STATUTORY INSTRUMENTS

1978 No. 987

MEDICINES

The Medicines (Prescription Only) Amendment (No. 2) Order 1978

Made - - - -	17*th July* 1978
Laid before Parliament	21*st July* 1978
Coming into Operation	11*th August* 1978

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 58(1) and (4) and 129(4) of the Medicines Act 1968(**a**) and now vested in them(**b**) 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 consulting and taking into account the advice of the Medicines Commission and the Committee on Dental and Surgical Materials(**c**), hereby make the following order:—

Citation, commencement and interpretation

1. This order, which may be cited as the Medicines (Prescription Only) Amendment (No. 2) Order 1978, shall be read as one with the Medicines (Prescription Only) Order 1977 (**d**) as amended(**e**) (hereinafter referred to as "the principal order") and shall come into operation on 11th August 1978.

Amendment of Article 1(2) of the principal order

2. Article 1(2) of the principal order (definitions) is amended by—

(*a*) deleting the definition of "bank holiday", and

(*b*) inserting—

(i) immediately after the definition of "the Act" the following definitions:—

" "aerosol dispenser" means a container the contents of which are dispersed by a propellent gas or liquid;

"carbon copy health prescription" means a health prescription written wholly or partly by means of carbon paper or similar

(**a**) 1968 c. 67.

(**b**) 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).

(**c**) A committee established under section 4 of the Act by virtue of the Medicines (Committee on Dental and Surgical Materials) Order 1975 (S.I. 1975/1473).

(**d**) S.I. 1977/2127.

(**e**) S.I. 1978/189. The amending order is not relevant to the subject matter of this order.

material and of which the parts not so written are in indelible ink and which is not a prescription for a medicinal product consisting of or containing one or more of the substances specified in Schedule 2 to the Misuse of Drugs Act 1971(**a**);

"certified midwife" has the same meaning as in section 11 of the Act;",

(ii) immediately after the definition of "dosage unit" the following definition: —

" "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(**b**),

(ii) in relation to Scotland, under the Nurses (Scotland) Act 1951(**c**), and

(iii) in relation to Northern Ireland, under section 17 of the Nurses and Midwives Act (Northern Ireland) 1970(**d**);",

(iii) immediately after the definition of "external use" the following definitions:—

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

(i) in England and Wales, either the National Health Service Act 1946(**e**) and the National Health Service Reorganisation Act 1973(**f**) or the National Health Service Act 1977(**g**),

(ii) in Scotland, the National Health Service (Scotland) Acts 1947 to 1976, and

(iii) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972(**h**);

"inhaler" does not include a product in an aerosol dispenser;",

(iv) immediately after the definition of "maximum strength" the following definition:—

" "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;", and

(v) immediately after the definition of "prescription only medicine" the following definition:—

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

Amendment of Article 4(2) of the principal order

3. In Article 4(2) of the principal order (medicinal products that are not prescription only) for "consisting of or containing" there is substituted "which are not veterinary drugs and which consist of or contain".

(**a**) 1971 c. 38.
(**b**) 1957 c. 15.
(**c**) 1951 c. 55.
(**d**) 1970 c. 11 (N.I.).
(**e**) 1946 c. 81.
(**f**) 1973 c. 32.
(**g**) 1977 c. 49.
(**h**) S.I. 1972/1265 (N.I. 14).

Amendment of Article 5 of the principal order

4. In Article 5 of the principal order (exemption from the restriction on administration for certain prescription only medicines for parenteral administration to human beings in an emergency) there are inserted immediately after the words "Chlorpheniramine Injection' the words "Cobalt Edetate Injection" and immediately after the words "Diphenhydramine Injection" the words "Hydrocortisone Injection".

Amendment of Article 6(4) of the principal order

5.—(1) Article 6(4) of the principal order (which specifies conditions relating to emergency supply subject to which there is an exemption from the restrictions on the sale or supply of prescription only medicines for persons lawfully conducting a retail pharmacy business) is amended in accordance with the following paragraphs of this Article.

(2) For sub-paragraph (b) there is substituted the following sub-paragraph:—

"(*b*) that no greater quantity of the prescription only medicine in question than will provide 5 days' treatment is sold or supplied except that there may be sold or supplied where the prescription only medicine in question—

(i) is an ointment, a cream or a preparation for the relief of asthma in an aerosol dispenser, 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,

(ii) is an oral contraceptive, a full cycle,

(iii) is an antibiotic in liquid form for oral administration, where pharmaceutical considerations require that there be sold or supplied a quantity of the antibiotic in question sufficient for a full course of treatment, the smallest quantity that will provide a full course of treatment;".

(3) For sub-paragraph (*e*) there is substituted the following sub-paragraph:—

"(*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 was 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 requiring the prescription only medicine,

(iv) the name and address of the registered pharmacy from which the prescription only medicine was sold or supplied, and

(v) the words "Emergency Supply".".

Amendment of Article 7 of the principal order

6. For Article 7 of the principal order (exemption from the restriction on administration) there is substituted the following Article:—

"**7.** Without prejudice to the application of Article 5 of this order, the restriction imposed by section 58(2)(*b*) of the Act (restriction on administra-

tion) shall not apply to the administration of a prescription only medicine which is not for parenteral administration or a veterinary drug.".

Amendment of Article 8 of the principal order

7. In Article 8 of the principal order (exemption from the restrictions on sale, supply and administration for certain medicinal products at high dilutions) for "Parts I and II" there is substituted "Part I or II".

Addition of new Articles 11B and 11C to the principal order

8. Immediately after Article 11A of the principal order there are inserted the following Articles:—

"Temporary exemption for administration

11B.—(1) The restriction imposed by section 58(2)(*b*) of the Act (restriction on administration) shall not apply until 11th February 1979 to the parenteral administration to a human being of a prescription only medicine administered in the circumstances specified in paragraph (2) below.

(2) The circumstances referred to in paragraph (1) above are where the person administering the prescription only medicine in question is a person who, though not an appropriate practitioner for the purposes of section 58 of the Act,—

(*a*) immediately before 11th August 1978 could lawfully have administered that product otherwise than in accordance with a prescription given by a practitioner,

(*b*) customarily administers medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, chiropody, naturopathy or other similar field, and

(*c*) if not a state registered chiropodist, has been requested by or on behalf of the person to whom that product is administered and in that person's presence to use his own judgment as to the treatment required.

Temporary exemption for sale supply or administration

11C.—(1) The restrictions imposed by section 58(2) of the Act (restrictions on sale, supply or administration) shall not apply until 11th February 1979 to the sale, supply or administration of a veterinary drug which, if or when for parenteral administration, is a prescription only medicine sold or supplied in the circumstances specified in paragraph (2) below.

(2) The circumstances referred to in paragraph (1) above are where the person selling or supplying the veterinary drug in question is a person who, immediately before 11th August 1978, could lawfully have sold or supplied that drug otherwise than in accordance with a prescription given by a practitioner.".

Amendment of Article 12 of the principal order

9.—(1) Article 12 of the principal order (which specifies conditions relating to prescriptions for the purposes of section 58(2)(*a*) of the Act) is amended in accordance with the following paragraphs of this Article.

(2) In paragraph (2)—

(*a*) in sub-paragraph (*a*) after "indelible ink" there is added "unless it is

a carbon copy health prescription signed in indelible ink by the practitioner giving it";

(*b*) for sub-paragraph (*b*)(ii) there is substituted the following: —

"(ii) the appropriate date,";

(*c*) for sub-paragraphs (*c*) and (*d*) there is substituted the following: —

"(*c*) where it is not a repeat prescription, shall not be dispensed later than 6 months after the appropriate date;

(*d*) where it is a repeat prescription, shall not be dispensed—

(i) for the first time later than 6 months after the appropriate date, nor

(ii) otherwise than in accordance with the direction contained therein;".

(3) After paragraph (2) there is added the following paragraph: —

"(3) In paragraph (2) above "the appropriate date" means—

(*a*) in relation to a carbon copy health prescription, the date indicated by the practitioner giving it as being the date before which it shall not be dispensed, and

(*b*) in relation to a prescription which is not a carbon copy health prescription, the date on which it was signed by the practitioner giving it.".

Amendment of Schedule 1 to the principal order

10.—(1) Schedule 1 to the principal order (descriptions and classes of prescription only medicines) is amended in accordance with the following paragraphs of this Article.

(2) Part I is amended by—

(*a*) adding to columns 1, 2, 3 and 4 in the principal order the entries contained in columns 1, 2, 3 and 4 respectively in Schedule 1 to this order,

(*b*) deleting from it any entries in columns 2, 3 and 4 in the principal order which relate to the substances specified in column 1 in Schedule 2 to this order and inserting in columns 2, 3 and 4 in the principal order in relation to each such substance any entry in column 2, 3 or 4 respectively in Schedule 2 to this order which relates to that substance, and

(*c*) deleting from it the entry in column 1 "Nifenazone".

(3) In Part II for "840 mcg" and for "740 mcg" (which relate to the maximum doses for morphine and its salts and medicinal opium) there is substituted throughout "3 mg" and for "185 mcg" (which relates to the maximum strength for morphine and its salts in solid form) there is substituted "300 mcg".

(4) For Part III there is substituted the Part III set out in Schedule 3 to this order.

Amendment of Schedule 4 to the principal order

11.—(1) Schedule 4 to the principal order (exemption for certain persons from the restrictions imposed by section 58(2) of the Act) is amended in accordance with the following paragraphs of this Article.

(2) In Part I (exemption from restrictions on sale or supply), for items 5, 7, 8 and 9 there are substituted respectively the items 5, 7, 8 and 9 set out in Part I of Schedule 4 to this order and in the entry in column 2 relating to item 6 (registered ophthalmic opticians) for "5(3)" there is substituted "5(2)".

(3) To Part II (exemption from the restriction on supply) there is added the item 5 set out in Part II of Schedule 4 to this order.

(4) In Part III (exemption from the restriction on administration)—

(*a*) in the entry in column 2 relating to item 2 (certified midwives) there are inserted immediately after "Pentazocine lactate" the following substances: —

"Pethidine
Pethidine hydrochloride";

(*b*) for item 3 there is substituted the item 3 set out in Part III of Schedule 4 to this order; and

(*c*) there are added the items 6 and 7 set out in Part IV of Schedule 4 to this order.

David Ennals,
Secretary of State for Social Services.

11th July 1978.

John Morris,
Secretary of State for Wales.

14th July 1978.

Bruce Millan,
Secretary of State for Scotland.

17th July 1978.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 14th July 1978.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 17th day of July 1978.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 17th day of July 1978.

(L.S.)

J. A. Young,
Permanent Secretary.

Article 10(2)(*a*)

SCHEDULE 1

ENTRIES ADDED TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER

Column 1	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
	Column 2	Column 3	Column 4
Substance	Maximum strength	Purpose, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Apramycin Sulphate			
Buprenorphine			
Buprenorphine Hydrochloride			
Clioquinol	35 mg	(1) Human use: (*a*) Internal: preparations for the treatment of mouth ulcers (*b*) External (2) Veterinary use	350 mg (MDD)
Colestipol Hydrochloride			
Demeclocycline Calcium			
Diflunisal			
Doxapram Hydrochloride			
Feprazone			
Flurbiprofen			
1 α-Hydroxy-cholecalciferol			
Indapamide Hemihydrate			
Ipratropium Bromide			
Lomustine			
Methotrexate Sodium			
Nomifensine Hydrogen Maleate			
Oxpentifylline			
Pecilocin			
Pivmecillinam Hydrochloride			
Proligestone			
Pyrimethamine		(1) Human use (2) Veterinary use: incorporation in feed as a coccidiostat for broiler chickens at levels not exceeding 5 parts per million	
Sera and Antisera:— Veterinary— Feline Infectious Enteritis (Panleucopaenia) Antiserum			
Tretinoin	0.05 per cent	External	
Uredofos			
Vaccines:— Veterinary— For cats: Vaccines for Feline Calici Virus Infections Vaccines for Feline Viral Rhinotracheitis			
Vidarabine			

SCHEDULE 2 Article 10(2)(*b*)

AMENDMENTS TO PART 1 OF SCHEDULE 1 TO THE PRINCIPAL ORDER

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
Acetylcholine Chloride	0.2 per cent	External	
Adrenaline		(1) Inhalers (2) External	
Adrenaline Acid Tartrate		(1) Inhalers (2) External	
Adrenaline Hydrochloride		(1) Inhalers (2) External	
Atropine		(1) Internal except when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	300 mcg (MD) 1 mg (MDD)
		(2) Internal when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	
Atropine Methobromide		(1) Internal except when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	400 mcg (MD) 1.3 mg (MDD)
		(2) Internal when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	

SCHEDULE 2 *(continued)*

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER *(continued)*

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 and 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
Atropine Methonitrate		(1) Internal except when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	400 mcg (MD) 1.3 mg (MDD)
		(2) Internal when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
Atropine Oxide Hydrochloride		(1) Internal except when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	360 mcg (MD) 1.2 mg (MDD)
		(2) Internal when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	
Atropine Sulphate		(1) Internal except when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	360 mcg (MD) 1.2 mg (MDD)

SCHEDULE 2 *(continued)*

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER *(continued)*

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 and 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
		(2) Internal when combined with Hyoscine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	
Bacitracin Methylene Disalicylate			
Bacitracin Zinc	6,300,000 iu/kg	Veterinary use: Incorporation in feed as growth promoter	
Bambermycin	30g/kg	Veterinary use: Incorporation in feed as growth promoter	
Deanol Bitartrate			26 mg (MDD)
Dicyclomine Hydrochloride			10 mg (MD) 60 mg (MDD)
Hexachlorophane		(1) Human use:— External:	
	2.0 per cent	(*a*) soaps	
	0.1 per cent	(*b*) preparations in aerosol dispensers	
	0.75 per cent	(*c*) preparations other than soaps or those in aerosol dispensers	
		(2) Veterinary use— (*a*) Internal as a liver fluke remedy	
		(*b*) External use—	
	2.0 per cent	(i) soaps or shampoos	
	0.1 per cent	(ii) preparations in aerosol dispensers	
	0.75 per cent	(iii) preparations other than soaps shampoos or those in aerosol dispensers	
Homatropine		External (except local ophthalmic use)	0.15 mg (MD) 0.45 mg (MDD)
Hyoscine	0.15 per cent	(1) Internal except when combined Atropine or Hyoscyamine or their salts:	

SCHEDULE 2 (*continued*)

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER (*continued*)

Substance specified in the principal order	ENTRIES INSERTED IN COLUMS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
		(2) Internal when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	
Hyoscine Butylbromide		(1) Internal except when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	3 mg (MD) 9 mg (MDD)
		(2) Internal when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscyamine or their salts	
Hyoscine Hydrobromide		(1) Internal except when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	300 mcg (MD) 900 mcg (MDD)
		(2) Internal when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External (except local ophthalmic use)	

SCHEDULE 2 (*continued*)

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER (*continued*)

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
Hyoscine Methobromide		(1) Internal except when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	2.5 mg (MD) 7.5 mg (MDD)
		(2) Internal when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscyamine or their salts	
Hyoscine Methonitrate		(1) Internal except when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	2.5 mg (MD) 7.5 mg (MDD)
		(2) Internal when combined with Atropine or Hyoscyamine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscyamine or their salts	
Hyoscyamine		(1) Internal except when combined with Atropine or Hyoscine or their salts: (*a*) inhalers	

SCHEDULE 2 *(continued)*

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER *(continued)*

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
		(*b*) preparations other than inhalers	300 mcg (MD) 1 mg (MDD)
		(2) Internal when combined with Atropine or Hyoscine or their salts: (*a*) inhalers	
		(*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscine or their salts	
		(4) When present as an alkaloid of Stramonium in preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants	
Hyoscyamine Hydrobromide		(1) Internal except when combined with Atropine or Hyoscine or their salts: (*a*) inhalers	
		(*b*) preparations other than inhalers	Equivalent of 300 mcg of base (MD) Equivalent of 1 mg of base (MDD)
		(2) Internal when combined with Atropine or Hyoscine or their salts: (*a*) inhalers	
		(*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscine or their salts	
Hyoscyamine Sulphate		(1) Internal except when combined with Atropine or Hyoscine or their salts:	

SCHEDULE 2 *(continued)*

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER *(continued)*

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
		(*a*) inhalers (*b*) preparations other than inhalers	Equivalent of 300 mcg of base (MD) Equivalent of 1 mg of base (MDD)
		(2) Internal when combined with Atropine or Hyoscine or their salts: (*a*) inhalers (*b*) preparations other than inhalers	1 mg of the total alkaloids calculated as the base (MDD)
		(3) External when combined with Atropine or Hyoscine or their salts	
Isopropamide Iodide			Equivalent of 2.5 mg of isopropamide ion (MD) Equivalent of 5.0 mg of isopropamide ion (MDD)
Lithium Carbonate			Equivalent of 5 mg of base (MD) Equivalent of 15 mg of base (MDD)
Monensin Sodium		Veterinary use: Incorporation in feed— (1) as a coccidiostat for chickens for fattening at levels not exceeding 125 parts per million (2) as a growth promoter for cattle for fattening at levels not exceeding 40 parts per million	
Papaverine		(1) Inhalers (2) Preparations other than inhalers	50 mg (MD) 150 mg (MDD)

SCHEDULE 2 (*continued*)

AMENDMENTS TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER (*continued*)

Substance specified in the principal order	ENTRIES INSERTED IN COLUMNS 2, 3 AND 4 IN THE PRINCIPAL ORDER		
	Column 2	Column 3	Column 4
Papaverine Hydrochloride		(1) Inhalers (2) Preparations other than inhalers	Equivalent of 50 mg of base (MD) Equivalent of 150 mg of base (MDD)
Papaverine Nitrate		(1) Inhalers (2) Preparations other than inhalers	Equivalent of 50 mg of base (MD) Equivalent of 150 mg of base (MDD)
Pituitary Gland (Whole Dried)		Inhalers	
Pituitary Powdered (Posterior Lobe)		Inhalers	
Sodium Fluoride	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	2.2 mg (MDD)
	0.2 per cent	(*b*) mouth rinses other than those for daily use	
	0.05 per cent	(*c*) mouth rinses for daily use	
Sulphaquinoxaline	225g/kg	Veterinary use: Incorporation in feed as a coccidiostat at levels not exceeding (1) 125 parts per million for poultry (2) 250 parts per million for rabbits	
L-Tryptophan		(1) Ingredient in dietary or nutritional products as essential amino-acid (2) External	

SCHEDULE 3 Article 10(4)

PART III OF SCHEDULE 1 TO THE PRINCIPAL ORDER AS SUBSTITUTED BY THIS ORDER

PART III Article 3(1)(*c*)

NAME AND PRODUCT LICENCE NUMBER OF MEDICINAL PRODUCTS

Chendol
0495/0003

Debrisan
0009/0021

Eustidil Tablets for Dogs and Cats
0003/4109

Flagyl Compak
0012/5091

Flagyl Suppositories 500 mg
0012/0113

Flagyl Suppositories 1g
0012/0114

Flagyl Tablets 200 mg
0012/5256

Flagyl Tablets 400 mg
0012/0084

Fortracin 100
1654/4012

Infacol
0027/0027

Movelat Cream
0542/5001

Movelat Gel
0542/0006

Mucaine
0011/5014

Quixalud Feed Additive
0034/4001

Syndol Tablets
0027/0011

Walpole's Buffer Solution
1732/4057

Whitsyn 10
0308/4001

SCHEDULE 4

Article 11(2)

PART I

ITEMS 5, 7, 8 AND 9 IN PART I OF SCHEDULE 4 TO THE PRINCIPAL ORDER AS SUBSTITUTED BY THIS ORDER

Column 1 Persons exempted	Column 2 Prescription only medicines to which the exemption applies	Column 3 Conditions
5. Persons lawfully conducting a retail pharmacy business within the meaning of section 69 of the Act.	5.—(1) Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977(**a**), as amended(**b**), which, if or when for parenteral administration, is a prescription only medicine, other than those the entry in relation to which in the fourth column of Part A of Schedule 1 to the said order does not permit sale for parenteral use.	5.—(1) The sale or supply shall be subject to the conditions specified in Article 3(2)(*d*) and (4) of the said order or, until 31st January 1980, to the conditions specified in Articles 3(4) and 7(2) of the said order.
	(2) Prescription only medicines which are eye drops or eye ointments containing Mafenide propionate or not more than 30.0 per cent of Sulphacetamide sodium or Sulphafurazole diethanolamine equivalent to not more than 4.0 per cent Sulphafurazole and prescription only medicines containing any of the following substances but no other substance listed in column 1 of Part I or Part II of Schedule 1 to this order— Atropine sulphate Bethanecol chloride	(2) The sale or supply shall be subject to the presentation of an order signed by a registered ophthalmic optician.

(**a**) S.I. 1977/2167. (**b**) S.I. 1978/1001.

SCHEDULE 4 *(continued)*

ITEMS 5, 7, 8 AND 9 IN PART I OF SCHEDULE 4 TO THE PRINCIPAL ORDER AS SUBSTITUTED BY THIS ORDER *(continued)*

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
	Carbachol Cyclopentolate hydrochloride Homatropine hydrobromide Hyoscine hydrobromide Naphazoline hydrochloride Naphazoline nitrate Neostigmine methylsulphate Physostigmine salicylate Physostigmine sulphate Pilocarpine hydrochloride Pilocarpine nitrate Tropicamide.	
7. Persons the sale or supply by whom is exempted by Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as amended, from the restrictions imposed by section 52 of the Act.	7. Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as amended, which, if or when for parenteral administration, is a prescription only medicine, other than those the entry in relation to which in the fourth column of Part A of Schedule 1 to the said order does not permit sale for parenteral use.	7. The sale or supply shall be subject to the conditions specified in Article 3(2) to (8) of the said order or, until 31st January 1980, to the conditions specified in Articles 3(4) and 7(2) of the said order.
8. Persons the sale or supply by whom is exempted by Article 4 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as	8. Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 4 of the said order which is a prescription only medicine.	8. The sale or supply shall be— (1) subject to the presentation of an order signed by or on behalf of the purchaser stating– (*a*) the name and address of the purchaser,

SCHEDULE 4 (*continued*)

ITEMS 5, 7, 8 AND 9 IN PART I OF SCHEDULE 4 TO THE PRINCIPAL ORDER AS SUBSTITUTED BY THIS ORDER (*continued*)

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
amended, from the restrictions imposed by section 52 of the Act.		(*b*) the name and address of the purchaser's business, and (*c*) the amount of the veterinary drug required; (2) subject to the conditions specified in Article 4(2) to (6) of the said order or, until 31st January 1980, to the conditions specified in Article 7(2) of the said order.
9. Persons providing a poultry vaccination service.	9. Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as amended, which is a poultry vaccine and which, if or when for parenteral administration, is a prescription only medicine.	9. The sale or supply shall be only to a person who has charge of animals for the purpose of and in the course of carrying on a business, whether as his sole business activity or as a substantial part of his business activities.

PART II

Article 11(3)

ITEM 5 ADDED TO PART II OF SCHEDULE 4 TO THE PRINCIPAL ORDER

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
5. Persons operating an occupational health scheme.	5. Prescription only medicines sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor, a registered nurse or an enrolled 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*) a registered nurse or an enrolled nurse, and (*b*) acting in accordance with the written general 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.

Article 11(4)(*a*)

PART III

ITEM 3 IN PART III OF SCHEDULE 4 TO THE PRINCIPAL ORDER AS SUBSTITUTED BY THIS ORDER

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
3. Persons providing a poultry vaccination service.	3. Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as amended, which is a poultry vaccine and which, if or when for parenteral administration is a prescription only medicine.	3. The administration shall be only in the course of providing a poultry vaccination service.

PART IV

Article 11(4)(*b*)

ITEMS ADDED TO PART III OF SCHEDULE 4 TO THE PRINCIPAL ORDER

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
6. Persons operating an occupational health scheme.	6. Prescription only medicines sold or supplied to the person operating an occupational health scheme in response to an order in writing signed by a doctor, a registered nurse or an enrolled nurse.	6.—(1) The administration shall be in the course of an occupational health scheme. (2) The individual administering the prescription only medicine, if neither a doctor nor acting in accordance with the directions of a doctor, shall be— (*a*) a registered nurse or an enrolled nurse, and (*b*) acting in accordance with the written general 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.
7. Persons who have in their charge or who maintain animals for the purposes of and in the course of carrying on a business whether as their sole business activity or as a substantial part of their business activities.	7. Any veterinary drug such as is described in paragraph (1)(*a*)(i) or (ii) of Article 3 of the Medicines (Exemptions from Restrictions on the Retail Sale or Supply of Veterinary Drugs) Order 1977, as amended, which, if or when for parenteral administration is a prescription only medicine, other than those the entry in relation to which in the fourth column of Part A of Schedule 1 to the said order does not permit sale for parenteral use.	7. The administration shall be only to animals in their charge or under their maintenance for the purposes of and in the course of carrying on a business.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order amends the Medicines (Prescription Only) Order 1977. It makes changes to the descriptions and classes of medicinal products that are prescription only medicines. The scope of certain exemptions from the restrictions imposed by section 58(2) of the Medicines Act 1968 (restrictions on the sale, supply and administration of prescription only medicines) is modified. The exemptions affected include those from the restrictions on sale or supply of certain prescription only medicines in an emergency by persons conducting a retail pharmacy business and on sale, supply or administration of certain prescription only medicines by specified persons. The conditions prescribed in relation to prescriptions under section 58(4)(*b*) of the Medicines Act 1968 are also modified.

The Order grants temporary exemptions until 11th February 1979 from the restrictions on sale, supply and administration imposed by section 58(2) of the Medicines Act 1968. These relate to the administration of certain injectable products to humans by certain persons, and to the sale, supply and administration of injectable veterinary drugs, in each case where the person selling, supplying or administering the medicinal product could have done so lawfully before 11th August 1978 otherwise than in accordance with a prescription.

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