1987 No. 674

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1987

Made - - - -	*6th April 1987*
Laid before Parliament	*9th April 1987*
Coming into force	*30th April 1987*

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), (4) and (5) 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, interpretation and commencement

1. This Order, which may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1987, amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983**(c)** (hereinafter referred to as "the principal Order") and shall come into force on 30th April 1987.

Amendment of articles 1, 6 and 12 of the principal Order

2.—(1) In article 1(2) of the principal Order (interpretation) for the definition of "the Misuse of Drugs Regulations" there is substituted the following definition:

> " "the Misuse of Drugs Regulations" means, in relation to England, Wales and Scotland, the Misuse of Drugs Regulations 1985 **(d)** and, in relation to Northern Ireland, the Misuse of Drugs (Northern Ireland) Regulations 1986 **(e)**;".

(2) In article 6(2)(d), (4)(c) and (5) of the principal Order (which refers to emergency sale or supply by a retail pharmacist) and in article 12(2)(b) of the principal Order (conditions relating to prescriptions), for the words, "Schedule 2, 3 or 4 to the Misuse of Drugs Regulations" there are substituted the words, "Schedule 1, 2 or 3 to the Misuse of Drugs Regulations".

(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) S.I. 1983/1212, amended by S.I. 1984/756 and 1986/586.
(d) S.I. 1985/2066.
(e) S.R. (N. I.) 1986 No. 52.

[H87/1696]

Amendment of articles 3 and 4 of, and Schedule 1 to, the principal Order

3.—(1) In article 3(1)(a) of the principal Order (medicinal products on prescription only), after the words "subject to article 4(1)" there are inserted the words "and (1A), and Part IV of Schedule 1".

(2) In article 4 of the principal Order (medicinal products that are not prescription only), after paragraph (1) there is inserted the following paragraph–

"(1A) Notwithstanding article 3(1)(a), medicinal products specified in Part IV of Schedule 1 shall not be prescription only medicines."

(3) In Part I of Schedule 1 to the principal Order (which lists substances which render a medicinal product a prescription only medicine except in circumstances also listed)–

(a) there are inserted in column 1, at the appropriate point in the alphabetical order of the substances listed, the substances specified in column 1 of Schedule 1 to this Order and in columns 2 and 3, so as to appear against the particular substance to which it relates, there is inserted as the case may be any entry appearing in columns 2 and 3 of Schedule 1 to this Order against that substance;

(b) there are deleted from column 1 the substances specified in Schedule 2 to this Order;

(c) for the entry in columns 2 and 3 relating to the substance Podophyllum Resin listed in column 1 there is substituted the entry relating to that substance set out in columns 2 and 3 of Schedule 3 to this Order;

(d) (i) in the footnote to the column 4 entries relating to the substances Atropine, Atropine Methobromide, Atropine Methonitrate, Atropine Oxide Hydrochloride, Atropine Sulphate, Hyoscine Butylbromide, Hyoscine Hydrobromide, Hyoscine Methobromide, Hyoscine Methonitrate, Hyoscyamine, Hyoscyamine Hydrobromide and Hyoscyamine Sulphate, after the words, "Subject to" there are inserted the words, "paragraph 1 of"; and

(ii) in column 2 opposite each of the substances Sodium Fluoride, Sodium Monofluorophosphate and Stannous Fluoride there is inserted "**(b)**" and at the foot of each page where such an insertion is made there are inserted the words, "**(b)** Subject to paragraph 2 of the note at the end of Part I of Schedule 1."; and

(iii) after the word "Note:" where it appears at the end of that Part there is inserted the number "1." and after the entry for the Note numbered 1. there is inserted the following new paragraph:

"2. In relation to a medicinal product which contains more than one of the substances Sodium Fluoride, Sodium Monofluorophosphate and Stannous Fluoride combined in a dentifrice, the maximum strength of the combination for the purposes of column 2 shall not exceed 0.15 per cent calculated as Fluorine."

(4) In Part III of Schedule 1 to the principal Order (medicinal products, specified by name and product licence number, which are prescription only medicines) there is deleted the entry "Debrisan 0009/0021".

(5) After Part III of Schedule 1 to the principal Order there is added Part IV as set out in Schedule 4 to this Order.

Amendment of Schedule 2 to the principal Order

4. From Schedule 2 to the principal Order (substances not to be contained in a prescription only medicine sold or supplied under the exemption conferred by article 6(3) of the principal Order), there are deleted the substances Phentermine Hydrochloride and Phentermine Resin Complex.

Signed by authority of the Secretary of State for Social Services.

Tony Newton
Minister of State,
Department of Health and Social Security

1st April 1987

Nicholas Edwards
Secretary of State for Wales

31st March 1987

Malcolm Rifkind
Secretary of State for Scotland

31st March 1987

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 1st April 1987.

Michael Jopling
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 3rd day of April 1987.

Maurice N. Hayes
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 6th day of April 1987.

W. H. Jack
Permanent Secretary

SCHEDULE 1

Article 3(3)(a)

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

	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	*Maximum strength*	*Use, pharmaceutical form or route of administration*	*Maximum dose and maximum daily dose*
Amsacrine			
Betamethasone Dipropionate			
Bromperidol			
Ceftazidime			
Ceftizoxime Sodium			
Dipivefrin Hydrochloride			
Enalapril Maleate			
Epirubicin			
Fluvoxamine Maleate			
Gemfibrozil			
Iohexol			
Lachesine Chloride			
Lithium Citrate			
Lofepramine Hydrochloride			
Meglumine Ioxaglate			
Metronidazole Benzoate			
Minoxidil			
Mitozantrone Hydrochloride			
Nicergoline			
Plicamycin			
Saralasin Acetate			
Sulconazole Nitrate		External (except vaginal use)	
Suprofen			
Tetroxoprim			
Tioconazole	2.0 per cent	External (except vaginal use)	
Tobramycin			
Vecuronium Bromide			

(a) Note: all columns appearing in Part I of Schedule 1 to the principal Order are set out in this Schedule, although no entries are inserted by this Schedule in column 4 of Part I of Schedule 1 to that Order.

SCHEDULE 2

Article 3(3)(b)

SUBSTANCES DELETED FROM PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER

Alprazolam
Bromazepam
Chlordiazepoxide
Clobazam
Clonazepam
Dextropropoxyphene Hydrochloride
Dextropropoxyphene Napsylate
Diazepam
Ethchlorvynol
Flunitrazepam
Flurazepam Hydrochloride
Flurazepam Monohydrochloride
Glutethimide
Ketazolam
Loprazolam Mesylate
Lorazepam
Lormetazepam
Mazindol
Medazepam
Meprobamate
Methyprylone
Mithramycin
Nitrazepam
Oxazepam
Pentazocine Hydrochloride
Pentazocine Lactate
Phentermine Hydrochloride
Phentermine Resin Complex
Prazepam
Sutoprofen
Temazepam
Triazolam

SCHEDULE 3

Article 3(3)(c)

ENTRY SUBSTITUTED IN COLUMNS 2 AND 3 OF PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER(a)

	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
Column 1	*Column 2*	*Column 3*	*Column 4*
Substance	*Maximum strength*	*Use, pharmaceutical form or route of administration*	*Maximum dose and maximum daily dose*
Podophyllum Resin	2.0 per cent	External: ointment or impregnated plaster	

(a) Note: all columns appearing in Part I of Schedule 1 to the principal Order are set out in this Schedule, although no entries are inserted by this Schedule in column 4 of Part I of Schedule 1 to that Order.

SCHEDULE 4

Article 3(5)

ADDITION OF PART IV OF SCHEDULE 1 TO THE PRINCIPAL ORDER

"PART IV

Articles 3(1)(a) and 4(1A)

NAME AND PRODUCT LICENCE NUMBER OF MEDICINAL PRODUCTS THAT ARE NOT PRESCRIPTION ONLY MEDICINES

Anflam Cream
0142/0190

Anflam Ointment
0142/0191

Beechams Hydrocortisone Cream
0079/0203

Cortaid Cream 1%
0032/0126

Cortaid Ointment 1%
0032/0127

Corteze Cream
0001/0107

Cortiderm
2855/0010

Cortovate Hydrocortisone Cream 1%
0039/0198

Cortril Topical Ointment 1% (non-greasy)
0057/0251

CP Hydrocortisone Cream 0.5%
4543/0238

CP Hydrocortisone Cream 1%
4543/0239

CP Hydrocortisone Ointment 0.5%
4543/0236

CP Hydrocortisone Ointment 1%
4543/0237

Dermacort Hydrocortisone Cream
0129/0076

Efcortelan P Cream 1%
0004/0327

Efcortelan P Ointment 1%
0004/0326

Femafen
0188/0071

Hc45 Hydrocortisone Cream
0327/0039

Kerfoot Hydrocortisone Cream 1%
0058/0092

Lanacort Cream
3157/0008

Lanacort Ointment
3157/0011

Medicort Cream
3920/0010

Oriel Capsules
0073/0023

Pharmacort Cream 0.5%
0011/0077

Proflex Sustained Relief Capsules
0001/0109

Suspren
0188/0072

Timocort Hydrocortisone Cream
0044/0090

Wasp-Eze Hydrocortisone Cream
0232/0058

Wasp-Eze Hydrocortisone Ointment
0232/0059

'Zenoxone Cream
0181/0033

Zenoxone Ointment
0181/0032"

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 (the principal Order) 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 an appropriate practitioner and which may be administered only by or in accordance with the directions of such a practitioner.

The amendments made by this Order are as follows:

Article 2 amends the definition of the "Misuse of Drugs Regulations" in the principal Order and makes consequential amendments to the references to those Regulations in articles 6 and 12 of the principal Order.

Article 3 amends articles 3 and 4 of, and Schedule 1 to, the principal Order.

Article 3(1) and (2) makes provision whereby certain topical Hydrocortisone preparations and certain sustained release preparations of Ibuprofen shall not be prescription only medicines notwithstanding that they would otherwise be so by reason that they consist of or contain a substance specified in Part I of Schedule 1 to the principal Order. Such products are specified by name and product licence number in a new Part IV of Schedule 1 to the principal Order which is added by Article 3(5) of this Order.

Article 3(3) amends Part I of Schedule.1 to the principal Order. Article 3(3)(a) adds to the list of prescription only medicines those substances which are set out in Schedule 1 to this Order. Article 3(3)(b) deletes from that list those substances which are set out in Schedule 2 to this Order although such substances remain subject to the provisions of the principal Order by reason either of their being controlled drugs or because they have been relisted in Part I of Schedule 1 to the principal Order under a new approved name. Article 3(3)(c) substitutes a new entry in the list relating to the substance Podophyllum Resin. Article 3(3)(d) makes provision for the circumstances in which a medicinal product containing more than one of the substances Sodium Fluoride, Sodium Monofluorophosphate and Stannous Fluoride combined in a dentifrice shall be a prescription only medicine.

Article 3(4) amends Part III of Schedule 1 to the principal Order (medicinal products, specified by name and product licence number, which are prescription only medicines) by deletion of the entry "Debrisan 0009/0021".

Article 4 amends Schedule 2 to the principal Order (substances not to be contained in a prescription only medicine sold or supplied under the exemption conferred by article 6(3) of the principal Order, which relates to emergency sale or supply by a retail pharmacist), by deleting certain substances which nonetheless remain excluded from the exemption conferred by article 6(3) by reason of their being controlled drugs.

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