

1988 No. 2017

MEDICINES

The Medicines (Products Other Than Veterinary Drugs)
(Prescription Only) Amendment Order 1988

<i>Made</i> - - - -	<i>16th November 1988</i>
<i>Laid before Parliament</i>	<i>25th November 1988</i>
<i>Coming into force</i>	<i>16th December 1988</i>

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 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 1988, 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 16th December 1988.

Amendment of article 4 of the principal Order

2. In article 4 of the principal Order (medicinal products that are not prescription only) -

(a) the following paragraph is inserted after paragraph (1A) -

"(1B) Notwithstanding Article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it consists of or contains the substance astemizole where-

(a) 1968 c.67; by virtue of section 132(1) of that Act the expression "the appropriate Ministers" is to be construed in accordance with section 1(2) thereof. (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); 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, as amended by S.I. 1984/756, 1986/586 and 1987/674 and 1250.

- (a) it is for oral use;
 - (b) it is not a sustained release preparation;
 - (c) it is sold or supplied in a container or package containing not more than 100mg;
 - (d) it is indicated only for the treatment of hay fever in adults or in children over the age of 12 years; and
 - (e) its container or package is labelled to show a maximum daily dose of 10mg.”;
- (b) the following paragraph is substituted for paragraph (3) –
“(3) Notwithstanding Article 3(1)(d), any preparation of insulin for parenteral administration to human beings shall not be a prescription only medicine.”.

Insertion of article 11A into the principal Order

3. The following article is inserted after article 11 of the principal Order:–

“Exemption in the case of a forged prescription

11A. The restrictions imposed by section 58(2)(a) (restrictions on sale and supply) shall not apply to the sale or supply of a prescription only medicine by a pharmacist in accordance with a forged prescription where the pharmacist, having exercised all due diligence, believes on reasonable grounds that the prescription is genuine.”.

Amendment of Part I of Schedule 1 to the principal Order

4. 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) the following substances are inserted at the appropriate point in the alphabetical order of the substances listed in Column 1–

“Alclometasone Dipropionate
Astemizole
Auranofin
Buspirone Hydrochloride
Ciprofloxacin
Ciprofloxacin Hydrochloride
Clavulanic Acid
Danthron
Desogestrel
Disodium Etidronate
Etodolac
Gemeprost
Mesalazine
Metergoline
Mupirocin
Nabumetone
Nicardipine Hydrochloride
Potassium Clavulanate
Somatrem
Sulbactam Sodium
Thiabendazole
Trientine Dihydrochloride
Zidovudine
Zuclopenthixol Hydrochloride”;

- (b) the following substances in Column 1 are deleted –

“Chlordiazepoxide Hydrochloride
Etidronate Disodium
Potassium Clorazepate”;

- (c) in Column 3 of the entry relating to Amodiaquine Hydrochloride, the words "Prophylaxis of malaria" are deleted;
- (d) for the entry relating to Ibuprofen there is substituted the entry set out in the Schedule to this Order.

Amendment of Part III of Schedule 1 to the principal Order

5. In Part III of Schedule 1 to the principal Order (medicinal products, specified by name and product licence number, which are prescription only medicines), the following entry is deleted:—

"Cedocard 20
0424/0036"

Amendment of Part IV of Schedule 1 to the principal Order.

6. In Part IV of Schedule 1 to the principal Order (specified medicinal products that are not prescription only medicines) —

- (a) the heading "TABLE A" is inserted above the words "NAME AND PRODUCT LICENCE NUMBER OF MEDICINAL PRODUCTS THAT ARE NOT PRESCRIPTION ONLY MEDICINES";
- (b) the following entries are inserted at the appropriate point in the alphabetical order of medicinal products already listed therein —

Anflam Cream 0.5%
0142/0263

Anflam Ointment 0.5%
0142/0262

Dermacort Hydrocortisone Cream
8265/0002".

- (c) the following Table is inserted at the end of the list of medicinal products already listed therein —

"TABLE B

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

Leo Laboratories Limited:

Hydrocortisone Acetate Cream BP 0.5%
—0043/0150

Hydrocortisone Acetate Cream BP 1.0%
—0043/0151

Richard Daniel and Son Limited:

Hydrocortisone Cream BP 1.0%
—0842/0011".

Signed by authority of the Secretary of State for Health.

7th November 1988

D. Mellor
Minister of State,
Department of Health

9th November 1988

Peter Walker
Secretary of State for Wales

10th November 1988

Malcolm Rifkind
Secretary of State for Scotland

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 16th November 1988.

John MacGregor
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 14th day of November 1988.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 14th day of November 1988.

W. H. Jack
Permanent Secretary

SCHEDULE

Article 4(d)

ENTRY SUBSTITUTED IN PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER

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
Ibuprofen		Rheumatic and muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza: (1) Internal	(1) 400 mg (MD) 1200 mg (MDD)

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 makes two amendments to article 4 of the principal Order: it exempts certain products containing astemizole from being a prescription only medicine; and it exempts all preparations of insulin for parenteral administration from being prescription only medicines;
- Article 3 inserts a new article 11A into the principal Order which exempts from the restrictions on sale or supply of prescription only medicines contained in section 58(2)(a) of the Medicines Act 1968 the sale or supply by a pharmacist of such a medicine in accordance with a forged prescription but only in limited circumstances;
- Article 4 amends Part I of Schedule 1 to the principal Order which lists substances which render medicinal products a prescription only medicine except in circumstances also listed;
- Article 5 deletes an entry from Part III of Schedule 1 to the principal Order which lists the name and product licence number of medicinal products that are prescription only medicines;
- Article 6 inserts entries into Part IV of Schedule 1 to the principal Order which lists the name and product licence number of medicinal products that are not prescription only medicines and also inserts therein a new list of medicinal products identified by reference to the name of the relevant product licence holder as well as the name and product licence number of the product.

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