#### STATUTORY INSTRUMENTS

## 1980 No. 1924

### **MEDICINES**

# The Medicines (Pharmacy and General Sale—Exemption) Order 1980

Made - - - - 8th December 1980
Laid before Parliament 29th December 1980
Coming into Operation 30th January 1981

The Secretary of State Concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, 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 by sections 57(1) and (2) and 129(4) of the Medicines Act 1968 and now vested in them(1) and the Secretaries of State concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 55(2)(b) and 129(4) of the Act 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 the following order, and after taking into account the advice of the Medicines Commission, hereby make the following order:—

#### Citation, commencement and interpretation

- 1.—(1) This order may be cited as the Medicines (Pharmacy and General Sale—Exemption) Order 1980 and shall come into operation on 30th January 1981.
  - (2) In this order, unless the context otherwise requires,—
    - (a) "the Act" means the Medicines Act 1968;

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

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

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

"cosmetic" means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purposes of perfuming them, cleaning them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration;

"enrolled nurse" means a person for the time being enrolled as a nurse—

- (i) in relation to England and Wales, under the Nurses Act 1957,
- (ii) in relation to Scotland, under the Nurses (Scotland) Act 1951, and
- (iii) in relation to Northern Ireland, under section 17 of the Nurses and Midwives Act (Northern Ireland) 1970;

"external use" means—

- (i) in relation to medicinal products for use by being administered to human beings, application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal,
- (ii) in relation to veterinary drugs, application to the skin, hair, fur, feathers, scales, hoof, horn, ear, eye, mouth or mucosa of the throat or prepuce,

in either case 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 in relation to paragraph (i) in this definition such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

"food" includes beverages, confectionery and articles and substances used as ingredients in the preparation of food and includes any manufactured substance to which there has been added any vitamin and which is advertised (within the meaning of section 92) as available and for sale to the general public as a dietary supplement; "health outbority."

"health authority"—

- (i) in relation to England and Wales, has the same meaning as in the National Health Service Act 1977(3)
- (ii) in relation to Scotland, means a Health Board Constituted under section 2 of the National Health Service (Scotland) Act 1978, and
- (iii) in relation to Northern Ireland, means a Health and Social Services Board established under Article 16 of the Health and Personal Social Services (Northern Ireland) Order 1972;

"master" has the same meaning as in the Merchant Shipping Act 1894;

"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;

"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;

<sup>(3)</sup> the definition of health authority was amended by the Health Services Act 1980 (c. 53) section 1(7) and Schedule 1, Part I, paragraph 77(b).

"pharmacy medicine" means a medicinal product which is not a prescription only medicine or a medicinal product on a general sale list;

"pre-school dental scheme" means a scheme supervised by a doctor or dentist in which medicinal products are supplied to parents or guardians of children under five, for use by such children for the purpose of preventing dental caries;

"prescription only medicine" means a medicinal product of a description for falling within a class specified in Article 3 of the Medicines (Prescription Only) Order 1980;

"registered nurse" has the same meaning as in section 11;

"registered ophthalmic optician" means a person who is registered in either of the registers of ophthalmic opticians established and maintained under section 2(a) of the Opticians Act 1958;

"school dental scheme" means a scheme supervised by a doctor or dentist in which medicinal products are supplied at a school to pupils of that school for the purpose of preventing dental caries;

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

"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 by the Chiropodists Board;

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

"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 for the purposes of being administered to human beings; and

(b) a reference to a numbered section is to the section of the Act which bears that number, a reference to a numbered Article or Schedule is to the Article of or Schedule to this order which bears that number and a reference in an Article or Schedule to a numbered paragraph is to the paragraph which bears that number in that Article or Schedule.

#### Temporary exemption for certain products for human use

- 2.—(1) The restrictions imposed by section 52 shall not apply during the period set out in paragraph (2) to the sale, offer or exposure for sale or supply of any medicinal product which is for use by being administered to human beings and in respect of which a product licence has been granted containing, or has been varied so as to contain, a provision to the effect that the method of sale or supply of that product may be otherwise than by or under the supervision of a pharmacist (whether the grant or variation is made before, on or after the date on which this order comes into operation), if and so long as the conditions specified in section 53 are fulfilled.
  - (2) The period referred to in paragraph (1) is—
    - (a) where the product licence is granted containing the provision referred to in paragraph (1), that of two years from the date of the grant of that licence, and
    - (b) where the product licence is varied so as to contain the provision referred to in paragraph (1), that of one year from the date of that variation of that licence.

#### Exemption in cases involving another's default

- **3.** The restrictions imposed by section 52 shall not apply to the sale, offer or exposure for sale or supply of a medicinal product by a person who, having exercised all due diligence, believes on reasonable grounds that the product is a medicinal product—
  - (a) on a general sale list, or
  - (b) which he may lawfully sell, offer or expose for sales or supply, as the case may be, free from the restrictions imposed by section 52, by reason of the exemption conferred by Article 2.

where, due to the act or default of another person, that product is not such a medicinal product, if and so long as the conditions specified in section 53 are fulfilled.

#### Exemption for products used by midwives in the course of their professional practice

- **4.** There are hereby specified for the purposes of section 55(2)(b) (exemptions for certified midwives) the following classes of medicinal products—
  - (a) all medicinal products that are not prescription only medicines, and
  - (b) prescription only medicines which, by virtue of an exemption conferred by an order made under section 58(4)(a), may be sold or supplied by a certified midwife otherwise than in accordance with a prescription given by a practitioner.

#### **Exemption for certain persons**

- **5.**—(1) The restrictions imposed by section 52 shall not apply—
  - (a) to the sale, offer or exposure for sale or supply by any person listed in column 1 of Part I of Schedule 1, or
  - (b) to the supply by any person listed in column 1 of Part II of Schedule 1,

of the prescription only medicines and the pharmacy medicines referred to in column 2 of Part I or Part II, as the case may be, of Schedule 1 in relation to that person, if and so long as the conditions specified in the corresponding paragraphs in column 3 of Part I or Part II, as the case may be, of Schedule 1 are fulfilled.

- (2) The restrictions imposed by section 53 shall not apply to the sale, offer or exposure for sale or supply by any person listed in column 1 of Part I or Part II of Schedule 1 of any medicinal product on a general sale list referred to in column 2 of Part I or Part II, as the case may be, of Schedule 1 in relation to that person if and so long as the conditions specified in the corresponding paragraphs in column 3 of Part I or Part II, as the case may be, of Schedule 1 are fulfilled.
- (3) For the purposes of the sale, offer or exposure for sale or supply of any veterinary drug on a general sale list, section 53 shall have effect without the conditions in subsection (3) of that section being required to be fulfilled if and so long as the sale or supply is by the holder of a product licence granted under Part II of the Act in respect of the veterinary drug in question and is to a person who has in his charge or maintains animals for the purposes of and in the course of carrying on a business, either as his sole business activity or as a substantial part of his business activities.

#### Exemption for medicinal products at high dilutions

- **6.**—(1) The restrictions imposed by sections 52 and 53 shall not apply to the sale, offer or exposure for sale or supply of a medicinal product which is neither for parenteral administration nor a controlled drug and which consists solely of one or more unit preparations of—
  - (a) any substance where the unit preparation has been diluted to at least one part in a million (6x), or

- (b) any substance listed in Part I of Schedule 2 where the unit preparation has been diluted to at least one part in a thousand (3x), or
- (c) any substance listed in column 1 of Table A of Schedule 3 to the Medicines (General Sale List) Order 1980 or in Part III of Schedule 2 to this order or, if the medicinal product in question is for external use only, any substance listed in column 1 of Table B of Schedule 3 to the Medicines (General Sale List) Order 1980 or in Part IV of Schedule 2 to this order, in each case where the unit preparation has been diluted to at least one part in ten (1x),

if and so long as the person selling or supplying 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.

- (2) The restrictions imposed by section 52 shall not apply to the sale, offer or exposure for sale or supply of a medicinal product which is neither for parenteral administration nor a controlled drug and which consists solely of one or more unit preparations of—
  - (a) any substance where the unit preparation has been diluted to at least one part in a million (6c), or
  - (b) any substance listed in Part II of Schedule 2 where the unit preparation has been diluted to at least one part in a million (6x), or
  - (c) any substance listed in column 1 of Table A of Schedule 3 to the Medicines (General Sale List) Order 1980 or in Part III of Schedule 2 to this order or, if the medicinal product in question is for external use only, any substance listed in column 1 of Table B of Schedule 3 to the Medicines (General Sale List) Order 1980 or in Part IV of Schedule 2 to this order, in each case where the unit preparation has been diluted to at least one part in ten (1x),

if and so long as the conditions specified in section 53 are fulfilled.

#### **Exemption for foods and cosmetics**

7. For the purposes of the sale, offer or exposure for sale or supply of any medicinal product on a general sale list which is for sale either for oral administration as a food or for external use as a cosmetic, section 53 shall have effect without the condition in subsection (2) of that section being required to be fulfilled.

#### Revocations

**8.** The Medicines (Pharmacy and General Sale—Exemption) Order 1977 and the Medicines (Pharmacy and General Sale—Exemption) Amendment Order 1978 are revoked.

27th November 1980

Patrick Jenkin Secretary of State for Social Services

27th November 1980

Nicholas Edwards
Secretary of State for Wales

1st December 1980

George Younger Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agrica affixed on 3rd December 1980.	ulture, Fisheries and Food is hereunto
L.S. Mini	Peter Walker ister of Agriculture, Fisheries and Food
Sealed with the official seal of the Department of Health and this 8th day of December 1980.	d Social Services for Northern Ireland
L.S.	N. Dugdale
	Permanent Secretary
Sealed with the official seal of the Department of Agricultur December 1980.  L.S.	re for Northern Ireland this 5th day of
L.U.	J. A. Young Permanent Secretary

#### SCHEDULE 1

## EXEMPTIONS FOR CERTAIN PERSONS FROM SECTIONS 52 AND 53 Article 5(1)(a) and (2)

## PART I

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
State registered chiropodists.	a general sale list which are for external use and are not veterinary drugs and the following pharmacy medicines—	1. The sale or supply shall be only in the course of their professional practice, and the medicinal product must have been made up for sale or supply in a container elsewhere than at the place a
	Paint containing not more than 9.0 per cent Borotannic complex	which it is sold or supplied.
	Ointment, tincture or dusting powder containing not more than 5.0 per cent Diamthazole hydrochloride Ointment or lotion containing not more than 10.0 per cent Buclosamide or not more than 10.0 per cent Crotamiton	
	Cream, jelly or powder containing not more than 1.0 per cent Fenticlor	
	Pastes containing not more than 70.0 per cent Salicylic acid or not more than 70.0 per cent Pyrogallol	
	Powder or cream containing not more than 2.0 per cent 1- Phenoxypropan-2-01	
	Dusting powder or jelly or tincture containing not more than 0.4 per cent Hydrargaphen	
	Potassium permanganate crystals or solution	

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies Cream, powder or solution containing not more than 1.0 per cent Clotrimazole	Conditions
	Ointment containing not more than 3.0 per cent Chlorquinaldol	
	Solution containing not more than 10.0 per cent Glutaraldehyde	
	Ointment containing Hyaluronidase and a heparinoid	
	Cream containing not more than 2.0 per cent Mepyramine maleate	
	Cream or powder containing not more than 2.0 per cent Miconazole nitrate	
	Cream, jelly or powder containing not more than 10.0 per cent Polynoxylin	
	Salicylic Acid Lotion BPC	
	Cream or tincture containing not more than 0.1 per cent Thiomersal.	
2. Registered ophthalmic opticians.	2. All medicinal products on a general sale list, all pharmacy medicines and prescription only medicines which are not for parenteral administration and which—	2. The sale or supply shall be only in the course of their professional practice and only in an emergency.
	(a) are eye drops or eye ointments and are prescription only medicines by reason only that they contain:	
	(i) Mafenide propionate,	
	(ii) not more than 30.0 per cent Sulphacetamide Sodium, or	

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies (iii) Sulphafurazole diethanolamine equivalent to not more than 4.0 per cent Sulphafurazole, or	Conditions
	(b) are prescription only medicines by reason only that they contain any of the following substances:  Atropine sulphate Bethanecol chloride Carbachol Cyclopentolate hydrochloride Homatropine hydrobromide Hyoscine hydrobromide Naphazoline hydrochloride Naphazoline nitrate Neostigmine methylsulphate Physostigmine salicylate Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.	
3. Holders of manufacturer's licences where the licence in question contains a provision that the licence holder shall manufacture the medicinal product to which the licence relates only for a particular person after being requested by or on behalf of that person and in that person's presence to	3. Medicinal products on a general sale list which are for external use and are not veterinary drugs and pharmacy medicines which are for external use in the treatment of hair and scalp conditions and which contain any of the following—	3. The licence holder shall sell or supply the medicinal product in question only to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.
use his own judgment as to the treatment required.	not more than 5.0 per cent of Boric acid	
	Isopropyl myristate or Lauryl sulphate	
	not more than 0.004 per cent Oestrogens	
	not more than 1.0 per cent of Resorcinol	
	9	

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies not more than 3.0 per cent of Salicylic acid	Conditions
	not more than 0.2 per cent of Sodium pyrithione or Zinc pyrithione.	
4. Persons selling or supplying medicinal products to universities, other institutions	4. All medicinal products.	4. The sale or supply shall be—
concerned with higher education or institutions concerned with research.		(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 medicinal product is required,
		(ii) the purpose for which the medicinal product is required, and
		(iii) the total quantity required, and
		(b) for the purposes of the education or research with which the institution is concerned.
5. Persons selling or supplying medicinal products to any of the following—	5. All medicinal products.	5. The sale or supply shall be subject to the presentation of an order signed by, or on behalf of, any person listed in
(1) a public analyst appointed under section 89 of the Food and Drugs Act 1955, section 27 of the Food and Drugs (Scotland) Act 1956 or section 31 of the Food and Drugs Act (Northern Ireland) 1958		sub-paragraphs (1), (2), (3), (4) or (5) of column 1 of this paragraph stating the status of the person signing it and the amount of the medicinal product required, and shall be only in connection with the exercise by those persons of their statutory functions.
(2) an agricultural analyst appointed under section 67 of the Agriculture Act 1970,	10	

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
(3) a person duly authorised by an enforcement authority under sections 111 and 112,		
(4) a sampling officer within the meaning of the Food and Drugs Act 1955, the Food and Drugs (Scotland) Act 1956 or the Food and Drugs Act (Northern Ireland) 1958, or		
(5) a sampling officer within the meaning of Schedule 3 to the Act		
6. Persons selling or supplying medicinal products 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, the National Health Service (Scotland) Act 1978 and the Health and Personal Social Services (Northern Ireland) Order 1972 or under any subordinate legislation made under those Acts or that order.	6. All medicinal products.	6. 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 the medicinal product required, and  (b) for the purposes of a scheme referred to in column 1 in this paragraph.
7. Persons providing a poultry vaccination service.	7. The poultry vaccines listed in paragraph 11 of Schedule 1 to the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1979.(4).	7. The sale or supply shall be only to a person who has charge of animals for the purposes of and in the course of carrying on a business, either as his sole business activity or as a substantial part of his business activities.
8. Persons selling or supplying medicinal products to the persons referred to in paragraph 7.	8. The poultry vaccines referred to in paragraph 7.	8. The sale or supply shall be subject to the presentation of an order signed by the purchaser stating the amount of the poultry vaccine required.
9. Persons selling or supplying medicinal products to	9. All medicinal products.	9. No conditions.

<sup>(4)</sup> relevant amending instruments are S.I. 1980/283, 1650.

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
veterinary surgeons and veterinary practitioners.		
10. Persons selling or supplying medicinal products to the British Standards Institution.	10. All medicinal products.	10. 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 medicinal of the
		medicinal product required, and  (b) only for the purpose of testing containers of medicinal products or determining the standards for such containers.
11. Holders of product licences and holders of manufacturer's licences.	11. Medicinal products referred to in the licences.	<ul><li>11. The sale or supply shall be only—</li><li>(a) to a pharmacist,</li></ul>
		(b) so as to enable that pharmacist to prepare an entry relating to the medicinal product 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.

Article 5(1)(b) and (2)

## PART II

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
1. Royal National Lifeboat Institution and certificated first aiders of the Institution.	1. All medicinal products.	1. The supply shall be only so far as is necessary for the treatment of sick or injured persons.

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
2. British Red Cross Society and certificated first aid and certificated nursing members of the Society.	2. All pharmacy medicines and all medicinal products on a general sale list.	2. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
3. St. John Ambulance Association and Brigade and certificated first aid and certificated nursing members of the Association and Brigade.	3. All pharmacy medicines and all medicinal products on a general sale list.	3. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
4. St. Andrew's Ambulance Association and certificated first aid and certificated nursing members of the Association.	4. All pharmacy medicines and all medicinal products on a general sale list.	4. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
5. Order of Malta Ambulance Corps and certificated first aid and certificated nursing members of the Corps.	5. All pharmacy medicines and all medicinal products on a general sale list.	5. The supply shall be only so far as is necessary for the treatment of sick or injured persons.
6. Persons authorised by licences granted under regulation 5 of the Misuse of Drugs Regulations 1973(5) or regulation 5 of the Misuse of Drugs (Northern Ireland) Regulations 1974(6) to supply a controlled drug.	6. Such prescription only medicines and such pharmacy medicines as are specified in the licence.	6. The supply shall be subject to such conditions and in such circumstances and to such an extent as may be specified in the licence.
7. Persons requiring medicinal	7. Such prescription only	7. The supply shall be—
products 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	medicines and such pharmacy medicines as may be specified in the relevant enactment and medicinal products on a general sale list.	(a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and
treatment of their employees.		(b) subject to such conditions and in such circumstances as may be specified in the relevant enactment.
8. The owner or the master of a ship which does not carry a doctor on board as part of her complement.	8. All medicinal products.	8. The supply shall be only so far as is necessary for the treatment of persons on the ship.

<sup>(5)</sup> to which there are no amendments relevant to this order.(6) to which there are no amendments relevant to this order.

Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
9. Persons operating an occupational health scheme.	9. All pharmacy medicines, all medicinal products on a general sale list and such prescription only medicines as	9.—(1) The supply shall be in the course of an occupational health scheme.
	are sold or supplied to a person operating an occupational health scheme in response to an order in writing signed by a	(2) The individual supplying the medicinal product, if not a doctor, shall be—
	doctor, a registered nurse or an enrolled nurse.	(a) a registered nurse or an enrolled nurse, and
		(b) where the medicinal product in question is a prescription only medicine, 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.
10. Persons carrying on the business of a school providing full-time education.	10. Pharmacy medicines that are for use in the prevention of dental caries and consist of or contain Sodium Fluoride.	<ul><li>10. The supply shall be—</li><li>(a) in the course of a school dental scheme, and</li></ul>
		(b) if to a child under 16 only where the parent or guardian of that child has consented to such supply.
11. Health authorities.	11. Pharmacy medicines that are for use in the prevention of dental caries and consist of or	11. The supply shall be in the course of—
	contain Sodium Fluoride.	(a) a pre-school dental scheme, and the individual supplying the medicinal product shall be a registered nurse or an enrolled nurse, or
		(b) a school dental scheme, and if to a child under 16 only where the parent or guardian of that child has consented to such supply.
12. The operator or commander of an aircraft.	12. All pharmacy medicines, all medicinal products on a general sale list and	12. The supply shall be only so far as is necessary for the immediate treatment of sick

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Column 1	Column 2	Column 3
Persons exempted	Medicinal products to which the exemption applies	Conditions
	prescription only medicines	or injured persons on the
	which are not for parenteral	aircraft and, in the case of a
	administration and which have	prescription only medicine,
	been sold or supplied to the	shall be in accordance with
	operator or commander of the	the written instructions of a
	aircraft in response to an order	doctor as to the circumstances
	in writing signed by a doctor.	in which prescription only medicines of the description in question are to be used on the
		aircraft.

SCHEDULE 2

Article 6

## PART I

Dilutions of unit preparations diluted to at least one part in a thousand (3x)

Agaricus muscarius

Ailanthus glandulosa

Apocynum cannabinum

Aurum iodatum

Belladonna

Bismuth Subgallate

Bryonia alba dioica

Calcium Fluoride

Cantharis

Cerium oxalicum

Chelidonium majus

Chenopodium oil

Cina

Colocynthis

Convallaria majalis

Gelsemium sempervirens

Hyoscyamus niger

Lycopodium

Manganese acetate

Ranunculus bulbosus

Terebinthinae oleum

#### PART II

Dilutions of unit preparations diluted to at least one part in a million (6x)

Adonisvernalis

Agaricus bulbosus

Agaricus muscarius

Agnus castus

Ailanthus glandulosa

Alum

Amethyst

Ammonium Iodide

Amygdalae amarae

Apatite

Apocynum androsaemifolium

Apocynum cannabinum

Argentite

Argentum Chloride

Argentum Iodide

Arnica

Artemisia cina

Aspidium filix-mas

Aspidium anthelmintica

Aurum Sulphide

Balsamum copaivae

Balsamum peruvianum

Barium Citrate

Barium Sulphate

Bismuth Metal

Bismuth Subgallate

Bismuth Subnitrate

Boletus laricis

Bovista

Cade Oil

Calcium Fluoride

Cantharis

Carduus marianus

Cedar Wood Oil

Cerium Oxalicum

Chalcocite

Chalcopyrite

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Chelidonium majus

Chenopodium Oil

Colocynthis

Convallaria majalis

Copper Silicate, Nat.

Crotalus horridus

Cucurbita

Cucumis melo

Datura stramonium

Derris

Diamond

Ephedra vulgaris

Ferric Acetate

Ferrous Iodide

Ferrous Oxalate

Ferrous Sulphide

Formic Acid

Gall

Gelsemium sempervirens

Gneiss

Granatum (Pomegranate Bark)

Hamamelis virginiana

Hepar Sulfuris

Hyoscyamus niger

Iris florentine

Jaborandi

Juniperus sabina

Kaolinite

Lachmanthus tinctoria

Lapis Albus

Lycopodium

Magnesium

Magnesium Acetate

Magnesium Chloride

Magnetite

Manganese Acetate

Nicotiana tabacum

Nicotiana tabacum oil

Oleander

Opuntia vulgaris

Oxalic Acid

Petroleum

Phellandrum aquaticum

Pix Liquida

Platinum

Platinum Chloride

Potassium Hydroxide

Potassium Silicate

Pyrethrum

Pyrolusite

Ranunculus acris

Ranunculus bulbosus

Ranunculus flammula

Ranunculus repens

Ranunculus sceleratus

Rhodium Oxynitrate

Rhododendron chrysanthemum

Rhus toxicodendron

Salicylic Acid

Scrophularia aquatica

Sodium Aluminium Chloride

Sodium Auro-chloride

Sodium Hypochlorite

Sodium Nitrate

Squill

Stannum Metal

Staphisagria

Sulphur Iodide

Tamus communis

Tannic Acid

Terebinthinae Oleum

Theridion

Thuja occidentalis

Topaz

Uric Acid

Zinc Hypophosphite

Zinc Isovalerate

#### **PART III**

Dilutions of unit preparations diluted to at least one part in ten (1x)

a

Abies nigra

Abies nobilis

Acalypha indica

Agate

Alisma plantago Aq.

Alstonia scholaris

Aluminium

Amber (Succinum)

Ambra grisea

Ammonium Phosphate

Angostura vera

Anthoxanthum

Apis mellifera

Aqua Marina

Aqua Mellis

Aralia racemosa

Aranea diadema

Arum maculatum

Arum triphyllum

Asarum

Asperula odorata

Astacus fluviatilis

Auric Chloride

Badiaga

Beech (fagus sylvestris)

Bellis perennis

Berberis aquifolium

Borago officinalis

Butyric Acid

Calcium Metal

Calcium Chloride

Calcium Oxide

Calcium Sulphate

Castoreum

Ceanothus americanus

Cedron

Cerato (Ceratostigma Willmottiana)

Cherry Plum (Prunus cerasifera)

Chestnut, Red and Sweet

Cholesterinum

Chrysolite

Cistus canadensis

Clematis erecta

Conchae vera

Conchiolinum

Corallium Rubrum

Crab Apple

Crocus sativus

Erbium

Erigeron Canadense

**Fuligo** 

Genista tinctoria

Geum urbanum

Glycogen

Gnaphalium leontopodium

Gold

Gorse (Ulex europocus)

Graphites

Gratiola officinalis

Gymnocladus (American Coffee Tree)

Haematoxylon campechianum

Hecla Lava (Ash from Mount Hecla)

Hedeoma pulegioides

Hedera helix

Heliotrope

Heracleum spondylium

Herniaria

Hornbeam (Carpinus betulus)

Iberis amara

Impatiens

Iris germanica

Iris pseudacorus

Jacaranda procera

Jatropha curcas

Juncus communis

Justicia adhatoda

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Lamium album

Laurus nobilis oil

Laurocerasus

Ledum palustre

Lilium tigrinum

Lonicera caprifolium

Lysimachia vulgaris

Magnesium Phosphate

Magnesite

Magnolia

Marum verum

Melilotus officinalis

Menispermum canadense

Mephitis putorius

Mercurialis perennis

Mimulus (Mimullis guttatus)

Moschus

Myrica gale

Myrtus communis

Ocimum basilicum

Olive

Oxalis acetosella

Pangamic Acid

Paullinia cupana

Penthorum sedoides

Pollen (mixed)

Polygonatum multiflorum

Polygonum aviculare

Polypodium vulgare

Primula vulgaris

Prunella vulgaris

Ptelea trifoliata

Ratanhia

Robinia pseudoacacia

Rubia tinctorum

Rumex acetosella

Sal Marina

Sarcolactic Acid

Sarracenia purpurea

Scleranthus (Sclcranthus annuus)

Silica

Silphium laciniatum

Sodium Benzoate

Spongia marina

Star of Bethlehem (Ornithogalum umbellatum)

Ulmus campestris

Vine

Walnut (juglerus regia)

Water Violet (Hottonia palustris)

Wild Oat

Wild Rose

#### **PART IV**

Dilutions of unit preparations diluted to at least one part in ten (1x) for external use

Adonis vernalis

Agaricus bulbosus

Agaricus muscarius

Agnus castus

Ailanthus glandulosa

Alum

Amethyst

Ammonium Iodide

Amygdalae amarae

Apatite

Apocynum androsaemifolium

Apocynum cannabinum

Argentite

Argentum Chloride

Argentum Iodide

Artemisia cina

Aspidium filix-mas

Aspidium anthelmintica

Aurum Sulphide

Balsamum copaivae

Balsamum peruvianum

Barium Citrate

Barium Sulphate

Bismuth Metal

Bismuth Subgallate

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Bismuth Subnitrate

Boletus laricis

Bovista

Cade Oil

Calcium Fluoride

Carduus marianus

Cedar Wood Oil

Cerium Oxalicum

Chalcocite

Chalcopyrite

Chelidonium majus

Chenopodium Oil

Colocynthis

Convallaria majalis

Copper Silicate, Nat

Crotalus horridus

Cucurbita

Cucumis melo

Datura stramonium

Derris

Diamond

Ephedra vulgaris

Ferric Acetate

Ferrous Iodide

Ferrous Oxalate

Ferrous Sulphide

Formic Acid

Gall

Gelsemium sempervirens

Gneiss

Hamamelis virginiana

Hepar Sulfuris

Hyoscyamus niger

Iris florentine

Jaborandi

Juniperus sabina

Kaolinite

Lachmanthus tinctoria

Lapis Albus

Lycopodium

Magnesium

Magnesium Acetate

Magnesium Chloride

Magnetite

Manganese Acetate

Nicotiana tabacum

Nicotiana tabacum oil

Oleander

Opuntia vulgaris

Oxalic Acid

Petroleum

Phellandrium aquaticum

Pix Liquida

Platinum

Platinum Chloride

Potassium Hydroxide

Potassium Silicate

Pyrethrum

Pyrolusite

Ranunculus acris

Ranunculus bulbosus

Ranunculus flammula

Ranunculus repens

Ranunculus sceleratus

Rhodium Oxynitrate

Rhododendron chrysanthemum

Rhus toxicodendron

Salicylic Acid

Scrophularia aquatica

Sodium Aluminium Chloride

Sodium Auro-chloride

Sodium Hypochlorite

Sodium Nitrate

Squill

Stannum Metal

Sulphur Iodide

Tannic Acid

Terebinthinae Oleum

Topaz

Uric Acid

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Zinc Hypophosphite Zinc Isovalerate

#### **EXPLANATORY NOTE**

This Order consolidates, with amendments, provisions granting exemption from the restrictions imposed by sections 52 and 53 of the Medicines Act 1968. Section 52 provides that medicinal products not on a general sale list shall be sold or supplied only on premises that are a registered pharmacy and by or under the supervision of a pharmacist. Section 53 provides that medicinal products on a general sale list may be sold elsewhere than at a registered pharmacy only if certain specified conditions are fulfilled.

The principal changes made by this order are—

- (a) to alter the period of duration of a temporary exemption from the restrictions imposed by section 52 for certain medicinal products for human use following the grant or variation of a product licence;
- (b) to extend the scope of an exemption from those restrictions for certain medicinal products at high dilutions;
- (c) to vary the ranges of medicinal products which may be sold or supplied by state registered chiropodists and registered ophthalmic opticians free from the restrictions imposed by sections 52 and 53, and to vary the conditions relating to the exemption for registered ophthalmic opticians;
- (d) to add exemptions from the restrictions imposed by sections 52 and 53 in respect of certain sales or supplies by manufacturers and product licence holders to those compiling tablet and capsule identification guides, and certain supplies to those on board aircraft.

The Medicines (Pharmacy and General Sale—Exemption) Order 1977, as amended, is revoked by this order.