## 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 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

27th November 1980

Patrick Jenkin Secretary of State for Social Services

> *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 Agriculture, Fisheries and Food is hereunto affixed on 3rd December 1980.

L.S.

Peter Walker Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 8th day of December 1980.

L.S.

*N. Dugdale* Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 5th day of December 1980.

L.S.

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

Column 2	Column 3
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. 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	
	<ul> <li>which the exemption applies Cream, powder or solution containing not more than 1.0 per cent Clotrimazole</li> <li>Ointment containing not more than 3.0 per cent Chlorquinaldol</li> <li>Solution containing not more than 10.0 per cent Glutaraldehyde</li> <li>Ointment containing Hyaluronidase and a heparinoid</li> <li>Cream containing not more than 2.0 per cent Mepyramine maleate</li> <li>Cream or powder containing not more than 2.0 per cent Miconazole nitrate</li> <li>Cream, jelly or powder containing not more than 10.0 per cent Polynoxylin</li> <li>Salicylic Acid Lotion BPC</li> <li>Cream or tincture containing not more than 0.1 per cent Thiomersal.</li> <li>2. All medicinal products on a general sale list, all pharmacy medicines and prescription only medicines which are not for parenteral administration and which—</li> <li>(a) are eye drops or eye ointments and are prescription only medicines by reason only that they contain:</li> <li>(i) Mafenide propionate,</li> <li>(ii) not more than 30.0 per cent</li> </ul>

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
	<ul> <li>(b) are prescription only medicines by reason only that they contain any of the following substances:</li> <li>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.</li> </ul>	
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 to be a second to be a	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.
and in that person's presence to 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	

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Column 1 Persons exempted	Column 2 Medicinal products to which the exemption applies not more than 3.0 per cent of Salicylic acid	Column 3 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 concerned with higher education or institutions	4. All medicinal products.	<ul><li>4. The sale or supply shall be—</li><li>(a) Subject to the presentation of an order signed by the</li></ul>
concerned with research.		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	then statutory functions.

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Column 1	Column 2 Modicinal products to	Column 3
Persons exempted	<i>Medicinal products to</i> <i>which the exemption applies</i>	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	6. All medicinal products.	6. The sale or supply shall be—
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		(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
(Northern Ireland) Order 1972 or under any subordinate legislation made under those Acts or that order.		(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.	ŢŢ.	
10. Persons selling or supplying medicinal products to the British Standards Institution.	10. All medicinal products.	<ul><li>10. The sale or supply shall be—</li><li>(a) subject to the presentation of an order signed on behalf</li></ul>
		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.	11. The sale or supply shall be only—
licences.		(a) to a pharmacist,
		(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

ſ	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( <b>5</b> ) or regulation 5 of the Misuse of Drugs (Northern Ireland) Regulations 1974( <b>6</b> ) 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 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	7. Such prescription only medicines and such pharmacy medicines as may be specified in the relevant enactment and medicinal products on a general sale list.	<ul><li>7. The supply shall be—</li><li>(a) for the purpose of enabling them to comply with any requirements made by or in pursuance of any such enactment, and</li></ul>
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 prescription only medicines which are not for parenteral administration and which have been sold or supplied to the operator or commander of the aircraft in response to an order in writing signed by a doctor.	<i>Conditions</i> or injured persons on the aircraft and, in the case of a prescription only medicine, 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.

#### 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

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)Abies excelsa 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** 

**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

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.