

1982 No. 29

MEDICINES

The Medicines (Prescription Only) Amendment Order 1982

<i>Made</i> - - - -	14th January 1982
<i>Laid before Parliament</i>	21st January 1982
<i>Coming into Operation</i>	11th February 1982

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)(a), 59 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 this order pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Medicines Commission pursuant to sections 58(6) and 129(7) of that Act, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order, which may be cited as the Medicines (Prescription Only) Amendment Order 1982, amends the Medicines (Prescription Only) Order 1980(c) (hereinafter referred to as “the principal order”) and shall come into operation on 11th February 1982.

(2) In this order, a reference to adding an entry to a column in Part I of Schedule 1 to the principal order, or to adding an entry to Part III of that Schedule, is a reference to inserting that entry at the appropriate point in the alphabetical order of the entries in column 1 of Part I of that Schedule or, as the case may be, of the entries in Part III of that Schedule.

Amendment of Article 3 of the principal order

2. In Article 3(2) of the principal order (duration of restrictions for certain new products), for “three years” there is substituted “five years”.

(a) 1968 c. 67.

(b) In the case of the Secretaries of State concerned with health in England and 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) S.I. 1980/1921, amended by S.I. 1981/80.

Omission of Article 12 of the principal order

3. Article 12 of the principal order (temporary exemption for administration for certain persons) is omitted.

Amendment of Schedule 1 to the principal order

4.—(1) Schedule 1 to the principal order (descriptions and classes of prescription only medicines) is amended in accordance with paragraphs (2) and (3) of this Article.

(2) In Part I (which lists ingredients which render a product a prescription only medicine except in circumstances also listed)—

- (a) there are added to columns 1 and 3 the entries set out in columns 1 and 3 respectively in Schedule 1 to this order;
- (b) there are omitted from columns 2 and 3 the entries relating to Hexoestrol and to Tretinoin;
- (c) there are omitted from column 3 the words “Tablets for the” where they occur in relation to Chloroquine Phosphate, to Chloroquine Sulphate and to Hydroxychloroquine Sulphate; and
- (d) there are inserted in column 3, before “Administration” in the entry relating to Sodium Cromoglycate, the words “Human use:”.

(3) In Part III (which lists particular medicinal products as being prescription only medicines)—

(a) the following entries are added:

Dermisol Multicleanse Solution
0038/4059
Genebile
0015/4014
Neguvon Paste
0010/4053
Tracherine
0002/4068;

and

(b) the following entries are omitted:

Flagyl Compak
0012/5091
Flagyl Suppositories 500mg
0012/0113
Flagyl Suppositories 1g
0012/0114
Flagyl Tablets 200mg
0012/5256
Flagyl Tablets 400mg
0012/0084

and Part III shall have effect accordingly as set out in Schedule 2 to this order.

Amendment of Part III of Schedule 4 to the principal order

5. Part III of Schedule 4 to the principal order (exemption from the restriction on administration of prescription only medicines) is amended as follows—

- (a) in paragraph 2 (exemption for certified midwives) there is inserted after “Pethidine hydrochloride” in column 2 the word “Phytomenadione”; and

(b) after paragraph 8 there is added the paragraph 9 set out in Schedule 3 to this order.

12th January 1982.

Norman Fowler,
Secretary of State for Social Services.

13th January 1982.

Nicholas Edwards,
Secretary of State for Wales.

14th January 1982.

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 13th January 1982.

(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 13th day of January 1982.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 13th day January 1982.

(L.S.)

J. A. Young,
Permanent Secretary.

SCHEDULE 1

Article 4(2)(a)

ENTRIES ADDED TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER (a)

Column 1	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Amcinonide			
Amiodarone Hydrochloride			
Apramycin			
Arprinocid		Veterinary use: incorporation in feed for chickens for fattening at levels not exceeding 90 parts per million.	
Bacampicillin Hydrochloride			
Benoxaprofen			
Benzquinamide			
Budesonide			
Calcitriol			
Carmustine			
Cefadroxil			
Cefoxitin Sodium			
Ciclacillin			
Cinoxacin			
Clenbuterol Hydrochloride			
Clobazam			
Diclofenac Sodium			
Disopyramide Phosphate			
Dobutamine Hydrochloride			

(a) Note: all columns appearing in the principal order are set out in this order, although no entries are added by this order to columns 2 or 4.

Column 1	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Econazole		External (except vaginal use)	
Econazole Nitrate		External (except vaginal use)	
Etidronate Disodium			
Etomidate			
Fenbufen			
Flunisolide			
Flurbiprofen			
Flurazepam Monohydrochloride			
Gliquidone			
Halofuginone		Veterinary use: incorporation in feed for chickens for fattening at levels not exceeding 3 parts per million	
Ifosfamide			
Indoramin Hydrochloride			
Ketazolam			
Lidoflazine			
Metirosine			
Metronidazole			
Miconazole		External (except vaginal use)	
Miconazole Nitrate		External (except vaginal use)	
Nadolol			
Naproxen Sodium			
Narasin			
Oxantei Pamoate			
Piroxicam			
Pivampicillin Hydrochloride			

Column 1	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Probucol Reproterol Hydrochloride Ronidazole Sissomicin Talampicillin Talampicillin Napsylate Tianulin Hydrogen Fumarate Tinidazole Tolmetin Sodium Dihydrate Trazodone Triazolam Trilostane <i>Vaccines for Dogs</i> Vaccines for Bordetella bronchiseptera Xipamide		Veterinary use: incorporation in feed for turkeys at levels not exceeding 90 parts per million	

Article 4(3)

SCHEDULE 2

PART III OF SCHEDULE 1 TO THE PRINCIPAL ORDER
AS AMENDED BY THIS ORDER(a)

PART III

Article 3(1)(c)

NAME AND PRODUCT LICENCE NUMBER OF MEDICINAL PRODUCTS

Ancoloxin
0021/5060

Benoxyl 20
0174/0036

Debendox
0027/5001

Debrisan
0009/0021

Dermisol Multicleanse Solution
0038/4059

Eustidil Tablets for Dogs and Cats
0003/4109

Genebile
0015/4014

Fortracin 100
1654/4012

Infacol
0027/0027

Lopatul 100
1728/4056

Lopatul 500
1728/4057

Moveilat Cream
0542/5001

Moveilat Gel
0542/0006

Mucaine
0011/5014

Neguvon Paste
0010/4053

Paramol 118
0021/5056

Quixalud Feed Additive
0034/4001

Quixalud Premix
0034/4026

Syndol Tablets
0027/0011

Tracherine
0002/4068

Uromatic
0116/0077

Walpole's Buffer Solution
1732/4057

Whitsyn 10
0308/4001

(a) Products added by this order are indicated by the use of bold type.

SCHEDULE 3

Article 5(b)

PARAGRAPH 9 OF PART III OF SCHEDULE 4 TO THE PRINCIPAL
ORDER, ADDED BY THIS ORDER

Column 1	Column 2	Column 3
Persons exempted	Prescription only medicines to which the exemption applies	Conditions
<p>9. Persons who are, and at 11th February 1982 were, persons customarily administering medicinal products to human beings by parenteral administration in the course of a business in the field of osteopathy, naturopathy, acupuncture or other similar field except chiropody.</p>	<p>9. Medicinal products that are prescription only medicines by reason only that they fall within the class specified in Article 3(1)(d) (products for parenteral administration).</p>	<p>9. The person administering the prescription only medicine shall have been requested by or on behalf of the person to whom it is administered and in that person's presence to use his own judgment as to the treatment required.</p>

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order amends the Medicines (Prescription Only) Order 1980 which specifies descriptions and classes of prescription only medicines, that is to say medicinal products which (subject to exemptions) may be sold or supplied by retail only in accordance with a prescription given by a doctor, dentist, veterinary surgeon or veterinary practitioner and which may be administered only by or in accordance with the directions of such a person.

The amendments made by this Order are as follows:

- (a) the temporary period, specified for the purposes of section 59 of the Medicines Act 1968, during which new products may be prescription only medicines is increased from three to five years from the grant of a licence for the product;
- (b) additions are made to the list of substances which, if contained in a medicinal product, make that product a prescription only medicine (unless it is sold or supplied in specified circumstances), and in relation to some substances amendments are made to the circumstances in which a product, even though it contains that substance, is nevertheless not a prescription only medicine;
- (c) certain named products are specified as prescription only medicines, and other products cease to be so specified by name (their active ingredient being one of the additions to the list of substances referred to above);
- (d) an exemption for administration by certified midwives is extended to include products containing Phytomenadione;
- (e) an exemption (to replace an expired temporary exemption) is granted for the administration of injectable products by certain persons who are not doctors, dentists, veterinary surgeons or veterinary practitioners but who are acting in the course of a business. The exemption does not extend to products that are prescription only medicines for some reason other than that they are injectable.

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