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

(**1**) 1968 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.

(**2**) 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**);

"inhaler" does not include an aerosol;

"master" has the same meaning as in section 313(1) of the Merchant Shipping Act 1995(**9**);

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

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

"maximum strength" means–

(**3**) 1979 c. 36; the Parts of the professional register were determined by S.I. 1983/667, amended by S.I. 1989/104 and 1989/1455.
(**4**) Approved by S.I. 1983/873, to which there are amendments not relevant to this Order.
(**5**) 1971 c. 38.
(**6**) 1977 c. 49.
(**7**) 1978 c. 29.
(**8**) S.I. 1972/1265 (N.I. 14).
(**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;

(**10**) S.I. 1985/2066.
(**11**) SR 1986 No. 52.
(**12**) 1971 c. 61; section 1 was substituted by section 24 of the Oil and Gas (Enterprise) Act 1982 (c. 23).
(**13**) 1964 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:

"g" for gram,

"iu" for international unit of activity,

"mcg" for microgram,

"mg" for milligram,

"ml" for millilitre.

(**14**) 1989 c. 44.
(**15**) 1960 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[F1]...;

(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.

Textual Amendments

F1 Words in art. 3(c) omitted (13.8.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **2**

Duration of special provisions in relation to new medicinal products

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

(**16**) OJ No. L214, 24.8.93, p. 1.

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

(**17**) OJ No. L214, 24.8.93, p. 1.

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;

(**18**) S.I. 1980/1923, amended by S.I. 1997/1831.

(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.

(**19**) S.I. 1989/1852.

Signed by authority of the Secretary of State for Health

Baroness Jay
Minister of State,
Department of Health

Win Griffiths
Parliamentary Under Secretary of State, Welsh Office

Sam Galbraith
Parliamentary Under Secretary of State, The Scottish Office

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

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

D. C. Gowdy
Permanent Secretary

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

P. Small
Permanent Secretary

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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Acarbose				
Acebutolol Hydrochloride				
Acemetacin				
Acetarsol				
Acetazolamide				
Acetazolamide Sodium				
Acetohexamide				
Acetylcholine Chloride	0.2 per cent	External		
Acetylcysteine				
Acipimox				
Aciclovir	5.0 per cent	External For treatment of herpes simplex virus infections of the lips and face (Herpes labialis)		Container or package containing not more than 2g of medicinal product
Acitretin				
Aclarubicin Hydrochloride				
Aconite	1.3 per cent	External		
Acrivastine			24 mg (MDD)	Container or package containing not more than 240mg of Acrivastine

	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 4 Treatment limitations*	*Column 5 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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Alprenolol				
Alprenolol Hydrochloride				
Alprostadil				
Alseroxylon				
Amantadine Hydrochloride				
Ambenonium Chloride				
Ambutonium Bromide				
Amcinonide				
Ametazole Hydrochloride				
Amethocaine		Non-ophthalmic use		
Amethocaine Gentisate		Non-ophthalmic use		
Amethocaine Hydrochloride		Non-ophthalmic 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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Amylocaine Hydrochloride		Non-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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *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 For treatment of hayfever in adults and children not	10mg (MDD)	Container or package containing not more than 100mg of Astemizole

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 4 Treatment limitations*	*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 Methobromide		(1) Internal			
		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD) 1.3mg (MDD)		
		(2) External (except ophthalmic)			
Atropine Methonitrate		Internal			
		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 400mcg (MD) 1.3mg (MDD)		
Atropine Oxide Hydrochloride		(1) Internal			
		(a) by inhaler			
		(b) otherwise than by inhaler	(b) 360mcg (MD)		

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 4 Treatment limitations*	*Column 5 Maximum quantity*	
			1.2mg (MDD) 3		
		(2) External (except ophthalmic)			
Atropine Sulphate		(1) Internal			
		(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 containing not more than 5,040mcg of Azelastine Hydrochloride	
		For the treatment of seasonal allergic rhinitis	280mcg per nostril (MDD)		
		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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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 (non-aerosol) 200mcg per nostril (MDD) For the prevention and treatment of allergic rhinitis	100mcg per nostril (MD)	Container or package containing not more than 5,600mcg of Beclomethasone Dipropionate
For use in adults and children not				

	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 4* *Treatment limitations*	*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 Substance	*Column 2 Maximum strength*	*Column 3 Route of administration, use or pharmaceutical form*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
Benzoctamine Hydrochloride				
Benzoyl Peroxide	10.0 per cent	External		
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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Bethanechol Chloride				
Bethanidine Sulphate				
Bezafibrate				
Biperiden Hydrochloride				
Biperiden Lactate				
Bismuth Glycollylarsanilate				
Bisoprolol Fumarate				
Bleomycin				
Bleomycin Sulphate				
Bretylium Tosylate				
Bromhexine Hydrochloride				
Bromocriptine Mesylate				
Bromperidol				
Bromvaletone				
Brotizolam				
Budesonide		For nasal administration	200mcg per nostril (MD)	Container or package containing not more than 10mg of Budesonide
		For the prevention or treatment of seasonal allergic rhinitis	200mcg per nostril (MDD)	
		For use in adults and in children not		

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 4 Treatment limitations*	*Column 5 Maximum quantity*
		less than 12 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 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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Calcium Benzamidosalicylate				
Calcium Bromide				
Calcium Bromidolactobionate				
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) Pellet	(1) 5mg (MD) 25mg (MDD)	
	(2) 2.0 per cent	(2) Gel		
	(3) 1.0 per cent	(3) Granules for mouthwash in adults and children not	(3) 20mg (MD) 80mg (MDD)	(3) Container or package containing not more than **[**[F2]560mg**]** 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 4 Treatment limitations*	*Column 5 Maximum quantity*
		less than 12 years		Carbenoxolone 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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Chenodeoxycholic Acid				
Chloral Hydrate		External		
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 Phosphate		Prophylaxis of malaria		
Chloroquine Sulphate		Prophylaxis of malaria		
Chlorothiazide				
Chlorotrianisene				
Chlorphenoxamine Hydrochloride				

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

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

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 4 Treatment limitations*	*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					

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Clindamycin Palmitate Hydrochloride				
Clindamycin Phosphate				
Clioquinol		(1) External (other than treatment of mouth ulcers)		
	(2) 35mg	(2) Treatment of mouth ulcers	(2) 350mg (MDD)	
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 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 4* *Treatment limitations*	*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 Substance	*Column 2 Maximum strength*	*Column 3 Route of administration, use or pharmaceutical form*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Daunorubicin Hydrochloride				
Deanol Bitartrate			26mg (MDD)	
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 1 *Substance*	*Column 2* *Maximum strength*	*Column 3* *Route of administration, use or pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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) (b) in any other case: equivalent	

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*	
			of 15mg of Dextromethorphan (MD) equivalent of 75mg of Dextromethorphan (MDD)		
Dextrothyroxine Sodium					
Diazoxide					
Dibenzepin Hydrochloride					
Dichloralphenazone					
Dichlorphenamide					
Diclofenac Diethylammonium	1.16 per cent	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 rheumatism For use in adults and children not less than 12 years	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product	
Diclofenac Potassium					
Diclofenac Sodium					

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Dicyclomine Hydrochloride			10mg (MD) 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 Hydrochloride		Non-ophthalmic use		
Dimethisterone				
Dimethothiazine Mesylate				
Dimethyl Sulphoxide				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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		**[**F3For the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and	**[**F310mg (MD) 40mg (MD)**]**	**[**F3Container or package containing not more than 100mg of Domperidone as Domperidone Maleate;**]**

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 4 Treatment limitations*	*Column 5 Maximum quantity*
		belching, occasionally accompanied by epigastric discomfort and heartburn,]		
Dopamine Hydrochloride				
Dopexamine Hydrochloride				
Dothiepin				
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		

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
		treatment of vaginal candidiasis		
Econazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Ecothiopate Iodide				
Edrophonium Chloride				
Eflornithine Hydrochloride				
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, Tick-borne, Cent Eur				
Enoxacin				
Enoxaparin Sodium				
Enoximone				

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Ephedrine		(1) Internal (other than nasal sprays or nasal drops)	(1) 30mg (MD) 60mg (MDD)	
	(2) 2.0 per cent	(2) Nasal sprays or nasal drops (3) External		
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	(2) Nasal sprays or nasal drops (3) External		
Ephedrine Sulphate		(1) Internal (other than nasal sprays or nasal drops)	(1) Equivalent of 30mg of Ephedrine (MD) Equivalent of 60mg of Ephedrine (MDD)	
	(2) Equivalent of 2.0 per cent of Ephedrine	(2) Nasal sprays or nasal drops (3) External		
Epicillin				
Epirubicin				
Epirubicin Hydrochloride				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Epithiazide				
Epoetin Alfa				
Epoetin Beta				
Epoprostenol Sodium				
Ergometrine Maleate				
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				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
[[F4]Estramustine Sodium Phosphate**]**				
Etafedrine Hydrochloride				
Ethacrynic Acid				
Ethambutol Hydrochloride				
Ethamivan				
Ethamsylate				
Ethiazide				
Ethinyl Androstenediol				
Ethinyloestradiol				
Ethionamide				
Ethisterone				
Ethoglucid				
Ethoheptazine Citrate				
Ethopropazine Hydrochloride				
Ethosuximide				
Ethotoin				
Ethyl Biscoumacetate				
Ethynodiol Diacetate				
Etodolac				
Etomidate				
Etomidate Hydrochloride				
Etoposide				

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Etretinate				
Famciclovir				
Famotidine		For the short-term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity, and prevention of these symptoms when associated with food and drink, including nocturnal symptoms	10mg (MD) 20mg (MDD) For maximum period of 14 days	
Fazadinium 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 less than 12 years	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product
Felodipine				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Felypressin				
Fenbufen				
Fenclofenac				
Fenfluramine Hydrochloride				
Fenofibrate				
Fenoprofen				
Fenoprofen Calcium				
Fenoterol Hydrobromide				
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	150mg (MD)	Container or package containing

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 4 Treatment limitations*	*Column 5 Maximum quantity*
		treatment of vaginal candidiasis in persons aged not less than 16 but less than 60 years		not more than 150mg of Fluconazole
Flucytosine				
Fludrocortisone Acetate				
Flufenamic Acid				
Flumazenil				
Flumethasone				
Flumethasone Pivalate				
Flunisolide	0.025 per cent	(a) For the prevention and treatment of seasonal allergic rhinitis, including hay fever For use in adults and children not less than 16 years In the form of a non-pressurised nasal spray	(a) 50mcg per nostril (MD) 100mcg per nostril (MDD)	(a) Container or package containing not more than 6,000mcg of Flunisolide
		(b) For the prevention and treatment of seasonal allergic rhinitis	(b) 25mcg per nostril (MD) 75mcg per nostril (MDD)	(b) Container or package containing not more than 6,000mcg of Flunisolide

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 4 Treatment limitations*	*Column 5 Maximum quantity*	
		including hay fever			
		For use in children not less than 12 years but less than 16 years			
		In the form of a non-pressurised nasal spray			
Fluocinolone Acetonide					
Fluocinonide					
Fluocortin Butyl					
Fluocortolone					
Fluocortolone Hexanoate					
Fluocortolone Pivalate					
Fluorescein Dilaurate					
Fluorometholone					
Fluorouracil					
Fluorouracil Trometamol					
Fluoxetine Hydrochloride					
Flupenthixol Decanoate					
Flupenthixol Hydrochloride					
Fluperolone Acetate					

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Fluphenazine Decanoate				
Fluphenazine Enanthate				
Fluphenazine Hydrochloride				
Fluprednidene Acetate				
Fluprednisolone				
Fluprostenol Sodium				
Flurandrenolone				
Flurbiprofen				
Flurbiprofen Sodium				
Fluspirilene				
Flutamide				
Fluticasone Propionate				
Fluvastatin Sodium				
Fluvoxamine Maleate				
Folic Acic			500mcg (MDD)	
Formestane				
Formocortal				
Foscarnet Sodium				
Fosfestrol Sodium				
Fosfomycin Trometamol				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Fosinopril Sodium				
Framycetin Sulphate				
Frusemide				
Furazolidone				
Fusafungine				
Fusidic Acid				
Gabapentin				
Gadoteridol				
Gallamine Triethiodide				
Ganciclovir				
Ganciclovir Sodium				
Gelsemine	0.1 per cent			
Gelsemium			25mg (MD) 75mg (MDD)	
Gemeprost				
Gemfibrozil				
Gentamicin				
Gentamicin Sulphate				
Gestodene				
Gestrinone				
Gestronol				
Gestronol Hexanoate				
Glibenclamide				
Glibornuride				
Gliclazide				
Glipizide				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Gliquidone				
Glisoxepide				
Glucagon				
Glycopyrronium Bromide			1mg (MD) 2mg (MDD)	
Glymidine				
Gonadorelin				
Goserelin Acetate				
Gramicidin	0.2 per cent	External		
Granisetron Hydrochloride				
Griseofulvin				
Growth Hormone				
Guanethidine Monosulphate				
Guanfacine Hydrochloride				
Guanoclor Sulphate				
Guanoxan Sulphate				
Halcinonide				
Halofantrine Hydrochloride				
Haloperidol				
Haloperidol Decanoate				
Heparin		External		
Heparin Calcium		External		

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Heparin Sodium				
Hexachlorophane		External		
	(a) 2.0 per cent	(a) Soaps		
	(b) 0.1 per cent	(b) Aerosols		
	(c) 0.75 per cent	(c) preparations other than soaps and aerosols		
Hexamine Phenylcinchoninate				
Hexobarbitone				
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				

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 4 Treatment limitations*	*Column 5 Maximum quantity*
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 dermatitis, insect bite reactions, mild to moderate eczema, and either in combination with Clotrimazole **[**F5or Miconazole Nitrate**]** 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		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 4 Treatment limitations*	*Column 5 Maximum quantity*	
		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 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		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 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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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 In the form of pellets		Container or package containing not more than equivalent to 50mg of Hydrocortisone
Hydroflumethiazide				
Hydroxychloroquine Sulphate		Prophylaxis of malaria		
Hydroxyprogesterone				
Hydroxyprogesterone Enanthate				
Hydroxyprogesterone Hexanoate				
Hydroxyurea				
Hydroxyzine Embonate				
Hydroxyzine Hydrochloride		(a) For the management of pruritis associated with acute or chronic	(a) 25mg (MD) 75mg (MDD)	(a) Container or package containing not more than 750mg 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 4 Treatment limitations*	*Column 5 Maximum quantity*	
		urticaria or atopic dermatitis or contact dermatitis, in adults and in children not less than 12 years		Hydroxyzine Hydrochloride	
		(b) For the management of pruritis associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in children not less than 6 years but less than 12 years	(b) 25 mg (MD) 50mg (MDD)	(b) Container or package containing not more than 750mg of Hydroxyzine Hydrochloride	
Hyoscine	(1) 0.15 per cent	(1) Internal			
		(2) External (except ophthalmic)			
Hyoscine Butylbromide		(1) Internal			
		(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 Hydrobromide		(1) Internal			

Exemptions from the restrictions on the sale and supply of prescription only medicines				
Column 1 Substance	*Column 2 Maximum strength*	*Column 3 Route of administration, use or pharmaceutical form*	*Column 4 Treatment limitations*	*Column 5 Maximum quantity*
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 900mcg (MDD)	
		(2) External (except ophthalmic)		
Hyoscine Methobromide		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscine Methonitrate		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 2.5mg (MD) 7.5mg (MDD)	
		(2) External		
Hyoscyamine		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) 300mcg (MD) 1mg (MDD)	
		(2) External		
Hyoscyamine Hydrobromide		(1) Internal		
		(a) by inhaler		
		(b) otherwise than by inhaler	(b) Equivalent of 300mcg of Hyoscyamine (MD)	

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
			Equivalent of 1mg of Hyoscyamine (MDD)	
		(2) External		
Hyoscyamine Sulphate		(1) Internal		
		(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 non-serious arthritic conditions, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza		
		(1) Internal	(1)(a) In the case of a prolonged release preparation 600mg (MD)	
			1,200mg (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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
			(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				
Imipramine Ion Exchange Resin Bound Salt or Complex				
Indapamide Hemihydrate				
Indomethacin				
Indomethacin Sodium				
Indoprofen				
Indoramin Hydrochloride				
Inosine Pranobex				
[[F6]Insulin**]**				
Iodamide				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Iodamide Meglumine				
Iodamide Sodium				
Iohexol				
Iomeprol				
Iopamidol				
Iopentol				
Iothalamic Acid				
Ioversol				
Ioxaglic Acid				
Ipratropium Bromide				
Iprindole Hydrochloride				
Iproniazid Phosphate				
Isoaminile				
Isoaminile Citrate				
Isocarboxazid				
Isoconazole Nitrate		External but in the case of vaginal use only external use for the treatment of vaginal candidiasis		
Isoetharine				
Isoetharine Hydrochloride				
Isoetharine Mesylate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
Kanamycin Sulphate				
Ketamine Hydrochloride				
Ketoconazole	2.0 per cent	For the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp In the form of a shampoo	Maximum frequency of application of once every 3 days	Container or package containing not more than 120ml of medicinal product and containing not more than 2,400mg of Ketoconazole
Ketoprofen	2.5 per cent	External For rheumatic and muscular	For maximum period of 7 days	Container or package containing not more than 30g

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
		pain in adults and children not less than 12		of medicinal product
Ketorolac Trometamol				
Ketotifen Fumarate				
Labetalol Hydrocholoride				
Lachesine Chloride				
Lacidipine				
Lamotrigine				
Lanatoside C				
Lanatoside Complex A, B and C				
Latamoxef Disodium				
Levallorphan Tartrate				
Levobunolol Hydrochloride				
Levodopa				
Levonorgestrel				
Lidoflazine				
Lignocaine		Non-ophthalmic use		
Lignocaine Hydrochloride		Non-ophthalmic use		
Lincomycin				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Lincomycin Hydrochloride				
Liothyronine Sodium				
Lisinopril				
Lithium Carbonate			Equivalent of 5mg of Lithium (MD) Equivalent of 15mg of Lithium (MDD)	
Lithium Citrate				
Lithium Succinate				
Lithium Sulphate			Equivalent of 5mg of Lithium (MD) Equivalent of 15mg of Lithium (MDD)	
Lobeline		(1) Internal	(1) 3mg (MD) 9mg (MDD)	
		(2) External		
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	

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
			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		
Loratidine			10mg (MDD)	Container or package containing not more than 100mg of Loratidine
Loxapine Succinate				
Lung Surfactant Porcine				
Luteinising Hormone				
Lymecycline				
Lynoestrenol				
Lypressin				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
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		**[**F7(a) the symptomatic relief of irritable bowel syndrome	**[**F7(a) 135mg (MD) 405 mg (MDD)**]**	
		(b) For uses other than the symptomatic relief of	**[**F7(b) 100mg (MD) 300mg (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 4 Treatment limitations*	*Column 5 Maximum quantity*
		irritable bowel syndrome**]**		
Mebeverine Pamoate				
Mebhydrolin				
Mebhydrolin Napadisylate				
Mecamylamine Hydrochloride				
Mecillinam				
Meclofenoxate Hydrochloride				
Medigoxin				
Medrogestone				
Medroxyprogesterone Acetate				
Mefenamic Acid				
Mefloquine Hydrochloride				
Mefruside				
Megestrol				
Megestrol Acetate				
Meglumine Gadopentetate				
Meglumine Iodoxamate				
Meglumine Ioglycamate				
Meglumine Iothalamate				
Meglumine Iotroxate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
Metergoline				
Metformin Hydrochloride				
Methacycline				
Methacycline Calcium				

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 4 Treatment limitations*	*Column 5 Maximum quantity*
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 Hydrochloride	0.25 per cent	Nasal sprays or nasal drops not containing liquid paraffin as a vehicle		
Methsuximide				
Methyclothiazide				
Methyldopa				
Methyldopate Hydrochloride				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
Mezlocillin Sodium				
Mianserin Hydrochloride				
Miconazole		External but in the case 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 4 Treatment limitations*	*Column 5 Maximum quantity*
		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	**[**F8(1) 2.0 per cent**]**	**[**F8(1) External		
	[F8(2) 5.0 per cent	(2) External use for the treatment of alopecia androgenetica, in men aged 18 to 65 (but not in women);**]**		
Misoprostol				
Mitobronitol				
Mitomycin				
Mitozantrone Hydrochloride				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Mivacurium Chloride				
[[F4]Mizolastine**]**				
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				

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 4 Treatment limitations*	*Column 5 Maximum quantity*
Naltrexone Hydrochloride				
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				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Neostigmine Methylsulphate				
Netilmicin Sulphate				
Nicardipine Hydrochloride				
Nicergoline				
[F4Niceritrol**]**				
Nicotinic Acid		Any use, except for the treatment of hyperlipidaemia	600mg (MDD)	
Nicoumalone				
Nifedipine				
Nifenazone				
Nikethamide				
Nimodipine				
Niridazole				
Nitrendipine				
Nitrofurantoin				
Nitrofurazone				
Nizatidine		For the prevention **[**F9and treatment**]** of the symptoms of food-related heartburn **[**F9and meal-induced indigestion**]** For use in adults and children not less than 16 years	75mg (MD) **[**F10150mg (MDD)**]** **[**F11For a maximum period of 14 days**]**	

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Nomifensine Maleate				
Noradrenaline				
Noradrenaline Acid Tartrate				
Norethisterone				
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				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Oestradiol Dipropionate				
Oestradiol Diundecanoate				
Oestradiol Enanthate				
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				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Oxantel Embonate				
Oxaprozin				
Oxatomide				
Oxedrine Tartrate				
Oxethazaine			10mg (MD) 30mg (MDD)	Container or package containing not more than 400mg of Oxethazaine
Oxitropium Bromide				
Oxolinic Acid				
Oxpentifylline				
Oxprenolol Hydrochloride				
Oxybuprocaine Hydrochloride		Non-ophthalmic use		
Oxybutynin Hydrochloride				
Oxypertine				
Oxypertine Hydrochloride				
Oxyphenbutazone				
Oxyphencyclimine Hydrochloride				
Oxyphenonium Bromide			5mg (MD) 15mg (MDD)	
Oxytetracycline				
Oxytetracycline Calcium				

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Oxytetracycline Dihydrate				
Oxytetracycline Hydrochloride				
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 Hydrochloride		(1) By inhaler		
		(2) Otherwise than by inhaler	(2) Equivalent of 50mg of Papaverine (MD)	
			Equivalent of 150mg of Papaverine (MDD)	
Paraldehyde				
Paramethadione				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Paramethasone Acetate				
Parathyroid Gland				
Pargyline Hydrochloride				
Paroxetine Hydrochloride				
Pecilocin				
Penamecillin				
Penbutolol Sulphate				
Penicillamine				
Penicillamine Hydrochloride				
Pentamidine Isethionate				
Penthienate Bromide			5mg (MD) 15mg (MDD)	
Pentolinium Tartrate				
Perfluamine				
Pergolide Mesylate				
Perhexiline Maleate				
Pericyazine				
Perindopril				
Perindopril Erbumine				
Perphenazine				
Phenacetin	0.1 per cent			
Phenazone		External		

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Phenazone Salicylate				
Phenbutrazate Hydrochloride				
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		
		(1) all preparations except prolonged release	(1) 25mg (MD) 100mg (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 4 Treatment limitations*	*Column 5 Maximum quantity*	
		capsules, nasal sprays and nasal drops			
		(2) prolonged release capsules	(2) 50mg (MD) 100mg (MDD)		
	(3) 2.0 per cent	(3) nasal sprays and nasal drops			
Phenytoin					
Phenytoin Sodium					
Phthalylsulphathiazole					
Physostigmine					
Physostigmine Aminoxide Salicylate					
Physostigmine Salicylate					
Physostigmine Sulphate					
Picrotoxin					
Pilocarpine					
Pilocarpine Hydrochloride					
Pilocarpine Nitrate					
Pimozide					
Pindolol					
Pipenzolate Bromide			5mg (MD) 15mg (MDD)		
Piperacillin Sodium					

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Piperazine Oestrone Sulphate				
Piperidolate Hydrochloride			50mg (MD) 150mg (MDD)	
Pipothiazine Palmitate				
Piracetam				
Pirbuterol Acetate				
Pirbuterol Hydrochloride				
[[F12]Pirenzepine Dihydrochloride Monohydrate**]**				
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 years	For maximum period of 7 days	Container or package containing not more than 30g of medicinal product

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
[[F4]Piroxicam Beta-cyclodextrin**]**				
Pituitary Gland (Whole Dried)		By inhaler		
Pituitary Powdered (Posterior Lobe)		By inhaler		
Pivampicillin				
Pivampicillin Hydrochloride				
Pivmecillinam				
Pivmecillinam Hydrochloride				
Pizotifen				
Pizotifen Malate				
Plicamycin				
Podophyllotoxin				
Podophyllum				
Podophyllum Indian				
Podophyllum Resin	20.0 per cent	External Ointment or impregnated plaster		
Poldine Methylsulphate			2mg (MD) 6mg (MDD)	
Polidexide				
Polyestradiol Phosphate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Polymyxin B Sulphate				
Polythiazide				
Poppy Capsule				
Potassium Arsenite	0.0127 per cent			
Potassium Bromide				
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				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Prednisolone Metasulphobenzoate Sodium				
Prednisolone Pivalate				
Prednisolone Sodium Phosphate				
Prednisolone Steaglate				
Prednisone				
Prednisone Acetate				
Prenalterol Hydrochloride				
Prenylamine Lactate				
Prilocaine Hydrochloride		Non-ophthalmic use		
Primidone				
Probenecid				
Probucol				
Procainamide Hydrochloride				
Procaine Hydrochloride		Non-ophthalmic use		
Procaine Penicillin				
Procarbazine Hydrochloride				
Prochlorperazine				
Prochlorperazine Edisylate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Prochlorperazine Maleate				
Prochlorperazine Mesylate				
Procyclidine Hydrochloride				
Progesterone				
Prolactin				
Proligestone				
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				

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 4 Treatment limitations*	*Column 5 Maximum quantity*
Proxymetacaine Hydrochloride		Non-ophthalmic use		
Pseudoephedrine Hydrochloride		Internal	(a) In the case of a prolonged release preparation 120mg (MD) 240mg (MDD) (b) in any other case 60mg (MD) 240mg (MDD)	
Pseudoephedrine Sulphate			60mg (MD) 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	(c) 250mg MDD (as a single dose)	(c) Container or package containing not more than 750mg

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
		but not less than 2 years		of Pyrantel Embonate
Pyrantel Tartrate				
Pyrazinamide				
Pyridostigmine Bromide				
Pyrimethamine				
Quinapril				
[[F12]Quinapril Hydrochloride**]**				
Quinestradol				
Quinestrol				
Quinethazone				
Quinidine				
Quinidine Bisulphate				
Quinidine Polygalacturonate				
Quinidine Sulphate				
Quinine			100mg (MD) 300mg (MDD)	
Quinine Bisulphate			Equivalent of 100mg of Quinine (MD) Equivalent of 300mg of Quinine (MDD)	
Quinine Cinchophen			Equivalent of 100mg of Quinine (MD)	

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
			Equivalent of 300mg of Quinine (MDD)	
Quinine Dihydrochloride			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Ethyl Carbonate			Equivalent of 100mg of Quinine (MD)	
			Equivalent of 300mg of Quinine (MDD)	
Quinine Glycerophosphate			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)	

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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)	
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				

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Ramipril				
Ranitidine Hydrochloride		For the short term symptomatic relief of heartburn, dyspepsia, indigestion, acid indigestion and hyperacidity **[**F13or the prevention of these symptoms when associated with consuming food and drink**]**	Equivalent to 75mg of Ranitidine (MD) Equivalent to 300mg of Ranitidine (MDD) For a maximum period of 14 days	
Rauwolfia Serpentina				
Rauwolfia Vomitoria				
Razoxane				
Remoxipride Hydrochloride				
Reproterol Hydrochloride				
Rescinnamine				
Reserpine				
Rifabutin				
Rifampicin				
Rifampicin Sodium				
Rifamycin				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Rimiterol Hydrobromide				
Risperidone				
Ritodrine Hydrochloride				
Rolitetracycline Nitrate				
Sabadilla				
Salbutamol				
Salbutamol Sulphate				
Salcatonin				
Salcatonin Acetate				
Salmefamol				
Salmeterol Xinafoate				
Salsalate				
Saralasin Acetate				
Selegiline Hydrochloride				
Semisodium Valproate				
Serum Gonadotrophin				
Silver Sulphadiazine				
Simvastatin				
Sissomicin				
Sissomicin Sulphate				
Snake Venoms				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Sodium Acetrizoate				
Sodium Aminosalicylate				
Sodium Antimonylgluconate				
Sodium Arsanilate				
Sodium Arsenate				
Sodium Arsenite	0.013 per cent			
Sodium Bromide				
Sodium Clodronate				
Sodium Cromoglycate		(a) For nasal admistration		
	(b) 2.0 per cent	(b) For the treatment of acute seasonal allergic conjunctivitis **[**F14or perennial allergic conjunctivitis**]** In the form of aqueous eye drops		(b) Container or package containing not more than 10ml of medicinal product
	(c) 4.0 per cent	(c) For the treatment of acute seasonal allergic conjunctivitis In the form of an eye ointment		(c) Container or package containing not more than 5g of medicinal product

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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Sodium Ethacrynate				
Sodium Fluoride	(1) 0.33 per cent	(1) Dentifrices		
		(2) Other preparations for use in the prevention of dental caries		
		In the form of		
		(a) tablets or drops	(a) 2.2 mg (MDD)	
	(b) 0.2 per cent	(b) mouth rinses other than those for daily use		
	(c) 0.05 per cent	(c) mouth rinses for daily use		
Sodium Fusidate				
Sodium Metrizoate				
Sodium Monofluorophosphate	1.14 per cent	Dentrifrice		
Sodium Oxidronate				
Sodium Stibogluconate				
Sodium Valproate				
Somatorelin Acetate				
Sotalol Hydrochloride				
Spectinomycin				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Spectinomycin Hydrochloride				
Spiramycin				
Spiramycin Adipate				
Spironolactone				
Stannous Fluoride	0.62 per cent	Dentifrice		
Stilboestrol				
Stilboestrol Dipropionate				
Streptodornase		External		
Streptokinase		External		
Streptomycin				
Streptomycin Sulphate				
Strychnine				
Strychnine Arsenate				
Strychnine Hydrochloride				
Styramate				
Succinylsulphathiazole				
Sucralfate				
Sulbactam Sodium				
Sulbenicillin				
Sulbenicillin Sodium				
Sulconazole Nitrate		External (except vaginal)		
Sulfacytine				

	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 4 Treatment limitations*	*Column 5 Maximum quantity*
Sulfadoxine				
Sulfamerazine				
Sulfamerazine Sodium				
Sulfametopyrazine				
Sulfamonomethoxine				
Sulindac				
Sulphacetamide				
Sulphacetamide Sodium				
Sulphadiazine				
Sulphadiazine Sodium				
Sulphadimethoxine				
Sulphadimidine				
Sulphadimidine Sodium				
Sulphafurazole				
Sulphafurazole Diethanolamine				
Sulphaguanidine				
Sulphaloxic Acid				
Sulphamethizole				
Sulphamethoxazole				
Sulphamethoxydiazine				
Sulphamethoxypyridazine				
Sulphamethoxypyridazine Sodium				
Sulphamoxole				
Sulphanilamide				
Sulphaphenazole				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Sulphapyridine				
Sulphapyridine Sodium				
Sulphasalazine				
Sulphathiazole				
Sulphathiazole Sodium				
Sulphaurea				
Sulphinpyrazone				
Sulpiride				
Sultamicillin				
Sultamicillin Tosylate				
Sulthiame				
Sumatriptan Succinate				
Suprofen				
Suxamethonium Bromide				
Suxamethonium Chloride				
Suxethonium Bromide				
Tacrine Hydrochloride				
Talampicillin				
Talampicillin Hydrochloride				
Talampicillin Napsylate				
Tamoxifen				
Tamoxifen Citrate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Tazobactam Sodium				
Teicoplanin				
Temocillin Sodium				
Tenoxicam				
Terazosin Hydrochloride				
Terbinafine				
Terbutaline				
Terbutaline Sulphate				
Terfenadine			F15 . . .	F15 ...
Terlipressin				
Terodiline Hydrochloride				
Tetrabenazine				
Tetracosactrin				
Tetracosactrin Acetate				
Tetracycline				
Tetracycline Hydrochloride				
Tetracycline Phosphate Complex				
Tetroxoprim				
Thallium Acetate				
Thallous Chloride				
Thiabendazole				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Thiambutosine				
Thiethylperazine Malate				
Thiethylperazine Maleate				
Thiocarlide				
Thioguanine				
Thiopentone Sodium				
Thiopropazate Hydrochloride				
Thioproperazine Mesylate				
Thioridazine				
Thioridazine Hydrochloride				
Thiosinamine				
Thiotepa				
Thiothixene				
Thiouracil				
Thymoxamine Hydrochloride				
Thyroid				
Thyrotrophin				
Thyroxine Sodium				
Tiamulin Fumarate				
Tiaprofenic Acid				
Tibolone				
Ticarcillin Sodium				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
Tolazoline Hydrochloride		External		
Tolbutamide				
Tolbutamide Sodium				
Tolfenamic Acid				
Tolmetin Sodium				
[[F4]Torasemide**]**				
Tramadol Hydrochloride				
Trandolapril				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Tranexamic Acid				
Tranylcypromine Sulphate				
Trazodone Hydrochloride				
Treosulfan				
Tretinoin				
Triamcinolone				
Triamcinolone Acetonide	0.1 per cent	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				
Trientine Dihydrochloride				
Trifluoperazine				
Trifluoperazine Hydrochloride				
Trifluperidol				
Trifluperidol Hydrochloride				
Trilostane				
Trimeprazine				
Trimeprazine Tartrate				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
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				
Tulobuterol Hydrochloride				
Tyrothricin		Throat lozenges or throat pastilles		
Uramustine				
Urea Stibamine				
Urethane				
Uridine 5'-triphosphate				
Urofollitrophin				
Urokinase				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Ursodeoxychoic Acid				
Vaccine: Bacillus Salmonella Typhi				
Vaccine: Poliomyelitis (Oral)				
Valproic Acid				
Vancomycin Hydrochloride				
Vasopressin				
Vasopressin Tannate				
Vecuronium Bromide				
Verapamil Hydrochloride				
Veratrine				
Veratrum, Green				
Veratrum, White				
Vidarabine				
Vigabatrin				
Viloxazine Hydrochloride				
Vinblastine Sulphate				
Vincristine Sulphate				
Vindesine 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 pharmaceutical form*	*Column 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Viomycin Pantothenate				
Viomycin Sulphate				
Vitamin A		(1) Internal	(1) 7,500iu (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Acetate		(1) Internal	(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Vitamin A Palmitate		(1) Internal	(1) Equivalent to 7,500iu Vitamin A (2,250mcg Retinol equivalent) (MDD)	
		(2) External		
Warfarin				
Warfarin Sodium				
Xamoterol Fumarate				
Xipamide				
Yohimbine Hydrochloride				
Zidovudine				
Zimeldine Hydrochloride				

	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 4* *Treatment limitations*	*Column 5* *Maximum quantity*
Zolpidem Tartrate				
Zomepirac Sodium				
Zopiclone				
Zuclopenthixol Acetate				
Zuclopenthixol Decanoate				
Zuclopenthixol Hydrochloride**]**				

Textual Amendments

F2 Word in Sch. 1 substituted (16.9.1997) by The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), **2(a)**

F3 Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(a)**

F4 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(e)(i)**

F5 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(a)**

F6 Word in Sch. 1 inserted (13.8.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(e)(ii)**

F7 Words in Sch. 1 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(b)**

F8 Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(b)**

F9 Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(i)**

F10 Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(ii)**

F11 Words in Sch. 1 substituted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(c)(iii)**

F12 Words in Sch. 1 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **2(d)(i)**

F13 Words in Sch. 1 added (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(c)**

F14 Words in Sch. 1 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **3(d)**

F15 Words in Sch. 1 omitted (16.9.1997) by virtue of The Prescription Only Medicines (Human Use) Amendment Order 1997 (S.I. 1997/2044), arts. 1(1), **2(b)**

SCHEDULE 2

Articles 6(1) and 10

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

SCHEDULE 3

Article 2(b)

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

[[F16]Co-danthramer Capsules NPF**]**

[[F16]Co-danthramer Capsules, Strong NPF**]**

Co-danthramer-Oral Suspension NPF

Co-danthramer-Oral Suspension Strong NPF

Co-danthrusate Capsules

[[F16]Co-danthrusate Oral Suspension NPF**]**

Mebendazole Tablets NPF

Mebendazole Oral Suspension NPF

Miconazole Oral Gel NPF

Nystatin Oral Suspension

Nystatin Pastilles NPF

Streptokinase and Streptodornase Topical Powder NPF

Textual Amendments

F16 Words in Sch. 3 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **4**

SCHEDULE 4

Article 8(4)(c)

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

Ammonium Bromide

Calcium Bromide

Calcium Bromidolactobionate

Embutramide

Fencamfamin Hydrochloride

Fluanisone

Hexobarbitone

Hexobarbitone Sodium

Hydrobromic Acid

Meclofenoxate Hydrochloride

Methohexitone Sodium

Pemoline

Piracetam

Potassium Bromide

Prolintane Hydrochloride

Sodium Bromide

Strychnine Hydrochloride

Tacrine Hydrochloride

Thiopentone Sodium

SCHEDULE 5 Article 11(1)(a)

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

PART I

EXEMPTION FROM RESTRICTIONS ON SALE OR SUPPLY

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
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 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.
2. Persons selling or supplying prescription	2. All prescription only medicines.	2. The sale or supply shall be subject to the presentation of an order signed by or on behalf

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
only medicines to any of the following– (1) a public analyst appointed under section 27 of the Food Safety Act 1990(**21**) or article 36 of the Food (Northern Ireland) Order 1989(**22**), (2) an authorized officer within the meaning of section 5(6) of the Food Safety Act 1990, (3) a sampling officer within the meaning of article 38(1) of the Food (Northern Ireland) Order 1989, (4) a person duly authorized by an enforcement authority under sections 111 and 112, (5) a sampling officer within the meaning of Schedule 3 to the Act.		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.
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	3. All prescription only medicines.	3. The sale or supply shall be– (a) subject to the presentation of an order signed by or on behalf of the person so employed or engaged stating the status of the person signing it and the amount of prescription only

(**21**) 1990 c. 16.
(**22**) S.I. 1989/846 (N.I. 6).
(**23**) 1977 c. 49.
(**24**) 1978 c. 29.

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
Services (Northern Ireland) Order 1972(**25**), or under any subordinate legislation made under those Acts or that Order.		medicine required, and (b) for the purposes of a scheme referred to in column 1 in this paragraph.
4. Registered midwives.	4. Prescription only medicines containing any of the following substances– Chloral hydrate Ergometrine maleate Pentazocine hydrochloride Triclofos sodium.	4. The sale or supply shall be only in the course of their professional practice and in the case of Ergometrine maleate only when contained in a medicinal product which is not for parenteral administration.
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69.	5. Prescription only medicines which are not for parenteral administration and which– (a) are eyes drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent Chloramphenicol, or (b) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or (c) are prescription only medicines by reason only that they contain any of the following substances:	5. The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.

(**25**) S.I. 1972/1265 (N.I. 14).

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
	Atropine sulphate Bethanecol chloride Carbachol Cyclopentolate hydrochloride Homatropine hydrobromide Naphazoline hydrochloride Naphazoline nitrate Physostigmine salicylate Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.	
6. Registered ophthalmic opticians.	6. Prescription only medicines listed in column 2 of paragraph 5.	6. The sale or supply shall be only– (a) in the course of their professional practice and (b) in an emergency.
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

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
		standards for such containers.
8. Holders of marketing authorizations, product licences or manufacturer's licences.	8. Prescription only medicines referred to in the authorizations or licences.	8. The sale or supply shall be only– (a) to a pharmacist, (b) so as to enable that pharmacist to prepare an entry relating to the prescription only medicine in question in a tablet or capsule identification guide or similar publication, and (c) of no greater quantity than is reasonably necessary for that purpose.
9. Pharmacists selling or supplying to persons to whom cyanide salts may be sold by virtue of section 3 (regulation of poisons) or section 4 (exclusion of sales by wholesale and certain other sales) of the Poisons Act 1972(**26**) or by virtue of article 5 (prohibitions and regulations with respect to sale of poisons) or article 6 (exemption with respect to certain sales) of the Poisons (Northern Ireland) Order 1976(**27**).	9. Amyl nitrite.	9. The sale or supply shall only be so far as is necessary to enable an antidote to be available to persons at risk of cyanide poisoning.
[[F17]**10.** State registered chiropodists who hold a certificate of competence in the use of the medicines specified in Column 2 issued by or with the approval of the Chiropodists Board.	**10.** The following prescription only medicines— (a) Co-dydramol 10/500 tablets; (b) Amorolfine hydrochloride cream where the maximum strength	**10.** The sale or supply shall be only in the course of their professional practice and (a) in the case of Co-dydramol 10/500 tablets the quantity sold or supplied to a person at any one time shall not exceed the amount sufficient for 3 days'

(**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*
	of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight; (c) Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume; and (d) Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.	treatment to a maximum of 24 tablets.**]**

Textual Amendments

F17 Sch. 5 Pt. 1 para. 10 inserted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), art. 1, **Sch.**

Article 11(1)(b)

PART II

EXEMPTIONS FROM THE RESTRICTION ON SUPPLY

Column 1 *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	2. All prescription only medicines.	2. The supply shall be only so far as is necessary for the

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

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

Article 11(2)

PART III

EXEMPTIONS FROM RESTRICTION ON ADMINISTRATION Column 1

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
1. State registered chiropodists who hold a certificate of competence in the use of analgesics issued by or with the approval of the Chiropodists Board.	1. Prescription only medicines for parenteral administration that contain,as the sole active ingredient, not more than one of the following substances– **[**[F18]Bupivacaine hydrochloride Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride Lignocaine hydrochloride Lignocaine hydrochloride with	1. The administration shall be only in the course of their professional practice.

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
	adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lignocaine hydrochloride Prilocaine hydrochloride.**]**	
2. Registered midwives.	2. Prescription only medicines for parenteral administration containing any of the following substances but no other substance specified in column 1 of Schedule 1 to this Order– Ergometrine maleate Lignocaine Lignocaine hydrochloride Naloxone hydrochloride Oxytocins, natural and synthetic Pentazocine lactate Pethidine hydrochloride Phytomenadione Promazine hydrochloride.	2. The administration shall be only in the course of their professional practice and in the case of Promazine hydrochloride, Lignocaine and Lignocaine hydrochloride shall be only while attending on a woman in childbirth.
3. Persons who are authorized as members of a group by a group authority granted under regulations 8(3) or 9(3) of the Misuse of Drugs Regulations to supply a controlled drug by way of administration only.	3. Prescription only medicines that are specified in the group authority.	3. The administration shall be subject to such conditions and in such circumstances and to such extent as may be specified in the group authority.
4. The owner or master of a ship which does not carry a doctor on board as part of her complement.	4. All prescription only medicines that are for parenteral administration.	4. The administration shall be only so far as is necessary for the treatment of persons on the ship.
5. Persons operating an occupational health scheme.	5. Prescription only medicines for parenteral administration sold or supplied to the person operating an occupational	5. — (1) The administration shall be in the course of an

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

Column 1 *Persons exempted*	*Column 2* *Prescription only medicines to which the exemption applies*	*Column 3* *Conditions*
		the treatment of persons on the installation.
9. Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State.	9. The following prescription only medicines for parenteral administration– (a) Diazepam 5 mg per 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– Adrenaline Acid Tartrate Anhydrous Glucose **[**[F19]Bretylium Tosylate**]** Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution) Ergometrine Maleate Glucose Heparin Sodium Lignocaine Hydrochloride Nalbuphine Hydrochloride Naloxone Hydrochloride Polygeline Sodium Bicarbonate	9. The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of a prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing.

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

Textual Amendments

F18 Words in Sch. 5 Pt. 3 substituted (13.2.1998) by The Prescription Only Medicines (Human Use) Amendment Order 1998 (S.I. 1998/108), arts. 1, **5(2)**

F19 Words in Sch. 5 Pt. 3 para. 9 inserted (1.6.1998) by The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1998 (S.I. 1998/1178), arts. 1(1), **3**

SCHEDULE 6

Article 16(1)

ORDERS REVOKED

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

Column 1 *Orders*	*Column 2* *References*
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
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 (*see*Schedule 1) but others are included because of other criteria, such as their method of administration (*see*article 3). In many cases the provisions of the Act apply subject to exemptions (*see*articles 4 and 5 to 13 and Schedule 1).

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

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

(a) the deletion from Column 1 of substances which are no longer used in those medicinal products which are on the market;

(b) the use of current names for the substances which are specified in that Column where their names have changed;

(c) the incorporation in that Schedule of provisions from article 4 of, and Part IV of Schedule 1 to, the 1983 Order as amended so that they may be found more easily;

(d) a change in the legal base for the entries in Columns 2 to 4 so that those entries now form the criteria for exemptions from the sale or supply requirements of section 58(2) of the Medicines Act 1968 instead of the criteria for excluding medicinal products from the class of prescription only medicines (*see also*article 5);

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

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

Status:
Point in time view as at 13/08/1998.

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