject to such conditions and in such circumstances as may be specified |
|   | 150   |  |

Status: Point in time view as at 01/06/2010.

Changes to 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  |
|   | 11  | in the relevant enactment.  |
| 5. Persons operating an occupational health scheme.   | 5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.                                    | <ul> <li>(1) The supply shall be in the course of an occupational health scheme.</li> <li>(2) The individual supplying the prescription only medicine, if not a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme.</li> </ul> |
| 6. The operator or commander of an aircraft.  | 6. Prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor. | 6. The supply shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.  |
| 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.  |
| [F281 8. Persons who hold a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain | 8 Prescription only medicines supplied to a person specified in column 1 in response to an order in writing signed by a doctor.   | 8 The supply shall be only so far as is necessary for the treatment of sick or injured persons in the course of providing mountain rescue services.]  |

Changes to 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  Rescue Co-ordinating Committee.          | Column 2 Prescription only medicines to which the exemption applies | Column 3<br>Conditions  |
|---|---|---|
| [F282] Persons ("P") who are members of Her Majesty's armed forces. | 9. All prescription only medicines.                                 | <ul> <li>9. The supply shall be— <ul> <li>(a) in the course of P</li> <li>undertaking any function as a member of Her</li> <li>Majesty's armed forces; and</li> </ul> </li> <li>(b) where P is satisfied that it is not practicable for another person who is legally entitled to supply a prescription only medicine to do so; and</li> <li>(c) only in so far as is necessary— <ul> <li>(i) for the treatment of a sick or injured person in a medical emergency, or</li> <li>(ii) to prevent illhealth where there is a risk that a person would suffer illhealth if the prescription only medicine is not supplied.]</li> </ul> </li> </ul> |

#### **Textual Amendments**

- **F280** Sch. 5 Pt. 2 para. 3A inserted (30.6.2005) by The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2005 (S.I. 2005/1507), arts. 1(1), **7(2)**
- F281 Sch. 5 Pt. 2 para. 8 inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(3)
- **F282** Sch. 5 Pt. 3 para. 10 added (21.12.2009) by The Medicines (Exemptions and Miscellaneous Amendments) Order 2009 (S.I. 2009/3062), arts. 1(1), **3(2)**

Article 11(2)

Status: Point in time view as at 01/06/2010. Changes to legislation: There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997. (See end of Document for details)

### PART III EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

| Column 1   | Column 2  | Column 3   |  |
|--|---|--|--|
| Persons exempted   | Prescription only medicines to which the exemption applies  | Conditions   |  |
| [F283]. Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified in column 2] | 1. Prescription only medicines for parenteral administration that contain, as the sole active ingredient, not more than one of the following substances—  [F284] Adrenaline] [F285] Bupivacaine hydrochloride Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride [F284] Levobupivacaine hydrochloride [Lignocaine hydrochloride Lignocaine hydrochloride with adrenaline where the maximum strength of the adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride [F286] Mepivacaine hydrochloride [F286] Mepivacaine hydrochloride.] [F284] [F284] Methylprednisc Prilocaine hydrochloride.] [F284] [F284] Ropivacaine hydrochloride.] | ne   |  |
| 2. Registered midwives.  | 2. Prescription only medicines for parenteral   | 2. The administration shall be only in the course of their |  |

in the case of Promazine

administration containing professional practice and

Status: Point in time view as at 01/06/2010.

Changes to 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   |
|   | substances but no other substance specified in column 1 of Schedule 1 to this Order—  [F287] Adrenaline Anti-D immunoglobulin Carboprost Cyclizine hydrochloride Diamorphine Ergometrine maleate Gelofusine Haemaccel Hartmann's solution Hepatitis B vaccine Hepatitis immunoglobulin Lidocaine Lidocaine hydrochloride Morphine Naloxone hydrochloride Oxytocins, natural and synthetic Pethidine hydrochloride Phytomenadione Prochloperazine Sodium chloride 0.9%.] | hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.                                     |
| 3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only. | 3. Prescription only medicines that are specified in the group authority.   | 3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority. |
| 4. The owner or master of a ship which does not carry a doctor on board as part of her complement.  | 4. All prescription only medicines that are for parenteral administration.  | 4. The administration shall be only so far as is necessary for the treatment of persons on the ship.   |
| 5. Persons operating an occupational health scheme.   | 5. Prescription only medicines for parenteral administration  | 5. —   |
|   | 162   |  |

| Column 1  | Column 2  | Column 3  |
|---|---|---|
| Persons exempted  | Prescription only medicines to which the exemption applies  | Conditions  |
|   | 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.   | (1) The administration shall be in the course of an occupational health scheme.   |
|   |   | (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used in the course of the occupational health scheme. |
| 6. The operator or commander of an aircraft.  | 6. Prescription only medicines for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor. | 6. The administration shall be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.  |
| 7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, 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.  |

| Column 1  | Column 2   | Column 3   |
|---|--|--|
| Persons exempted  | Prescription only medicines to which the exemption applies   | Conditions   |
| 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 [F288] or persons who are [F289] registered] paramedics]. | 9. The following prescription only medicines for parenteral administration—  (a) Diazepam 5 mg per ml emulsion for injection;  (b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion;  (bb) [F290] medicines containing the substances Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml, but no other active ingredient]  (d) prescription only medicines containing one or more of the following substances, but no active ingredient—  Adrenaline Acid Tartrate [F291] Amiodaron Anhydrous Glucose [F292] Benzylpen [F293] Bretylium Tosylate] Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution) |  |

Changes to 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                      |            |
|                  | Ergometrine                  |            |
|                  | Maleate                      |            |
|                  | [ <sup>F292</sup> Frusemide  | e]         |
|                  | Glucose                      |            |
|                  | Heparin                      |            |
|                  | Sodium                       |            |
|                  | Lignocaine                   |            |
|                  | Hydrochloride                | e          |
|                  | [ <sup>F292</sup> Metoclopi  | ramide]    |
|                  | [F292Morphine                |            |
|                  | Sulphate]                    |            |
|                  | Nalbuphine                   |            |
|                  | Hydrochloride                | e          |
|                  | Naloxone                     |            |
|                  | Hydrochloride                | e          |
|                  | Polygeline                   |            |
|                  | [F294Reteplase               |            |
|                  | j                            |            |
|                  | Sodium                       |            |
|                  | Bicarbonate                  |            |
|                  | Sodium                       |            |
|                  | Chloride                     |            |
|                  | [ <sup>F292</sup> Streptokin | nase]      |
|                  | [F294Tenectepla              | ase.]      |

[F282] 10 . Persons ("P") who are members of Her Majesty's armed forces.

10. All prescription only medicines.

- 10. The administration shall be—
- (a) in the course of P undertaking any function as a member of Her Majesty's armed forces; and
- (b) where P is satisfied that it is not practicable for another person who is legally entitled to administer a prescription only medicine to do so; and
- (c) only in so far as is necessary—
  - (i) for the treatment of a sick or injured person in a medical emergency, or
  - (ii) to prevent illhealth where there is a risk that 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)

| Column 1         | Column 2   | Column 3   |
|------------------|--|--|
| Persons exempted | Prescription only medicines to which the exemption applies | Conditions   |
|                  |  | person would suffer ill-health if the prescription only medicine is not administered.] |

#### **Textual Amendments**

- **F283** Words in Sch. 5 Pt. 3 para. 1 substituted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(4)(a)
- F284 Words in Sch. 5 Pt. 3 para. 1 inserted (17.11.2006) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 (S.I. 2006/2807), arts. 1(1), 4(4)(b)
- F285 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)
- **F286** 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)
- F287 Words in Sch. 5 Pt. 3 para. 2 substituted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), 3(3)(b)
- **F288** 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)**
- **F289** 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)**
- **F290** 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)**
- **F291** Word in Sch. 5 Pt. 3 para. 9 inserted (19.11.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2004 (S.I. 2004/2693), arts. 1(1), 6
- **F292** 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)
- **F293** 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
- **F294** Words in Sch. 5 Pt. 3 para. 9 inserted (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 4

#### 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  |

Status: Point in time view as at 01/06/2010.

Changes to 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<br>Drugs) (Prescription Only) Amendment Order<br>1986   | S.I. 1986/586  |
| The Medicines (Products other than Veterinary<br>Drugs) (Prescription Only) Amendment Order<br>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<br>Drugs) (Prescription Only) Amendment Order<br>1988   | S.I. 1988/2017 |
| The Medicines (Products other than Veterinary<br>Drugs) (Prescription Only) Amendment Order<br>1991   | S.I. 1991/962  |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1992         | S.I. 1992/1534 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1992 | S.I. 1992/2937 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1993         | S.I. 1993/1890 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993 | S.I. 1993/3256 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment Order 1994         | S.I. 1994/558  |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994 | S.I. 1994/3016 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 3) Order 1994 | S.I. 1994/3050 |
| The Medicines (Products other than Veterinary<br>Drugs) (Prescription Only) Amendment Order<br>1995   | S.I. 1995/1384 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995 | S.I. 1995/3174 |

Document Generated: 2024-06-08

Status: Point in time view as at 01/06/2010.

Changes to 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<br>Drugs) (Prescription Only) Amendment Order<br>1996   | S.I. 1996/1514 |
| The Medicines (Products other than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1996 | S.I. 1996/3193 |

#### [F295SCHEDULE 7

Articles 12A to 12C

#### **Textual Amendments**

F295 Sch. 7 inserted (9.8.2000) by The Prescription Only Medicines (Human Use) Amendment Order 2000 (S.I. 2000/1917), arts. 1(1), 2(e)

#### **PART I**

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

- (a) the period during which the Direction shall have effect;
- (b) the description or class of prescription only medicine to which the Direction relates;
- (c) whether there are any restrictions on the quantity of medicine which may be [F296 sold or] 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;

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

- (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.

#### **Textual Amendments**

**F296** Words in Sch. 7 Pt. 1 inserted (1.9.2007) by The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2007 (S.I. 2007/2178), arts. 1(1), 5

#### **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 medicine is supplied or administered  | Person on whose behalf the Direction must be signed  |
| Common Services Agency  | The Agency   |
| [F297Strategic Health Authority]  | [F297The Strategic Health Authority]   |
| Health Authority  | The Health Authority   |
| Special Health Authority  | The Special Health Authority   |
| NHS trust [F298 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 Authority, an NHS trust, [F299], an NHS foundation trust] or a Primary Care Trust | The Common Services Agency, where the arrangement has been made with the Agency; or the Health Authority, Special Health Authority, NHS trust [F300] or NHS foundation trust] or Primary Care Trust with which the arrangement has been made |

#### **Textual Amendments**

- **F297** 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)
- **F298** 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**
- **F299** 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**
- **F300** 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**

### [F301PART 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**

**F301** 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   |
| The prison service in Scotland  | The Scottish Prison Service Management<br>Board   |
| The prison service in Northern Ireland                                  | The Northern Ireland Prison Service<br>Management Board   |
| Her Majesty's Forces  | (i) the Surgeon General,  |
|   | (ii) a Medical Director General, or   |
|   | (iii) a chief executive of an executive agency of the Ministry of Defence]                      |

#### **PART III**

### CLASSES OF INDIVIDUAL [F302BY WHOM PRESCRIPTION ONLY MEDICINES MAY BE SUPPLIED OR ADMINISTERED]

#### **Textual Amendments**

**F302** 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)** 

[F303Dental hygienist.

Dental therapist.]

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

[F304]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.

F305

Registered midwives.

Registered nurses.

[F306] Registered optometrists

[F307Registered] chiropodists.

[F308]Registered orthoptists.

Registered physiotherapists.

Registered radiographers.]

[F309"Registered dietitians.";]

[F309"Registered occupational therapists.";]

[F309" Registered orthotists and prosthetists."; and]

[F309. Registered speech and language therapists."]]

#### **Textual Amendments**

- **F303** Words in Sch. 7 Pt. 3 inserted (1.6.2010) by The Medicines for Human Use (Miscellaneous Amendments) Order 2010 (S.I. 2010/1136), arts. 1(1), **3(4)**
- F304 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)
- F305 Words in Sch. 7 Pt. 3 omitted (1.8.2004) by virtue of The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004 (S.I. 2004/1771), art. 1(1), Sch. para. 39(b)
- F306 Words in Order substituted (30.6.2005 as notified in the London Gazette dated 3.6.2005) by The Opticians Act 1989 (Amendment) Order 2005 (S.I. 2005/848), Sch. 1 para. 27(b)
- F307 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)
- F308 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)
- **F309** Words in Sch. 7 Pt. 3 added (18.5.2004) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2004 (S.I. 2004/1189), arts. 1(1), 5

#### **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.

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

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 01/06/2010.

### **Changes to legislation:**

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