#### STATUTORY INSTRUMENTS

# 1997 No. 1830

# **MEDICINES**

# The Prescription Only Medicines (Human Use) Order 1997

Made - - - - 25th July 1997

Laid before Parliament 28th July 1997

Coming into force - - 18th August 1997

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

### Citation, commencement and interpretation

- 1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Order 1997 and shall come into force on 18th August 1997.
  - (2) In this Order, unless the context otherwise requires—
    - "the Act" means the Medicines Act 1968;
    - "aerosol" means a product which is dispersed from its container by a propellent gas or liquid;
    - "appropriate nurse practitioner" means-
    - (a) a person who-
      - (i) is registered in Part 1 or 12 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of

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

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

- the Nurses, Midwives and Health Visitors Act 1979(3) (referred to below in this definition as "the professional register"), and
- (ii) has a district nursing qualification additionally recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(4); or
- (b) a person who is registered in Part 11 of the professional register as a health visitor; against whose name (in each case) is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances for patients;

"controlled drug" has the meaning assigned to it by section 2 of the Misuse of Drugs Act 1971(5);

"cyanogenetic substances" means preparations which-

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

"dosage unit" means-

- (a) where a medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other article, or
- (b) where a medicinal product is not in any such form, the unit of measurement which is used as the unit by reference to which the dose of the medicinal product is measured;

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

"health prescription" means a prescription issued by a doctor, dentist or nurse prescriber under or by virtue of—

- (a) in England and Wales, the National Health Service Act 1977(6),
- (b) in Scotland, the National Health Service (Scotland) Act 1978(7), and
- (c) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(8);

"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-

<sup>&</sup>quot;inhaler" does not include an aerosol;

<sup>&</sup>quot;master" has the same meaning as in section 313(1) of the Merchant Shipping Act 1995(9);

<sup>&</sup>quot;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;

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

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

<sup>(4)</sup> Approved b (5) 1971 c. 38.

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

<sup>(7) 1978</sup> c. 29.

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

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

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

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

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

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

"the Misuse of Drugs Regulations" means, in relation to England, Wales and Scotland, the Misuse of Drugs Regulations 1985(10) and in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986(11);

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

"offshore installation" means an offshore installation within the meaning of the Mineral Workings (Offshore Installations) Act 1971(12) which is within—

- (a) tidal waters and parts of the sea in or adjacent to the United Kingdom up to the seaward limits of territorial waters;
- (b) waters in any area designated under section 1(7) of the Continental Shelf Act 1964(13);

"operator", in relation to an aircraft, means the person for the time being having the management of the aircraft;

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

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

"prolonged release" in relation to a medicinal product means a formulation of that product which—

- (a) is used to reduce the rate at which the active ingredient in that product is released after administration, and
- (b) is sold or supplied as a prolonged, controlled or sustained release medicinal product;

"registered midwife" means a person who is registered in Part 10 of the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

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

<sup>(11)</sup> SR 1986 No. 52.

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

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

"registered nurse" means a person who is registered in the Register maintained by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting under section 10 of the Nurses, Midwives and Health Visitors Act 1979;

"registered ophthalmic optician" means a person who is registered in either of the Registers of ophthalmic opticians maintained under section 7(a) of the Opticians Act 1989(14);

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

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

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

"state registered chiropodist" means a person who is registered in the Register established and maintained under section 2(1) of the Professions Supplementary to Medicine Act 1960(15) by the Chiropodists Board;

"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.

- (3) For the purposes of this Order, the equivalence of a substance to a reference material shall be determined by calculating the amount of that reference material which is contained in that substance either by weight or, where the amount of the reference material is specified in terms of international units of activity, those units.
  - (4) In this Order, unless the context otherwise requires, a reference—
    - (a) to a numbered section is to the section of the Act which bears that number,
    - (b) to a numbered article or Schedule is to the article of, or Schedule to, this Order which bears that number,
    - (c) in an article or in a Part of a Schedule to a numbered paragraph is to the paragraph of that article or Part of that Schedule which bears that number, and
    - (d) in a paragraph to a lettered sub-paragraph is to the sub-paragraph of that paragraph which bears that letter.
  - (5) In Schedules 1 to 3–
    - (a) entries specified in columns 2 to 5 relate to the substances listed in column 1 against which they appear and where, in relation to a particular substance listed in column 1, an entry in columns 2 to 5 bears a number or letter it relates only to such entries in the other of those columns as bear the same number or letter;
    - (b) the following abbreviations are used:

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

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

<sup>(14) 1989</sup> c. 44.

<sup>(15) 1960</sup> c. 66.

(6) In Schedule 3, the abbreviation "NPF" means the Nurse Prescribers' Formulary Appendix in the British National Formulary.

## Appropriate practitioners

- **2.** For the purposes of section 58 (medicinal products on prescription only), the following shall be appropriate practitioners—
  - (a) in relation to the descriptions and classes of medicinal products specified in article 3, doctors, dentists, veterinary surgeons and veterinary practitioners;
  - (b) in relation to the descriptions and classes of medicinal products specified in Schedule 3, appropriate nurse practitioners.

# Medicinal products on prescription only

- **3.** Subject to article 6, the following descriptions and classes of medicinal products are specified for the purposes of section 58, namely—
  - (a) medicinal products consisting of or containing a substance listed in column 1 of Schedule 1;
  - (b) medicinal products that are controlled drugs;
  - (c) medicinal products that are for parenteral administration, other than preparations of insulin for parenteral administration;
  - (d) cyanogenetic substances, other than preparations for external use;
  - (e) medicinal products that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;
  - (f) medicinal products for human use which are classified as subject to medical prescription in marketing authorizations granted under Council Regulation 2309/93(16);
  - (g) medicinal products-
    - (i) which are not of a description and do not fall within a class specified in subparagraphs (a) to (f),
    - (ii) which are of a description in respect of which the conditions specified in section 59(1) are satisfied, and
    - (iii) in respect of which a product licence or marketing authorization has been granted which contains a provision to the effect that the method of sale or supply of the medicinal product is to be only in accordance with a prescription given by an appropriate practitioner.

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

**4.** The duration specified for the purposes of section 59(2)(a) (duration of restrictions for certain new products) shall be a period of 5 years.

### **Exempt medicinal products**

- **5.**—(1) A medicinal product shall be exempt from the restrictions imposed by section 58(2)(a) (restrictions on sale or supply) if it, or a substance in it, is listed in column 1 of Schedule 1 and there—
  - (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or

- (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.
- (2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.
- (3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.
- (4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use—
  - (a) where a purpose for which it may be used is so specified, for that purpose;
  - (b) where the class of persons in whom it may be used is so specified, in persons of that class.
- (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.

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

- **6.**—(1) A medicinal product shall not be a prescription only medicine by reason that it is a controlled drug listed in Schedule 2 to the Misuse of Drugs Act 1971 where, it—
  - (a) contains not more than one of the substances listed in column 1 of Schedule 2 to this Order and no other controlled drug;
  - (b) contains that substance at a strength that does not exceed the maximum strength specified in column 2 of that Schedule; and
  - (c) is sold or supplied-
    - (i) in such pharmaceutical form as may be specified in column 3 of that Schedule, and
    - (ii) for use at a maximum dose which does not exceed that specified in column 4 of that Schedule.
- (2) A medicinal product for human use in respect of which a marketing authorization has been granted under Council Regulation 2309/93/EEC(17) shall not be a prescription only medicine where that authorization does not classify the medicinal product as subject to medical prescription.

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

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

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

Atropine Sulphate Injection

Chlorpheniramine Injection

**Cobalt Edetate Injection** 

Dextrose Injection Strong B.P.C.

Diphenhydramine Injection

Glucagon Injection

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum
Sodium Nitrite Injection
Sodium Thiosulphate Injection
Sterile Pralidoxime

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

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

- **8.**—(1) The restrictions imposed by section 58(2)(a) (restriction on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (2) are satisfied.
  - (2) The conditions referred to in paragraph (1) are—
    - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor who by reason of an emergency is unable to furnish a prescription immediately;
    - (b) that the doctor has undertaken to furnish the person lawfully conducting a retail pharmacy business with a prescription within 72 hours of the sale or supply;
    - (c) that the prescription only medicine is sold or supplied in accordance with the directions of the doctor requesting it;
    - (d) subject to paragraph (5), that the prescription only medicine is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
    - (e) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(18) within the time specified in that regulation stating the particulars required under paragraph 1 of Schedule 2 to those Regulations.
- (3) The restrictions imposed by section 58(2)(a) shall not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business where the conditions specified in paragraph (4) are satisfied.
  - (4) The conditions referred to in paragraph (3) are-
    - (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting a prescription only medicine and has satisfied himself—
      - (i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay,
      - (ii) that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor for the person requesting it, and
      - (iii) as to the dose which in the circumstances it would be appropriate for that person to take;
    - (b) that no greater quantity of the prescription only medicine than will provide 5 days' treatment is sold or supplied except that where the prescription only medicine—
      - (i) is an aerosol for the relief of asthma, an ointment or cream, and has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply may be sold or supplied,

- (ii) is an oral contraceptive, a quantity sufficient for a full treatment cycle may be sold or supplied,
- (iii) is an antibiotic for oral administration in liquid form, the smallest quantity that will provide a full course of treatment may be sold or supplied;
- (c) subject to paragraph (5), that the prescription only medicine does not consist of or contain a substance specified in Schedule 4 to this Order and is not a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations;
- (d) that an entry is made in the record kept under regulation 6 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 within the time specified in that regulation stating the particulars required under paragraph 3 of Schedule 2 to those Regulations;
- (e) that the container or package of the prescription only medicine is labelled so as to show-
  - (i) the date on which the prescription only medicine is sold or supplied,
  - (ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine,
  - (iii) the name of the person requesting the prescription only medicine,
  - (iv) the name and address of the registered pharmacy from which the prescription only medicine is sold or supplied, and
  - (v) the words "Emergency Supply".
- (5) The conditions specified in paragraphs (2)(d) and (4)(c) shall not apply where the prescription only medicine consists of or contains phenobarbitone or phenobarbitone sodium (but no other substance specified in Schedule 4 to this Order or Schedule 1, 2 or 3 to the Misuse of Drugs Regulations) and is sold or supplied for use in the treatment of epilepsy.

#### **Exemption for non-parenteral administration to human beings**

**9.** The restriction imposed by section 58(2)(b) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration.

## Exemption for medicinal products at high dilutions

- 10. The restrictions imposed by section 58(2) (restrictions on sale, supply and administration) shall not apply to the sale, supply or administration of a medicinal product which is not for parenteral administration and which consists of or contains, any of the substances listed in column 1 of Schedule 1 or 2, only one or more unit preparation of such substances, if—
  - (a) each such unit preparation has been diluted to at least one part in a million (6x), and the person selling, supplying or administering the medicinal product has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required; or
  - (b) each such unit preparation has been diluted to at least one part in a million million (6c).

# **Exemptions for certain persons**

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

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

## Exemption for sale or supply in hospitals

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

## Exemption in cases involving another's default

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

#### **Exemption in the case of a forged prescription**

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

#### **Prescriptions**

- 15.—(1) For the purposes of section 58(2)(a) a prescription only medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless the conditions specified in paragraph (2) are fulfilled.
  - (2) The conditions referred to in paragraph (1) are that the prescription—
    - (a) shall be signed in ink with his own name by the appropriate practitioner giving it;
    - (b) shall, without prejudice to sub-paragraph (a), be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a controlled drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, in which case it may be written by means of carbon paper or similar material;
    - (c) shall contain the following particulars-
      - (i) the address of the appropriate practitioner giving it,
      - (ii) the appropriate date,
      - (iii) such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, an appropriate nurse practitioner, a veterinary surgeon or a veterinary practitioner,
      - (iv) where the appropriate practitioner giving it is a doctor, dentist or appropriate nurse practitioner, the name, address and the age, if under 12, of the person for whose treatment it is given, and

- (v) where the appropriate practitioner giving it is a veterinary surgeon or a veterinary practitioner, the name and address of the person to whom the prescription only medicine is to be delivered and a declaration by the veterinary surgeon or veterinary practitioner giving it that the prescription only medicine is prescribed for an animal or herd under his care:
- (d) shall not be dispensed after the end of the period of 6 months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
- (e) in the case of a repeatable prescription which does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for an oral contraceptive in which case it may be dispensed 6 times before the end of the period of 6 months from the appropriate date.
- (3) The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to a sale or supply of a prescription only medicine which is not in accordance with a prescription given by an appropriate practitioner by reason only that a condition specified in paragraph (2) is not satisfied where the person selling or supplying the prescription only medicine, having exercised all due diligence, believes on reasonable grounds that that condition is satisfied in relation to that sale or supply.
  - (4) In paragraph (2) "the appropriate date" means-
    - (a) in the case of a health prescription, the date on which it was signed by the appropriate practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed; and
    - (b) in every other case, the date on which the prescription was signed by the appropriate practitioner giving it;

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

#### Revocations

- **16.**—(1) The Orders specified in Schedule 6 are revoked.
- (2) In the Medicines (Prescription Only, Pharmacy and General Sale) Amendment Order 1989(19) articles 2 to 6 and Schedules 1 and 2 are revoked.

Signed by authority of the Secretary of State for Health

Baroness Jay
Minister of State,
Department of Health

21st July 1997

Win Griffiths
Parliamentary Under Secretary of State, Welsh
Office

25th July 1997

Sam Galbraith
Parliamentary Under Secretary of State, The
Scottish Office

23rd July 1997

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

25th July 1997

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



D. C. Gowdy Permanent Secretary

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



*P. Small* Permanent Secretary

#### SCHEDULE 1

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

# SUBSTANCES WHICH IF INCLUDED IN MEDICINAL PRODUCTS MAKE THOSE PRODUCTS PRESCRIPTION ONLY MEDICINES AND EXEMP TIONS 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 strength	Route of administration, use or pharmaceutical form		Maximum quantity	

Acarbose

Acebutolol

Hydrochloride

Acemetacin

Acetarsol

Acetazolamide

Acetazolamide

Sodium

Acetohexamide

Acetylcholine 0.2 per cent

External

Chloride

Acetylcysteine

Acipimox

Aciclovir 5.0 per cent External

Container or package For treatment containing not of herpes more than 2g simplex virus of medicinal infections of

the lips and face (Herpes labialis)

Acitretin

Aclarubicin Hydrochloride

Aconite

1.3 per cent

External

Acrivastine

24 mg (MDD) Container

or package containing not more than 240mg of

Acrivastine

product

	Exemptions fro prescription on	m the restrictions ly medicines	s on the sale ar	nd supply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration, use or pharmaceutical form		Maximum quantity

Acrosoxacin

Actinomycin

C

Actinomycin

D

Adenosine

Adrenaline (1) By inhaler

(2) External

Adrenaline Acid Tartrate (1) By inhaler

(2) External

Adrenaline Hydrochloride (1) By inhaler

(2) External

Adrenocortical

Extract

Albendazole

Alclofenac

Alclometasone Dipropionate

Alcuronium Chloride

Aldesleukin

Aldosterone

Alfacalcidol

Alfuzosin

Hydrochloride

Allergen

Extracts

Allopurinol

Allyloestrenol

Alphadolone

Acetate

Alphaxalone

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Alprenolol

Alprenolol Hydrochloride

Alprostadil

Alseroxylon

Amantadine Hydrochloride

Ambenonium Chloride

Ambutonium Bromide

Amcinonide

Ametazole Hydrochloride

Amethocaine

Nonophthalmic

use

Amethocaine Gentisate Nonophthalmic

use

Amethocaine Hydrochloride Nonophthalmic

use

Amikacin Sulphate

Amiloride Hydrochloride

Aminocaproic

Acid

Aminoglutethimide

Aminopterin Sodium

Amiodarone Hydrochloride

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** Maximum strength administration, limitations quantity use or pharmaceutical form

Amiphenazole

Hydrochloride

Amitriptyline

Amitriptyline

Embonate

Amitriptyline Hydrochloride

Amlodipine Besylate

Ammonium

Bromide

Amodiaquine Hydrochloride

Amorolfine Hydrochloride

Amoxapine

Amoxycillin

Amoxycillin

Sodium

Amoxycillin Trihydrate

Amphomycin Calcium

Amphotericin

Ampicillin

Ampicillin

Sodium

Ampicillin

Trihydrate

Amsacrine

Amygdalin

Amyl Nitrite

		from the restrictions only medicines	s on the sale a	nd supply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administration, use or pharmaceutical form		Maximum quantity	
Amylocaine		Non-			
Hydrochloride		ophthalmic			
		use			

Ancrod

Androsterone

Angiotensin Amide

Anistreplase

Anterior Pituitary Extract

Antimony Barium Tartrate

Antimony

Dimercaptosuccinate

Antimony Lithium Thiomalate

Antimony Pentasulphide

Antimony Potassium Tartrate

Antimony Sodium Tartrate

Antimony Sodium

Thioglycollate

Antimony Sulphate

Antimony Trichloride

Antimony Trioxide

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

Antimony

Trisulphide

Apiol

Apomorphine

Apomorphine

Hydrochloride

Aprotinin

Arecoline

Hydrobromide

Argipressin

Aristolochia

Aristolochia

Clematitis

Aristolochia

Contorta

Aristolochia

Debelis

Aristolochia

Fang-chi

Aristolochia

Manshuriensis

Aristolochia

Serpentaria

Arsenic

Arsenic

Triiodide

Arsenic

Trioxide

Arsphenamine

Astemizole

Oral 10mg (MDD) Container

For treatment of hayfever in adults and children not 10mg (MDD) Container or package containing not more than 100mg of Astemizole

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	Exemptions from prescription o	om the restriction. nly medicines	s on the sale and	l supply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
		less than 12 years			
		Not a prolonged release preparation			
Atenolol					
Atracurium Besylate					
Atropine		(1) Internal			
		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 300mcg (MD)		
			1mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		(1) Internal			
Methobromide		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine		Internal			
Methonitrate		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD)		
			1.3mg (MDD)		
Atropine		(1) Internal			
Oxide Hydrochloride		(a) by inhaler			
•		(b) otherwise than by inhaler	(b) 360mcg (MD)		

	Exemptions from prescription of	om the restriction	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3  Route of  administration,  use or  pharmaceutica  form		Column 5 Maximum quantity
			1.2mg (MDD) 3	
		(2) External (except ophthalmic)		
Atropine		(1) Internal		
Sulphate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 360mcg (MD)	
			1.2mg (MDD)	
		(2) External (except ophthalmic)		
Auranofin				
Azapropazone				
Azathioprine				
Azathioprine Sodium				
Azelaic Acid				
Azelastine Hydrochloride		For nasal administration	140mcg per nostril (MD)	Container or package
		For the treatment of seasonal allergic rhinitis	280mcg per nostril (MDD)	containing not more than 5,040mcg of Azelastine Hydrochloride
		For use in adults and children not less than 12 years		
		As a non- aerosol, aqueous form		
Azidocillin Potassium		-		

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Azithromycin

Azlocillin

Sodium

Aztreonam

Bacampicillin Hydrochloride

Bacitracin

Bacitracin

Methylene

Disalicylate

Bacitracin

Zinc

Baclofen

Bambuterol

Hydrochloride

Barium

Carbonate

Barium

Chloride

Barium

Sulphide

Beclamide

Beclomethasone

Beclomethasone Dipropionate

For nasal administration nostril (MD) (non-aerosol)

100mcg per

or package containing not more than 5,600mcg of Beclomethasone

Dipropionate

Container

200mcg per nostril (MDD)

For the prevention and treatment of allergic rhinitis

For use in adults and children not

	Exemptions from prescription o	om the restriction nly medicines	s on the sale an	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutica form		Column 5 Maximum quantity
less than 12 years				
Belladonna Herb		(1) Internal	(1) 1mg of the alkaloids (MDD)	
		(2) External		
Belladonna Root		(1) Internal	(1) 1mg of the alkaloids (MDD)	
		(2) External		
Bemegride				
Bemegride Sodium				
Benapryzine Hydrochloride				
Bendrofluazide				
Benethamine Penicillin				
Benoxaprofen				
Benperidol				
Benserazide Hydrochloride				
Bentiromide				
Benzathine Penicillin				
Benzbromarone				
Benzhexol Hydrochloride				
Benzilonium Bromide				
Benzocaine		Any use except ophthalmic use		

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

Benzoctamine Hydrochloride

Benzoyl

10.0 per cent External

Peroxide

N-Benzoyl Sulphanilamide

Benzquinamide

Benzquinamide Hydrochloride

Benzthiazide

Benztropine Mesylate

Benzylpenicillin

Calcium

Benzylpenicillin Potassium

Benzylpenicillin

Sodium

Beractant

Betahistine

Hydrochloride

Betamethasone

Betamethasone

Adamantoate

Betamethasone

Benzoate

Betamethasone

Dipropionate

Betamethasone

Sodium

Phosphate

Betamethasone

Valerate

Betaxolol

Hydrochloride

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Bethanechol

Chloride

Bethanidine Sulphate

Bezafibrate

Biperiden

Hydrochloride

Biperiden

Lactate

Bismuth

Glycollylarsanilate

Bisoprolol

Fumarate

Bleomycin

Bleomycin

Sulphate

Bretylium

T. 1.4

Tosylate

Bromhexine

Hydrochloride

Bromocriptine

Mesylate

Bromperidol

Bromvaletone

Brotizolam

Budesonide

For nasal 200mcg per administration nostril (MD)

For the 200mcg per prevention nostril (MDD)

prevention or treatment of seasonal allergic rhinitis

For use in adults and in children not

Container or package containing not more than 10mg of Budesonide

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form less than 12		Column 5 Maximum quantity	
		years As a non- aerosol, aqueous form			
Bufexamac					
Bumetanide					
Buphenine Hydrochloride			6mg (MD) 18mg (MDD)		
Bupivacaine		Any use except ophthalmic use			
Bupivacaine Hydrochloride		Any use except ophthalmic use			
Buserelin Acetate					
Buspirone Hydrochloride					
Busulphan					
Butacaine Sulphate		Any use except ophthalmic use			
Butorphanol Tartrate					
Butriptyline Hydrochloride					
Calcipotriol					
Calcitonin					
Calcitriol					
Calcium Amphomycin					

	Exemptions from prescription of	om the restrictions nlv medicines	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
Calcium Benzamidosalio	cylate			
Calcium Bromide				
Calcium Bromidolactobi	onate			
Calcium Carbimide				
Calcium Folinate				
Calcium Metrizoate				
Calcium Sulphaloxate				
Candicidin				
Canrenoic Acid				
Cantharidin	0.01 per cent	External		
Capreomycin Sulphate				
Captopril				
Carbachol				
Carbamazepine				
Carbaryl				
Carbenicillin Sodium				
Carbenoxolone Sodium			(1) 5mg (MD) 25mg (MDD)	
	(2) 2.0 per cent	(2) Gel		
	(3) 1.0 per cent		(3) 20mg (MD) 80mg (MDD)	(3) Container or package containing not more than 506mg of

	1 0	from the restrictions only medicines	s on the sale a	nd supply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administration, use or pharmaceutical form		Maximum quantity	
		less than 12		Carbenoxolone	
		years		Sodium	

Carbidopa

Carbimazole

Carbocisteine

Carbon

Tetrachloride

Carboplatin

Carboprost

Trometamol

Carbuterol

Hydrochloride

Carfecillin

Sodium

Carindacillin

Sodium

Carisoprodol

Carmustine

Carperidine

Carteolol

Hydrochloride

Cefaclor

Cefadroxil

Cefazedone

Sodium

Cefixime

Cefodizime

Sodium

Cefotaxime

Sodium

Cefoxitin

Sodium

Cefpodoxime

Proxetil

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

Cefsulodin

Sodium

Ceftazidime

Ceftizoxime

Sodium

Ceftriaxone

Sodium

Cefuroxime

Axetil

Cefuroxime

Sodium

Celiprolol

Hydrochloride

Cephalexin

Cephalexin

Sodium

Cephaloridine

Cephalothin

Sodium

Cephamandole

Nafate

Cephazolin

Sodium

Cephradine

Cerium

Oxalate

Cerivastatin

Ceruletide

Diethylamine

Cetirizine

Hydrochloride

10mg (MDD)

Container or package

containing not more than 100mg of Cetirizine

Hydrochloride

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Chenodeoxycholic

Acid

Chloral External

Hydrate

Chlorambucil

Chloramphenicol

Chloramphenicol

Cinnamate

Chloramphenicol

Palmitate

Chloramphenicol

Sodium Succinate

Chlorhexadol

Chlormadinone

Acetate

Chlormerodrin

Chlormethiazole

Chlormethiazole

Edisylate

Chlormezanone

Chloroform(**20**) (1) 5.0 per

cent

(1) Internal

(2) External

Chloroquine Prophylaxis of

Phosphate malaria

Chloroquine Prophylaxis of Sulphate malaria

Chlorothiazide Chlorotrianisene Chlorphenoxamine Hydrochloride

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

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

Chlorpromazine

Chlorpromazine

Embonate

Chlorpromazine Hydrochloride

Chlorpropamide

Chlorprothixene

Chlorprothixene Hydrochloride

Chlortetracycline

Chlortetracycline

Calcium

Chlortetracycline Hydrochloride

Chlorthalidone

Chlorzoxazone

Cholestyramine

Ciclacillin

Ciclobendazole

Cilastatin Sodium

Cilazapril

Cimetidine

(a) For the short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion

and hyperacidity and for the

prophylaxis of

(a) 200mg (MD) 800mg (MDD) For a maximum period of 14 days

	prescription or	•			
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
		meal-induced heartburn			
		(b) For the prophylactic management of nocturnal heartburn by a single dose taken at night	(b) 100mg (MD) to be taken as a single dose at night For a maximum period of 14 days		
Cimetidine Hydrochloride					
Cinchocaine	3.0 per cent	Non- ophthalmic use			
Cinchocaine Hydrochloride	Equivalent of 3.0 per cent of Cinchocaine	Non- ophthalmic use			
Cinchophen					
Cinoxacin					
Ciprofibrate					
Ciprofloxacin					
Ciprofloxacin Hydrochloride					
Cisapride					
Cisplatin					
Clarithromycin					
Clavulanic Acid					
Clidinium Bromide					
Clindamycin					
Clindamycin Hydrochloride					

	1 0	from the restrictions only medicines	s on the sale a	nd supply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administration, use or pharmaceutical		Maximum quantity	
		form			

Clindamycin Palmitate Hydrochloride Clindamycin

Phosphate

Clioquinol

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

(2) 35mg

(2) Treatment (2) 350mg of mouth (MDD)

ulcers

Clobetasol Propionate

Clobetasone Butyrate

Clofazimine

Clofibrate

Clomiphene Citrate

Clomipramine

Clomipramine Hydrochloride

Clomocycline

Clomocycline Sodium

Clonidine

Clonidine Hydrochloride

Clopamide

Clopenthixol Decanoate

Clopenthixol Hydrochloride

Clorexolone

	Exemptions from prescription o	om the restrictions nly medicines	s on the sale ar	nd supply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
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					
Colistin Sulphate					
Colistin Sulphomethate					
Colistin Sulphomethate Sodium					
Coniine					
Conium Leaf	7.0 per cent	External			
Corticotrophin					
Cortisone					
Cortisone Acetate					

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

Co-tetroxazine

Co-

trimoxazole

Cropropamide

Crotethamide

Croton Oil

Croton Seed

Curare

Cyclofenil

Cyclopenthiazide

Cyclopentolate

Hydrochloride

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cyproterone

Acetate

Cytarabine

Cytarabine

Hydrochloride

Dacarbazine

Dalteparin

Sodium

Danazol

Danthron

Dantrolene

Sodium

Dapsone

Dapsone

Ethane Ortho

Sulphonate

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

26mg (MDD)

Daunorubicin Hydrochloride

Deanol

Bitartrate

Debrisoquine Sulphate

Demecarium Bromide

Demeclocycline

Demeclocycline

Calcium

Demeclocycline Hydrochloride

Deoxycortone

Acetate

Deoxycortone Pivalate

Deptropine Citrate

Dequalinium Chloride (1) 0.25mg

(1) Internal: throat lozenges or

throat pastilles

(2) 1.0 per cent

(2) External: paint

Deserpidine

Desferrioxamine

Mesylate

Desflurane

Desipramine Hydrochloride

Deslanoside

Desmopressin

Desmopressin

Acetate

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Desogestrel

Desonide

Desoxymethasone

Dexamethasone

Dexamethasone

Acetate

Dexamethasone

Isonicotinate

Dexamethasone

Phenylpropionate

Dexamethasone

Pivalate

Dexamethasone

Sodium

Metasulphobenzoate

Dexamethasone

Sodium

Phosphate

Dexamethasone

Troxundate

Dexfenfluramine

Hydrochloride

Dextromethorphan Hydrobromide

Internal

(a) In the case of a prolonged

release preparation: equivalent of 30mg of

Dextromethorphan

(MD)

equivalent of 75mg of Dextromethorphan

(MDD)

(MDD)

(b) in any other case: equivalent

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

of 15mg of Dextromethorphan (MD)

equivalent of 75mg of Dextromethorphan (MDD)

Dextrothyroxine Sodium

Diazoxide

Dibenzepin Hydrochloride

Dichloralphenazone

Dichlorphenamide

Diclofenac 1.16 per cent Diethylammonium External
For local
symptomatic
relief of
pain and
inflammation
in trauma of
the tendons,
ligaments,
muscles and
joints and
in localised
forms of
soft tissue

For use in adults and children not less than 12 years

rheumatism

For maximum Container period of 7 or package containing

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

Diclofenac Potassium

Diclofenac Sodium

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Dicyclomine 10mg (MD) Hydrochloride 60mg (MDD)

Dienoestrol

Diethanolamine

**Fusidate** 

Diflucortolone

Valerate

Diflunisal

Digitalin

Digitalis Leaf

Digitalis

Prepared

Digitoxin

Digoxin

Dihydralazine

Sulphate

Dihydroergotamine

Mesylate

Dihydrostreptomycin

Dihydrostreptomycin

Sulphate

Diloxanide

Furoate

Diltiazem

Hydrochloride

Dimercaprol

Dimethisoquin Non-Hydrochloride ophthalmic

use

Dimethisterone

Dimethothiazine

Mesylate

Dimethyl Sulphoxide

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Dimethyltubocurarine

Bromide

Dimethyltubocurarine

Chloride

Dimethyltubocurarine

Iodide

Dinoprost

Dinoprost

Trometamol

Dinoprostone

Dipivefrin

Hydrochloride

Dipyridamole

Disodium

Etidronate

Disodium

Pamidronate

Disopyramide

Disopyramide

Phosphate

Distigmine

Bromide

Disulfiram

Dithranol 1.0 per cent

Dobutamine

Hydrochloride

Domperidone

Domperidone

Maleate

Dopamine

Hydrochloride

Dopexamine

Hydrochloride

Dothiepin

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

Dothiepin Hydrochloride

Doxapram Hydrochloride

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

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Ecothiopate

Iodide

Edrophonium

Chloride

Eflornithine Hydrochloride

Embutramide

Emepronium Bromide

Emetine

1.0 per cent

Emetine Bismuth Iodide

Emetine Hydrochloride Equivalent of 1.0 per cent of

Emetine

Enalapril Maleate

Encephalitis Virus, Tickborne, Cent

Eur

Enoxacin

Enoxaparin Sodium

Enoximone

Ephedrine

(1) Internal (1) 30mg (other than (MD) nasal sprays or

nasal drops)

60mg (MDD)

(2) 2.0 per cent

(2) Nasal sprays or nasal

drops

(3) External

	Exemptions fro	om the restriction	s on the sale and	supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration use or pharmaceutica form		Column 5 Maximum quantity
Ephedrine Hydrochloride		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD)	
			Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine			
		(3) External		
Ephedrine Sulphate		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD)	
			Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine			
		(3) External		
Epicillin				
Epirubicin				

Epirubicin

Epirubicin Hydrochloride

Epithiazide

Epoetin Alfa

Epoetin Beta

Epoprostenol Sodium

Ergometrine Maleate

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

Etafedrine

Hydrochloride

Ethacrynic

Acid

Ethambutol

Hydrochloride

Ethamivan

Ethamsylate

Ethiazide

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Ethinyl

Androstenediol

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Citrate

Ethopropazine

Hydrochloride

Ethosuximide

Ethotoin

Ethyl

Biscoumacetate

Ethynodiol

Diacetate

Etodolac

Etomidate

Etomidate

Hydrochloride

Etoposide

Etretinate

Famciclovir

Famotidine

For the 10mg (MD) short-term 20mg (MDD) symptomatic relief of For maximum heartburn, period of 14 dyspepsia, days indigestion, acid indigestion and hyperacidity, and prevention of these

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	Exemptions fr	om the restrictions	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
Fazadinium		symptoms when associated with food and drink, including nocturnal symptoms		
Bromide				
Felbinac	3.17 per cent	External  For the relief of symptoms associated with soft tissue injury such as strains, sprains and contusions  For use in adults and children not	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
		less than 12 years		
Felodipine				
Felypressin				
Fenbufen				
Fenclofenac				
Fenfluramine Hydrochloride				
Fenofibrate				
Fenoprofen Fenoprofen Calcium				
Fenoterol Hydrobromide				

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Fenticonazole

Nitrate

Feprazone

Ferrous

Arsenate

Filgrastim

Finasteride

Flavoxate Hydrochloride

Flecainide

Acetate

Flosequinan

Fluanisone

Flubendazole

Fluclorolone

Acetonide

Flucloxacillin

Magnesium Flucloxacillin

Sodium

Fluconazole

For oral administration for the treatment of vaginal candidiasis in persons aged not less than 16 but less than 60 years

150mg (MD)

Container or package containing not more than 150mg of Fluconazole

Flucytosine

Fludrocortisone

Acetate

Flufenamic

Acid

Flumazenil

	Exemptions from the restrictions on the sale and supply of prescription only medicines						
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutica form		Column 5 Maximum quantity			
Flumethasone							
Flumethasone Pivalate							
Flunisolide	0.025 per cent	(a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever	(a) 50mcg per nostril (MD) 100mcg per nostril (MDD)	(a) Container or package containing not more than 6,000mcg of Flunisolide			
		For use in adults and children not less than 16 years					
		In the form of a non- pressurised nasal spray					
		(b) For the prevention and treatment of seasonal allergic rhinitis including hay fever	(b) 25mcg per nostril (MD) 75mcg per nostril (MDD)	(b) Container or package containing not more than 6,000mcg of Flunisolide			
		For use in children not less than 12 years but less than 16 years					
Eluocinolone		In the form of a non- pressurised nasal spray					

Fluocinolone Acetonide

Fluocinonide

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

Fluocortin

Butyl

Fluocortolone

Fluocortolone

Hexanoate

Fluocortolone

Pivalate

Fluorescein

Dilaurate

Fluorometholone

Fluorouracil

Fluorouracil

Trometamol

Fluoxetine

Hydrochloride

Flupenthixol

Decanoate

Flupenthixol

Hydrochloride

Fluperolone

Acetate

Fluphenazine

Decanoate

Fluphenazine

Enanthate

Fluphenazine

Hydrochloride

Fluprednidene

Acetate

Fluprednisolone

Fluprostenol

Sodium

Flurandrenolone

Flurbiprofen

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

Flurbiprofen

Sodium

Fluspirilene

Flutamide

Fluticasone

Propionate

Fluvastatin

Sodium

Fluvoxamine

Maleate

Folic Acic 500mcg

(MDD)

Formestane

Formocortal

Foscarnet

Sodium

Fosfestrol

Sodium

Fosfomycin

Trometamol

Fosinopril

Sodium

Framycetin

Sulphate

Frusemide

Furazolidone

Fusafungine

Fusidic Acid

Gabapentin

Gadoteridol

Gallamine

Triethiodide

Ganciclovir

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 Maximum strength administration, limitations quantity use or pharmaceutical form Ganciclovir Sodium Gelsemine 0.1 per cent Gelsemium 25mg (MD)

75mg (MDD)

Gemeprost

Gemfibrozil

Gentamicin

Gentamicin Sulphate

Gestodene

Gestrinone

Gestronol

Gestronol

Hexanoate

Glibenclamide

Glibornuride

Gliclazide

Glipizide

Gliquidone

Glisoxepide

Glucagon

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

Glymidine

Gonadorelin

Goserelin Acetate

Gramicidin 0.2 per cent External

Granisetron Hydrochloride

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

Griseofulvin

Growth

Hormone

Guanethidine

Monosulphate

Guanfacine

Hydrochloride

Guanoclor

Sulphate

Guanoxan

Sulphate

Halcinonide

Halofantrine

Hydrochloride

Haloperidol

Haloperidol

Decanoate

External Heparin Heparin External

Calcium

Heparin

Sodium

Hexachlorophane External

cent

(a) 2.0 per cent

(a) Soaps

(b) 0.1 per

(b) Aerosols

(c) 0.75 per

(c)

preparations cent

other than soaps and aerosols

Hexamine

Phenylcinchoninate

Hexobarbitone

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Hexobarbitone

Sodium

Hexoestrol

Hexoestrol Dipropionate

L-Histidine Hydrochloride Dietary

supplementation

Homatropine

(1) Internal (1) 0.15mg

(MD) 0.45mg (MDD)

(2) External (except ophthalmic)

Homatropine Hydrobromide 0.2mg (MD)

0.6mg (MDD)

Homatropine Methylbromide

2mg (MD) 6mg (MDD)

Hydralazine Hydrochloride

Hydrargaphen

Local

application to

skin

Hydrobromic Acid

----

Hydrochlorothiazide

Hydrocortisone 1.0 per cent

External

For use either alone or in conjunction with

Crotamiton

in irritant

dermatitis, contact allergic Container or package containing not more than 15g of medicinal product (cream or ointment) or 30ml (spray)

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity		
		dermatitis, insect bite reactions, mild to moderate eczema, and either in combination with Clotrimazole for athlete's foot and candidal intertrigo or in combination with lignocaine for anal and perianal itch associated with haemorrhoids For use in adults and				
		children not less than 10 years Cream				
		ointment or spray				
Hydrocortisone Acetate	Equivalent to 1.0 per cent Hydrocortisone	External  For use in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema, and in combination with one or more of the		Container or package containing not more than 15g of medicinal product  In the case of suppositories, container or package containing no more than 12		

	Exemptions from prescription on	om the restrictions aly medicines	on the sale an	d supply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration,	Column 4 Treatment limitations	Column 5 Maximum quantity	
		use or pharmaceutical form	,		
		following: Benzyl Benzoate, Bismuth Oxide, Bismuth Subgallate, Peru Balsam, Pramoxine Hydrochloride, Zinc Oxide, for haemorrhoids			
		For use in adults and children not less than 10 years			
		Cream, ointment or suppositories			
Hydrocortisone Butyrate					
Hydrocortisone Caprylate					
Hydrocortisone Hydrogen Succinate					
Hydrocortisone Sodium Phosphate					
Hydrocortisone Sodium Succinate	Equivalent to 2.5mg Hydrocortisone	External  For 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	

		rom the restrictions	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
		In the form of pellets		
Hydroflumeth	iazide			
Hydroxychlor Sulphate	oquine	Prophylaxis of malaria		
Hydroxyproge	esterone			
Hydroxyproge Enanthate	esterone			
Hydroxyproge Hexanoate	esterone			
Hydroxyurea				
Hydroxyzine Embonate				
Hydroxyzine Hydrochloride		(a) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride
		(b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in children not	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride

	Exemptions from prescription o	om the restrictions	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form less than 6 years but less		Column 5 Maximum quantity
		than 12 years		
Hyoscine	(1) 0.15 per cent	(1) Internal		
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Butylbromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 20mg (MD) 80mg (MDD)	(b) Container or package containing not more
				than 240mg of Hyoscine Butylbromide
		(2) External		
Hyoscine		(1) Internal		
Hydrobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD)	
			900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine		(1) Internal		
Methobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD)	
			7.5mg (MDD)	
		(2) External		
Hyoscine		(1) Internal		
Methonitrate		(a) by inhaler		

		om the restriction.	s on the sale and	l supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
		(b) otherwise than by inhaler	(b) 2.5mg (MD)	
			7.5mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD)	
			1mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Hydrobromide		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
			Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
Sulphate		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD)	
			Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Ibuprofen		Rheumatic and muscular pain, pain of		

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
		non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza			
			(1)(a) In the case of a prolonged release preparation 600mg (MD)		
			1,200mg (MDD)		
			(b) in any other case 400mg (MD)		
			1,200mg (MDD)		
	(2) 5.0 per cent	(2) External			
Idarubicin Hydrochloride					
Idoxuridine					
Ifosfamide Ignatius Bean					
Imipenem Hydrochloride					
Imipramine					

Imipramine Hydrochloride

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

Imipramine Ion Exchange Resin Bound Salt or

Complex

Indapamide Hemihydrate

Indomethacin

Indomethacin Sodium

Indoprofen

Indoramin Hydrochloride

Inosine Pranobex

Iodamide

Iodamide Meglumine

Iodamide Sodium

Iohexol

Iomeprol

Iopamidol

Iopentol

Iothalamic

Acid

Ioversol

Ioxaglic Acid

Ipratropium Bromide

Iprindole

Hydrochloride

Iproniazid Phosphate

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Isoaminile

Isoaminile Citrate

Isocarboxazid

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

Isoetharine

Isoetharine Hydrochloride

Isoetharine Mesylate Isoniazid

Isoprenaline Hydrochloride

Isoprenaline Sulphate

Isopropamide Iodide

Equivalent of 2.5mg of

Isopropamide ion (MD)

Equivalent of 5.0mg of Isopropamide ion (MDD)

Isotretinoin

Isradipine

Itraconazole

Jaborandi External

Kanamycin Acid Sulphate

Latamoxef Disodium

	prescription o	om the restriction nly medicines	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutica form		Column 5 Maximum quantity
Kanamycin Sulphate				
Ketamine Hydrochloride				
Ketoconazole	2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp	Maximum frequency of application of once every 3 days	Container or package containing not more than 120ml of medicinal product and
		In the form of a shampoo		containing not more than 2,400mg of Ketoconazole
Ketoprofen	2.5 per cent	External	For maximum period of 7 days	Container
	For rheumatic and muscular pain in adults and children not less than 12	pain in adults and children not less than		or package containing not more than 30g of medicinal product
Ketorolac Trometamol				
Ketotifen Fumarate				
Labetalol Hydrocholoride				
Lachesine Chloride				
Lacidipine				
Lamotrigine				
Lanatoside C				
Lanatoside Complex A, B and C				

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

Levallorphan Tartrate

Levobunolol Hydrochloride

Levodopa

Levonorgestrel

Lidoflazine

Lignocaine Non-

ophthalmic

use

Lignocaine Hydrochloride Nonophthalmic

use

Lincomycin Lincomycin

Hydrochloride Liothyronine

Sodium Lisinopril

Lithium Carbonate

Equivalent of 5mg of

Lithium (MD)

Equivalent of 15mg of Lithium (MDD)

Lithium Citrate

Lithium Succinate

Lithium Equivalent Sulphate of 5mg of

Lithium (MD)

Equivalent of 15mg

		om the restriction	s on the sale and	supply of
Column 1	prescription of Column 2	nly medicines Column 3	Column 4	Column 5
Substance	Maximum	Route of	Treatment	Maximum
Suestance	strength	administration,		quantity
		use or	_	
		pharmaceutica form	l	
		jorni	of Lithium (MDD)	
Lobeline		(1) Internal	(1) 3mg (MD)	
			9mg (MDD)	
		(2) External		
Lobeline Hydrochloride		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lobeline Sulphate		(1) Internal	(1) Equivalent of 3mg of Lobeline (MD)	
			Equivalent of 9mg of Lobeline (MDD)	
		(2) External		
Lodoxamide Trometamol				
Lofepramine				
Lofepramine Hydrochloride				
Lofexidine Hydrochloride				
Lomefloxacin Hydrochloride				
Lomustine				
Loperamide Hydrochloride		Treatment of acute diarrhoea		

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
Loratidine			10mg (MDD)	Container or package containing not more than 100mg of Loratidine	
Loxapine Succinate					
Lung Surfactant Porcine					
Luteinising Hormone					
Lymecycline					
Lynoestrenol					
Lypressin					
Lysuride Maleate					
Mafenide					
Mafenide Acetate					
Mafenide Hydrochloride					
Mafenide Propionate	5.0 per cent	Eye drops			
Magnesium Fluoride					
Magnesium Metrizoate					
Mandragora Autumnalis					
Mannomustine Hydrochloride					
Maprotiline Hydrochloride					

Mebanazine

	prescription	rom the restriction. only medicines	s on the sale an	d supply of
	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
Mebendazole		For oral use in the treatment of enterobiasis in adults and in children not less than 2 years	100mg (MD)	Container or package containing not more than 800mg of Mebendazole
Mebeverine Hydrochloride		For the symptomatic relief of irritable bowel syndrome	135mg (MD) 405mg (MDD)	
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride				
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyprogesto Acetate	erone			
Mefenamic Acid				
Mefloquine Hydrochloride				
Mefruside				
Megestrol				
Megestrol Acetate				
Meglumine Gadopentetate				

	1 0	rom the restrictions only medicines	s on the sale ar	nd supply of
Column 1	Column 2	Column 3	Column 4	Column 5
Substance	Maximum strength	Route of administration, use or pharmaceutical form		Maximum quantity

Meglumine

Iodoxamate

Meglumine Ioglycamate

Meglumine Iothalamate

Meglumine Iotroxate

Meglumine Ioxaglate

Melphalan Melphalan Hydrochloride

Menotrophin

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

Mephenesin

Mephenesin Carbamate

Mepivacaine Hydrochloride Any use except ophthalmic use

Meptazinol Hydrochloride

Mequitazine

Mercaptopurine

Mersalyl

Mersalyl Acid

Mesalazine

Mesna

Mestranol

Metaraminol Tartrate

66

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

Metergoline

Metformin

Hydrochloride

Methacycline

Methacycline Calcium

Methacycline Hydrochloride

Methallenoestril

Methicillin Sodium

Methixene

Methixene

Hydrochloride

Methocarbamol

Methocidin

Throat lozenges and throat pastilles

Methohexitone

Sodium

Methoin

Methoserpidine

Methotrexate

Methotrexate

Sodium

Methotrimeprazine

Methotrimeprazine Hydrochloride

Methotrimeprazine

Maleate

Methoxamine 0.25 per cent Hydrochloride

Nasal sprays or nasal drops not containing liquid paraffin as a vehicle

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Methsuximide

Methyclothiazide

Methyldopa

Methyldopate Hydrochloride

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

Methylprednisolone

Methylprednisolone

Acetate

Methylprednisolone

Sodium Succinate

Methylthiouracil

Methysergide

Maleate

Metipranolol

Metirosine

Metoclopramide Hydrochloride

Metolazone

Metoprolol

Fumarate

Metoprolol

Succinate

Metoprolol

Tartrate

Metronidazole

Metronidazole

Benzoate

Metyrapone

Mexiletine

Hydrochloride

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 Maximum strength administration, limitations quantity use or pharmaceutical form

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 of vaginal candidiasis

Mifepristone

Miglitol

Milrinone

Milrinone Lactate

Minocycline

Minocycline Hydrochloride

Minoxidil 2.0 per cent External

Misoprostol
Mitobronitol
Mitomycin
Mitozantrone
Hydrochloride

Mivacurium Chloride

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

Moclobemide

Molgramostim

Molindone

Hydrochloride

Mometasone

Furoate

Moracizine

Hydrochloride

Morazone

Hydrochloride

Mupirocin

Mupirocin

Calcium

Mustine

Hydrochloride

Nabilone

Nabumetone

Nadolol

Nafarelin

Acetate

Naftidrofuryl

Oxalate

Naftifine

Hydrochloride

Nalbuphine

Hydrochloride

Nalidixic Acid

Nalorphine

Hydrobromide

Naloxone

Hydrochloride

Naltrexone

Hydrochloride

Methylsulphate

		Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity		
Naphazoline Hydrochloride	(1) 0.05 per cent	(1) Nasal sprays or nasal drops not containing liquid paraffin as a vehicle				
	(2) 0.015 per cent	(2) Eye drops				
Naphazoline Nitrate	0.05 per cent	Nasal sprays or nasal drops not containing liquid paraffin as a vehicle				
Naproxen						
Naproxen Sodium						
Natamycin						
Nedocromil Sodium						
Nefazodone Hydrochloride						
Nefopam Hydrochloride						
Neomycin						
Neomycin Oleate						
Neomycin Palmitate						
Neomycin Sulphate						
Neomycin Undecanoate						
Neostigmine Bromide						
Neostigmine Methylsulphate	<b>.</b>					

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Netilmicin Sulphate

Nicardipine Hydrochloride

Nicergoline

Nicotinic Acid

Any use, 600mg except for the treatment of hyperlipidaemia 600mg

Nicoumalone

Nifedipine

Nifenazone

Nikethamide

Nimodipine

Niridazole

Nitrendipine

Nitrofurantoin

Nitrofurazone

Nizatidine

For the prevention of the symptoms

75mg (MD)

the symptoms of food-related heartburn

Maximum of 4 such doses in any period of 14 days

For use in adults and children not less than 16 years

Nomifensine Maleate

Noradrenaline

Noradrenaline Acid Tartrate

Norethisterone

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

Norethisterone

Acetate

Norethisterone

Enanthate

Norethynodrel

Norfloxacin

Norgestimate

Norgestrel

Nortriptyline

Hydrochloride

Noscapine

Noscapine

Hydrochloride

Novobiocin

Calcium

Novobiocin

Sodium

Nux Vomica

Seed

Nystatin

Octacosactrin

Octreotide

Oestradiol

Oestradiol

Benzoate

Oestradiol

Cypionate

Oestradiol

Dipropionate

Oestradiol

Diundecanoate

Oestradiol

Enanthate

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

Oestradiol

Phenylpropionate

Oestradiol

Undecanoate

Oestradiol

Valerate

Oestriol

Oestriol

Succinate

Oestrogenic

Substances

Conjugated

Oestrone

Ofloxacin

Olsalazine

Sodium

Omeprazole

Ondansetron

Hydrochloride

Orciprenaline

Sulphate

Orphenadrine

Citrate

Orphenadrine

Hydrochloride

Ouabain

Ovarian Gland

Dried

Oxamniquine

Oxantel

Embonate

Oxaprozin

Oxatomide

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

Tartrate

Oxethazaine 10mg (MD) Container or package

30mg (MDD) containing not more than 400mg of Oxethazaine

Oxitropium Bromide

Oxolinic Acid

Oxpentifylline

Oxprenolol Hydrochloride

Non-Oxybuprocaine Hydrochloride ophthalmic use

Oxybutynin Hydrochloride

Oxypertine

Oxypertine Hydrochloride

Oxyphenbutazone

Oxyphencyclimine Hydrochloride

Oxyphenonium Bromide

Oxytetracycline

Oxytetracycline Calcium

Oxytetracycline Dihydrate

Oxytetracycline Hydrochloride

5mg (MD)

15mg (MDD)

	Exemptions fro prescription on	m the restrictions ly medicines	s on the sale and	d supply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
Oxytocin, natural					
Oxytocin, synthetic					
Pancreatin	(1) 21,000 European Pharmacopoeia units of lipase per capsule	(1) capsules			
	(2) 25,000 European Pharmacopoeia units of lipase per gram	(2) powder			
Pancuronium Bromide					
Papaverine		(1) By inhaler			
		(2) Otherwise than by inhaler	(2) 50mg (MD)		
			150mg (MDD)		
Papaverine		(1) By inhaler			
Hydrochloride		than by inhaler	(2) Equivalent of 50mg of Papaverine (MD)		
			Equivalent of 150mg of Papaverine (MDD)		
Paraldehyde					
Paramethadione	<del>)</del>				
Paramethasone Acetate					
Parathyroid					

Gland

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

Pargyline Hydrochloride

Paroxetine Hydrochloride

Pecilocin

Penamecillin

Penbutolol Sulphate

Penicillamine

Penicillamine Hydrochloride

Pentamidine Isethionate

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

Pentolinium Tartrate

Perfluamine

Pergolide Mesylate

Perhexiline Maleate

Pericyazine

Perindopril Perindopril Erbumine

Perphenazine

Phenacetin 0.1 per cent

Phenazone External

Phenazone Salicylate

Phenbutrazate Hydrochloride

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Phenelzine Sulphate

Phenethicillin

Potassium

Phenformin

Hydrochloride

Phenglutarimide

Hydrochloride

Phenindione

Phenoxybenzamine Hydrochloride

Phenoxymethylpenicillin

Phenoxymethylpenicillin

Calcium

Phenoxymethylpenicillin

Potassium

Phenprocoumon

Phensuximide

Phentolamine

Hydrochloride

Phentolamine

Mesylate

Phenylbutazone

Phenylbutazone

Sodium

Phenylpropanolamine

Hydrochloride

Internal

nasal drops

(1) all (1) 25mg preparations (MD) except prolonged release capsules, nasal sprays and (MDD)

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
		(2) prolonged release capsules	(2) 50mg (MD) 100mg (MDD)		
	(3) 2.0 per cent	(3) nasal sprays and nasal drops	(22)		
Phenytoin		•			
Phenytoin Sodium					
Phthalylsulphat	hiazole				
Physostigmine					
Physostigmine Aminoxide Salicylate					
Physostigmine Salicylate					
Physostigmine Sulphate					
Picrotoxin					
Pilocarpine					
Pilocarpine Hydrochloride					
Pilocarpine Nitrate					
Pimozide					
Pindolol					
Pipenzolate Bromide			5mg (MD) 15mg (MDD)		
Piperacillin Sodium					
Piperazine Oestrone Sulphate					

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutica form		Column 5 Maximum quantity		
Piperidolate			50mg (MD)			
Hydrochloride			150mg (MDD)			
Pipothiazine Palmitate						
Piracetam						
Pirbuterol Acetate						
Pirbuterol Hydrochloride						
Pirenzepine Hydrochloride						
Piretanide						
Piroxicam	0.5 per cent	External  For the relief of rheumatic pain, pain of non-serious arthritic conditions and muscular aches, pains and swellings such as strains, sprains and sports injuries  For use in adults and children not less than 12	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product		
		years				
Pituitary Gland (Whole Dried)		By inhaler				
Pituitary Powdered		By inhaler				

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 Maximum administration, limitations strength quantity use or pharmaceutical form

(Posterior

Lobe)

Pivampicillin

Pivampicillin

Hydrochloride

Pivmecillinam

Pivmecillinam

Hydrochloride

Pizotifen

Pizotifen

Malate

Plicamycin

Podophyllotoxin

Podophyllum

Podophyllum

Indian

Podophyllum 20.0 per cent

Resin

External

Ointment or impregnated

plaster

Poldine

2mg (MD)

Methylsulphate

6mg (MDD)

Polidexide

Polyestradiol

Phosphate

Polymyxin B

Sulphate

Polythiazide

Poppy

Capsule

Potassium 0.0127 per

Arsenite cent

Potassium Bromide

81

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

Potassium

Canrenoate

Potassium

Clavulanate

Potassium

Perchlorate

Practolol

Pralidoxime

Chloride

Pralidoxime

Iodide

Pralidoxime

Mesylate

Pravastatin

Sodium

Prazosin

Hydrochloride

Prednisolone

Prednisolone

Acetate

Prednisolone

Butylacetate

Prednisolone

Hexanoate

Prednisolone

Metasulphobenzoate

Prednisolone

Metasulphobenzoate

Sodium

Prednisolone

Pivalate

Prednisolone

Sodium

Phosphate

Prednisolone

Steaglate

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Prednisone

Prednisone

Acetate

Prenalterol Hydrochloride

Prenylamine Lactate

Prilocaine Hydrochloride Nonophthalmic use

Primidone

Probenecid

Probucol

Procainamide Hydrochloride

Procaine Hydrochloride Nonophthalmic use

Procaine Penicillin

Procarbazine Hydrochloride

Prochlorperazine

Prochlorperazine

Edisylate

Prochlorperazine

Maleate

Prochlorperazine

Mesylate

Procyclidine Hydrochloride

Progesterone

Prolactin

Proligestone

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Prolintane Hydrochloride

Promazine Embonate

Promazine Hydrochloride

Propafenone

Propafenone Hydrochloride

Propanidid

Propantheline Bromide 15mg (MD) 45mg (MDD)

Propofol

Propranolol Hydrochloride

Propylthiouracil

Proquazone

Protamine Sulphate

Prothionamide

Protirelin

Protriptyline Hydrochloride

Proxymetacaine Hydrochloride Nonophthalmic

use

Pseudoephedrine Hydrochloride Internal

(a) In the case of a prolonged release

preparation 120mg (MD)

240mg (MDD)

Quinestradol

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutica form		Column 5 Maximum quantity		
			(b) in any other case 60mg (MD)			
			240mg (MDD)			
Pseudoephedrin	e		60mg (MD)			
Sulphate			180mg (MDD)			
Pyrantel Embonate		(a) For the treatment of enterobiosis, in adults and children not less than 12 years	(a) 750mg MDD (as a single dose)	(a) Container or package containing not more than 750mg of Pyrantel Embonate		
		(b) For the treatment of enterobiosis, in children less than 12 years but not less than 6 years	(b) 500mg MDD (as a single dose)	(b) Container or package containing not more than 750mg of Pyrantel Embonate		
		(c) For the treatment of enterobiosis in children less than 6 years but not less than 2 years	(c) 250mg MDD (as a single dose)	(c) Container or package containing not more than 750mg of Pyrantel Embonate		
Pyrantel Tartrate						
Pyrazinamide						
Pyridostigmine Bromide						
Pyrimethamine						
Quinapril						

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** Maximum strength administration, limitations quantity use or pharmaceutical form

Quinestrol

Quinethazone

Quinidine

Quinidine Bisulphate

Quinidine

Polygalacturonate

Quinidine Sulphate

Quinine 100mg (MD)

300mg (MDD)

Quinine Equivalent Bisulphate of 100mg of

Quinine (MD)

Equivalent of 300mg of Quinine (MDD)

Quinine Equivalent Cinchophen of 100mg of

Quinine (MD)

Equivalent of 300mg of Quinine (MDD)

Equivalent

Quinine

Dihydrochloride of 100mg of

Quinine (MD)

Equivalent of 300mg of Quinine (MDD)

Quinine Ethyl Equivalent
Carbonate of 100mg of

Quinine (MD)

	Exemptions from prescription of	om the restrictions	s on the sale and	supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
			Equivalent of 300mg of Quinine (MDD)	
Quinine Glycerophospha	ate		Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Hydrobromide			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Hydrochloride			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Iodobismuthate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Phosphate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	

	Exemptions from the restrictions on the sale and supply of prescription only medicines					
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutica form		Column 5 Maximum quantity		
Quinine Salicylate			Equivalent of 100mg of Quinine (MD)			
			Equivalent of 300mg of Quinine (MDD)			
Quinine Sulphate			Equivalent of 100mg of Quinine (MD)			
			Equivalent of 300mg of Quinine (MDD)			
Quinine Tannate			Equivalent of 100mg of Quinine (MD)			
			Equivalent of 300mg of Quinine (MDD)			
Quinine in combination with Urea Hydrochloride						
Ramipril						
Ranitidine Hydrochloride		For the short term symptomatic relief of	Equivalent to 75mg of Ranitidine (MD)			
		heartburn, dyspepsia, indigestion, acid indigestion	Equivalent to 300mg of Ranitidine (MDD)			
		and hyperacidity	For a maximum period of 14 days			

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

Rauwolfia

Serpentina

Rauwolfia

Vomitoria

Razoxane

Remoxipride

Hydrochloride

Reproterol

Hydrochloride

Rescinnamine

Reserpine

Rifabutin

Rifampicin

Rifampicin

Sodium

Rifamycin

Rimiterol

Hydrobromide

Risperidone

Ritodrine

Hydrochloride

Rolitetracycline

Nitrate

Sabadilla

Salbutamol

Salbutamol

Sulphate

Salcatonin

Salcatonin

Acetate

Salmefamol

Salmeterol

Xinafoate

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

Salsalate

Saralasin

Acetate

Selegiline

Hydrochloride

Semisodium

Valproate

Serum

Gonadotrophin

Silver

Sulphadiazine

Simvastatin

Sissomicin

Sissomicin

Sulphate

Snake Venoms

Sodium

Acetrizoate

Sodium

Aminosalicylate

Sodium

Antimonylgluconate

Sodium

Arsanilate

Sodium

Arsenate

Sodium 0.013 per cent

Arsenite

Sodium Bromide

Sodium Clodronate

Sodium (a) For nasal Cromoglycate admistration

Sodium Metrizoate

		rom the restrictions only medicines	s on the sale a	nd supply of	
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
	(b) 2.0 per cent	(b) For the treatment of acute seasonal allergic conjunctivitis		(b) Container or package containing not more than 10ml of medicinal	
		In the form of aqueous eye drops		product	
	(c) 4.0 per cent	(c) For the treatment of acute seasonal allergic conjunctivitis		(c) Container or package containing not more than 5g of medicinal	
		In the form of an eye ointment		product	
Sodium Ethacrynate					
Sodium	(1) 0.33 per	(1) Dentifrices			
Fluoride	cent	(2) Other preparations for use in the prevention of dental caries			
		In the form of			
		(a) tablets or drops	(a) 2.2 mg (MDD)		
	(b) 0.2 per cent	(b) mouth rinses other than those for daily use			
	(c) 0.05 per cent	(c) mouth rinses for daily use			
Sodium Fusidate					

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 Maximum administration, limitations strength quantity use or pharmaceutical form Dentrifrice

Sodium 1.14 per cent

Monofluorophosphate

Sodium

Oxidronate

Sodium

Stibogluconate

Sodium

Valproate

Somatorelin

Acetate

Sotalol

Hydrochloride

Spectinomycin

Spectinomycin

Hydrochloride

Spiramycin

Spiramycin

Adipate

Spironolactone

Stannous

0.62 per cent

Dentifrice

Fluoride

Stilboestrol

Stilboestrol

Dipropionate

Streptodornase

External

Streptokinase

External

Streptomycin

Streptomycin

Sulphate

Strychnine

Strychnine

Arsenate

Strychnine

Hydrochloride

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

Styramate

Succinylsulphathiazole

Sucralfate

Sulbactam

Sodium

Sulbenicillin

Sulbenicillin

Sodium

Sulconazole Nitrate External (except vaginal)

Sulfacytine

Sulfadoxine

Sulfamerazine

Sulfamerazine

Sodium

Sulfametopyrazine

Sulfamonomethoxine

Sulindac

Sulphacetamide

Sulphacetamide

Sodium

Sulphadiazine

Sulphadiazine

Sodium

Sulphadimethoxine

Sulphadimidine

Sulphadimidine

Sodium

Sulphafurazole

Sulphafurazole

Diethanolamine

Sulphaguanidine

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

Sulphaloxic

Acid

Sulphamethizole

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethoxypyridazine

Sodium

Sulphamoxole

Sulphanilamide

Sulphaphenazole

Sulphapyridine

Sulphapyridine

Sodium

Sulphasalazine

Sulphathiazole

Sulphathiazole

Sodium

Sulphaurea

Sulphinpyrazone

Sulpiride

Sultamicillin

Sultamicillin

Tosylate

Sulthiame

Sumatriptan

Succinate

Suprofen

Suxamethonium

Bromide

Suxamethonium

Chloride

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 Maximum strength administration, limitations quantity use or pharmaceutical form

Suxethonium

Bromide

Tacrine

Hydrochloride

Talampicillin

Talampicillin

Hydrochloride

Talampicillin

Napsylate

Tamoxifen

Tamoxifen

Citrate

Tazobactam

Sodium

Teicoplanin

Temocillin

Sodium

Tenoxicam

Terazosin

Hydrochloride

Terbinafine

Terbutaline

Terbutaline

Sulphate

Terfenadine

120mg Container (MDD) or package

or package containing no more than 1,200mg of Terfenadine

Terlipressin

Terodiline

Hydrochloride

Tetrabenazine

Tetracosactrin

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

Tetracosactrin

Acetate

Tetracycline

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

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

Thymoxamine Hydrochloride

Thyroid

Thyrotrophin

Thyroxine Sodium

Tiamulin Fumarate

Tianrofeni

Tiaprofenic

Acid

Tibolone

Ticarcillin Sodium

Tigloidine

Hydrobromide

Timolol Maleate

Tinidazole

Tinzaparin

Tioconazole

(1) 2.0 per cent

(1) External (except vaginal)

(2) Vaginal for treatment of vaginal candidiasis

Tobramycin

Tobramycin Sulphate

Tocainide Hydrochloride

Tofenacin Hydrochloride

Tolazamide

	1 0	from the restrictions only medicines	s on the sale a	nd supply of	
Column 1	Column 2	Column 3	Column 4	Column 5	
Substance	Maximum strength	Route of administration, use or pharmaceutical form		Maximum quantity	
Tolazoline		External			

Tolazoline

Hydrochloride

Tolbutamide

Tolbutamide Sodium

Tolfenamic

Acid

Tolmetin

Sodium

Tramadol Hydrochloride

Trandolapril

Tranexamic

Acid

Tranylcypromine

Sulphate

Trazodone

Hydrochloride

Treosulfan

Tretinoin

Triamcinolone

Triamcinolone 0.1 per cent

Acetonide

For the treatment of common mouth ulcers Container or package containing not more than 5g of medicinal product

Triamcinolone

Diacetate

Triamcinolone

Hexacetonide

Triamterene

Tribavirin

Triclofos

Sodium

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

Trientine

Dihydrochloride

Trifluoperazine

Trifluoperazine Hydrochloride

Trifluperidol

Trifluperidol Hydrochloride

Trilostane

Trimeprazine

Trimeprazine

Tartrate

Trimetaphan Camsylate

Trimetazidine

Trimetazidine Hydrochloride

Trimethoprim

Trimipramine Maleate

Trimipramine Mesylate

Tropicamide

Tropisetron Hydrochloride

Troxidone

L-Tryptophan

(1) Oral

Dietary supplementation

(2) External

Tubocurarine Chloride

Tulobuterol

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

Tulobuterol Hydrochloride

Tyrothricin

Throat lozenges or throat pastilles

Uramustine

Urea

Stibamine

Urethane

Uridine 5'triphosphate

Urofollitrophin

Urokinase

Ursodeoxychoic

Acid

Vaccine:

Bacillus

Salmonella

Typhi

Vaccine:

Poliomyelitis

(Oral)

Valproic Acid

Vancomycin Hydrochloride

Vasopressin

Vasopressin

Tannate

Vecuronium

Bromide

Verapamil

Hydrochloride

Veratrine

Veratrum,

Green

	Exemptions fr prescription o	om the restrictions	s on the sale and	d supply of
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity
Veratrum, White				
Vidarabine				
Vigabatrin				
Viloxazine Hydrochloride				
Vinblastine Sulphate				
Vincristine Sulphate				
Vindesine Sulphate				
Viomycin Pantothenate				
Viomycin Sulphate				
Vitamin A			(1) 7,500iu (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Acetate			(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Palmitate			(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	

	Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	Column 2 Maximum strength	Column 3 Route of administration, use or pharmaceutical form		Column 5 Maximum quantity	
		(2) External			
Warfarin					
Warfarin Sodium					
Xamoterol Fumarate					
Xipamide					
Yohimbine Hydrochloride					
Zidovudine					
Zimeldine Hydrochloride					
Zolpidem Tartrate					
Zomepirac Sodium					
Zopiclone					
Zuclopenthixol Acetate					
Zuclopenthixol Decanoate					
Zuclopenthixol Hydrochloride					

## SCHEDULE 2 Articles 6(1) and 10

Circumstances excluding medicinal products from the class of prescription only medicines			from the class of
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical Form	Column 4 Maximum Dose
Codeine and its salts	Equivalent of 1.5 per cent of codeine monohydrate		Equivalent of 20 mg of codeine monohydrate

	Circumstances excludi prescription only medi	ng medicinal products J	from the class of
Column 1 Substance	Column 2 Maximum strength	Column 3 Pharmaceutical Form	Column 4 Maximum Dose
Dihydrocodeine and its salts	Equivalent of 1.5 per cent of dihydrocodeine		Equivalent of 10 mg of dihydrocodeine
Ethylmorphine andits salts	Equivalent of 0.2 per cent of ethylmorphine		Equivalent of 7.5 mg of ethylmorphine
Morphine and its salts	(1) Equivalent of 0.02 per cent anhydrous morphine	(1) Liquid	(1) Equivalent of 3 mg of anhydrous morphine
	(2) Equivalent of 0.04 per cent of anhydrous morphine; equivalent of 300 mcg of anhydrous morphine	(2) Solid	(2) Equivalent of 3 mg of anhydrous morphine
Medicinal Opium	(1) Equivalent of 0.02 per cent of anhydrous morphine	(1) Liquid	(1) Equivalent of 3 mg of anhydrous morphine
	(2) Equivalent of 0.04 per cent of anhydrous morphine	(2) Solid	(2) Equivalent of 3 mg of anhydrous morphine
Pholcodine and its salts	Equivalent of 1.5 per cent of pholoodine monohydrate		Equivalent of 20 mg of pholcodine monohydrate

#### SCHEDULE 3

Article 2(b)

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

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

#### SCHEDULE 4

Article 8(4)(c)

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

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone Sodium

Hydrobromic Acid

Meclofenoxate Hydrochloride

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

#### SCHEDULE 5

Article 11(1)(a)

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

# PART I EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

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

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

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

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

- Persons selling or supplying prescription only medicines to any of the following
  - a public analyst appointed under section 27 of the Food Safety Act 1990(21) or article 36 of the Food (Northern Ireland) Order 1989(22),
  - (2) an authorized officer within the meaning of section 5(6) of the

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

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

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

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
Food Safety Act 1990,		
(3) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989,		
(4) a person duly authorized by an enforcement authority under sections 111 and 112,		
(5) a sampling officer within the meaning of Schedule 3 to the Act.		

- 3. Persons selling or supplying prescription only medicines to any person employed or engaged in connection with a scheme for testing the quality and checking the amount of the drugs and appliances supplied under the National Health Service Act 1977(23), the National Health Service (Scotland) Act 1978(24) and the Health and Personal Social Services (Northern Ireland) Order 1972(**25**), or under any subordinate legislation made under those Acts or that Order.
- 3. All prescription only medicines.
- - 4. Prescription only medicines containing any of the following substances-

Chloral hydrate Ergometrine maleate

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

4. Registered midwives.

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

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

<sup>(25)</sup> S.I. 1972/1265 (N.I. 14).

Column 1	Column	2	Column 3
Persons exempted	Prescrip	otion only medicines the exemption	Conditions
		Pentazocine hydrochloride Triclofos sodium.	
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	me not adr	scription only dicines which are for parenteral ninistration and ich— are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or are prescription only medicines by reason only that they contain any of the following substances: Atropine sulphate Bethanecol chloride Carbachol Cyclopentolate hydrochloride Homatropine hydrochloride Naphazoline hydrochloride Naphazoline nitrate Physostigmine salicylate	e

Column 1	Column 2	Column 3		
Persons exempted	Prescription only medicines to which the exemption applies	Conditions		
	Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.			
6. Registered ophthalmic opticians.	6. Prescription only medicines listed in column 2 of paragraph 5.	<ul> <li>6. The sale or supply shall be only—</li> <li>(a) in the course of their professional practice and</li> <li>(b) in an emergency.</li> </ul>		
7. Persons selling or supplying prescription only medicines to the British Standards Institution.	7. All prescription only medicines.	7. The sale or supply shall be—  (a) subject to the presentation of an order signed on behalf of the British Standards Institution stating the status of the person signing it and the amount of the prescription only medicine required, and  (b) only for the purpose of testing containers of medicinal products or determining the standards for such containers.		
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	8. The sale or supply shall be only—  (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification		

Column 1	Column 2	Column 3		
Persons exempted	Prescription only medicines to which the exemption applies	Conditions		
		(c)	guide or similar publication, and of no greater quantity than is reasonably necessary for that purpose.	
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(26) or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons) or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(27).	9. Amyl nitrite.	only be so to enable	e or supply shall of far as is necessary an antidote to be to persons at risk of oisoning.	

Article 11(1)(b)

PART II EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
1. Royal National Lifeboat Institution and certified first aiders of the Institution.	1. All prescription only medicines.	1. The supply shall be only so far as is necessary for the the treatment of sick or injured persons in the exercise of the functions of the Institution.
2. The owner or the master of a ship which does not carry a doctor on board as part of her complement.	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the treatment of persons on the ship.

<sup>(</sup>**26**) 1972 c. 66. (**27**) S.I. 1976/1214 (N.I. 23).

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
3. Persons authorized by licences granted under regulation 5 of the Misuse of Drugs Regulations to supply a controlled drug.	3. Such prescription only medicines, being controlled drugs, as are specified in the licence.	3. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
4. Persons requiring prescription only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or in pursuance of any enactment with respect to the medical treatment of their employees.	4. Such prescription only medicines as may be specified in the relevant enactment.	<ul> <li>4. The supply shall be— <ul> <li>(a) for the purpose</li> <li>of enabling them</li> <li>to comply with</li> <li>any requirements</li> <li>made by or in</li> <li>pursuance of any</li> <li>such enactment,</li> <li>and</li> </ul> </li> <li>(b) subject to such <ul> <li>conditions and in</li> <li>such circumstances</li> <li>as may be specified</li> <li>in the relevant</li> <li>enactment.</li> </ul> </li> </ul>
5. Persons operating an occupational health scheme.	5. Prescription only medicines sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.	<ul> <li>(1) The supply shall be in the course of an occupational health scheme.</li> <li>(2) The individual supplying the prescription only medicine, if not a doctor, shall be a registered nurse acting in accordance with the 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	6. Prescription only medicines	6. The supply shall be only

administration and which have

which are not for parenteral

been sold or supplied to the

so far as is necessary for the

immediate treatment of sick or

injured persons on the aircraft

of an aircraft.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
	operator or commander of the aircraft in response to an order in writing signed by a doctor.	and shall be in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be used on the aircraft.
7. Persons employed as qualified first-aid personnel on offshore installations.	7. All prescription only medicines.	7. The supply shall be only so far as is necessary for the treatment of persons on the installation.

Article 11(2)

PART III
EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1	Column 2		Column 3
Persons exempted	-	on only medicines he exemption	Conditions
1. State registered chiropodists who hold a certificate of competence in the use of analgesics issued by or with the approval of the Chiropodists Board.	medi admi conta ingre one c	eription only cines for parenteral nistration that in,as the sole active dient, not more than of the following ances— Bupivacaine hydrochloride Lignocaine hydrochloride Prilocaine hydrochloride.	1. The administration shall be only in the course of their professional practice.
2. Registered midwives.	medi admi any c subst subst colur	eription only cines for parenteral nistration containing of the following ances but no other ance specified in nn 1 of Schedule 1 s Order— Ergometrine maleate Lignocaine	2. The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption	Conditions
	applies  Lignocaine	
	hydrochloride Naloxone	
	hydrochloride	
	Oxytocins, natural and synthetic	
	Pentazocine lactate	
	Pethidine hydrochloride	
	Phytomenadione Promazine	
	hydrochloride.	
3. Persons who are authorized	3. Prescription only medicines	3. The administration shall

- 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.
- 4. The owner or master of a ship which does not carry a doctor on board as part of her complement.
- 5. Persons operating an occupational health scheme.

- 3. Prescription only medicines that are specified in the group authority.
- 4. All prescription only medicines that are for parenteral administration.
- 5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor or a registered nurse.
- 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 administration shall be only so far as is necessary for the treatment of persons on the ship.
- 5.
  - (1) The administration shall be in the course of an occupational health scheme.
  - (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be a registered nurse acting in accordance with the written instructions of a doctor as to the circumstances in which prescription only medicines of the description in question are to be

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
		used in the course of the occupational health scheme.
6. The operator or commander of an aircraft.	6. Prescription only medicine for parenteral administration which have been sold or supplied to the operator or commander of the aircraft in response to an order in writin signed by a doctor.	be only so far as is necessary for the immediate treatment of sick or injured persons on the aircraft and shall be in
7. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.	7. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in article 3(c) (products for parenteral administration).	7. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgement as to the treatment required.
8. Persons employed as qualified first-aid personnel on offshore installations.	8. All prescription only medicines that are for parenteral administration.	8. The administration shall be only so far as is necessary for the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.	9. The following prescription only medicines for parentera administration—  (a) Diazepam 5 mg p ml emulsion for injection;  (b) Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion;  (c) prescription only medicines containing one or more of the following substances, but no active ingredient—	injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines	Conditions
	to which the exemption	
	applies	
	Adrenaline	
	Acid Tartrat	te
	Anhydrous	
	Glucose	
	Compound	
	Sodium	
	Lactate	
	Intravenous	
	Infusion	
	(Hartmann's	S
	Solution)	
	Ergometrine	e
	Maleate	
	Glucose	
	Heparin	
	Sodium	
	Lignocaine	
	Hydrochlor	
	Nalbuphine	
	Hydrochlor	ide
	Naloxone	
	Hydrochlor	ide
	Polygeline	
	Sodium	
	Bicarbonate	
	Sodium	
	Chloride	

## SCHEDULE 6

Article 16(1)

## ORDERS REVOKED

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

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

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

#### **EXPLANATORY NOTE**

(This note is not part of the Order)

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

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

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

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

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

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