STATUTORY INSTRUMENTS

1993 No. 3256

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993

Made - - - -	*31st December 1993*
Laid before Parliament	*31st December 1993*
Coming into force - -	*21st January 1994*

The Secretaries of State respectively 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 the powers conferred upon them by sections 58(1), (4) and (5), 129(4) and 132(1) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by those provisions 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 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 may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993, and shall come into force on 21st January 1994.

(2) In this Order "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(**3**).

Amendment of article 3 of the principal Order

2. In article 3(1)(a) of the principal Order (medicinal products on prescription only), for "Article 4(1) to (1J)" there is substituted "Article 4(1) to (1P)".

(**1**) 1968 c. 67. The expressions "the Health Ministers" and "the appropriate Ministers" are defined in section 1 of that Act as amended.

(**2**) 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 Department of Health and Social Services for Northern Ireland 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).

(**3**) S.I. 1983/1212, as amended by S.I. 1984/756, 1986/586, 1987/674 and 1250, 1988/2017, 1989/1852, 1991/962, 1992/ 1534 and 2937 and 1993/1890.

Amendment of article 4 of the principal Order

3.—(1) In article 4 of the principal Order (medicinal products that are not prescription only), for paragraph (1C), there is substituted the following paragraph:—

"(1C) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance mebendazole where—

(a) the medicinal product is indicated for oral use in the treatment of enterobiasis in adults and in children over the age of 2 years;

(b) its container or package is labelled to show a maximum dose of 100 milligrams of mebendazole; and

(c) it is sold or supplied in a container or package containing not more than 400 milligrams of mebendazole.".

(2) In article 4 of the principal Order the following paragraphs are inserted after paragraph (1J):—

"(1K) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance beclomethasone dipropionate where—

(a) the medicinal product is indicated only for the treatment of seasonal allergic rhinitis by non-aerosol nasal administration, in adults and in children over the age of 12 years;

(b) it is sold or supplied in a container or package containing not more than 200 doses; and

(c) its container or package is labelled to show a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril of beclomethasone dipropionate.

(1L) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance cimetidine where—

(a) the medicinal product is indicated for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity; and

(b) its container or package is labelled to show a maximum dose of 200 milligrams and a maximum daily dose of 800 milligrams of cimetidine for a maximum period of 14 days.

(1M) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance cimetidine where—

(a) the medicinal product is for the prophylactic management of nocturnal heartburn; and

(b) its container or package is labelled to show a maximum dose of 100 milligrams of cimetidine to be taken once daily at night for a maximum period of 14 days.

(1N) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance famotidine where—

(a) the medicinal product is indicated for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity; and

(b) its container or package is labelled to show a maximum dose of 10 milligrams and a maximum daily dose of 20 milligrams of famotidine for a maximum period of 14 days.

(1O) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance sodium cromoglycate where—

(a) the medicinal product is indicated for the treatment of acute seasonal allergic conjunctivitis;

(b) it is in the form of aqueous eye drops;

(c) the maximum strength of the sodium cromoglycate in the medicinal product does not exceed two per cent. calculated in terms of weight in volume; and

(d) it is sold or supplied in a container containing not more than 10 millilitres of the medicinal product.

(1P) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance sodium cromoglycate where—

(a) the medicinal product is indicated for the treatment of acute seasonal allergic rhinitis;

(b) it is in the form of an eye ointment;

(c) the maximum strength of the sodium cromoglycate in the medicinal product is four per cent. calculated in terms of weight in weight; and

(d) it is sold or supplied in a container or package containing not more than 5 grams of the medicinal product.".

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 substance is inserted at the appropriate point in the alphabetical order of the substances listed in Column 1:—

Naftifine Hydrochloride;

(b) for the entries relating to pseudoephedrine hydrochloride and tioconazole respectively there are substituted the entries relating to those substances 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 entries relating to "Anhydrol Forte 0173/0030" and "Nicorette Plus 0458/0021" are deleted.

Amendment to Table A of Part IV of Schedule 1 to the principal Order

6. In Table A of Part IV of Schedule 1 to the principal Order (medicinal products specified by name and product licence number that are not prescription only medicines)—

(a) immediately before the entry relating to Cortaid Cream 1% 0032/0126 there are inserted the following entries:

(i) "Calacort Cream 12650/0001",

(ii) "Corlan Pellets 0039/0397"; and

(b) immediately before the entry relating to Efcortelan P Cream 1% 0004/0327 there is inserted the entry "Dioderm Hydrocortisone Cream 0173/0153".

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
23rd December 1993 Department of Health

Sir Wyn Roberts
31st December 1993 Minister of State, Welsh Office

Fraser of Carmyllie
23rd December 1993 Minister of State, The Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this

L.S.

F. A. Elliott
23rd day of December 1993. Permanent Secretary

SCHEDULE Article 4(b)

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

Column 1	CIRCUMSTANCES EXCLUDING MEDICINAL PRODUCTS FROM THE CLASS OF PRESCRIPTION ONLY MEDICINES		
Column 2 Substances	Column 3 Maximum Strength	Column 4 Use, Pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Pseudoephedrine Hydrochloride		Internal	(a) (a) In the case of a controlled release preparation: 90mg (MD), 180mg (MDD); (b) in any other case: 60mg (MD), 180mg (MDD).
Tioconazole	(1) 2.0 per cent.	(1) External (except vaginal use) (2) External vaginal use for treatment of vaginal candidiasis	

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 subject to section 58(2) of the Medicines Act 1968, 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 article 3(1)(a) of the principal Order consequentially on the changes made to article 4 of the principal Order;

article 3 amends article 4 of the principal Order so as to exempt certain products containing beclomethasone dipropionate, cimetidine, famotidine, mebendazole, and sodium cromoglycate from being prescription only medicines;

article 4 amends 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;

article 5 amends Part III of Schedule 1 to the principal Order which lists medicinal products specified by name and product licence number which are prescription only medicines;

article 6 amends Table A of Part IV of Schedule 1 to the principal Order which lists medicinal products specified by name and product licence number that are not prescription only medicines.