STATUTORY INSTRUMENTS

1995 No. 1384

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1995

Made - - - -	*25th May 1995*
Laid before Parliament	*5th June 1995*
Coming into force - -	*30th June 1995*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred on them by sections 58(1), (4) and (5) and 129(4) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said 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 Order 1995 and shall come into force on 30th June 1995.

(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 (1V)" there is substituted "Article 4(1) to (1Z)".

(**1**) 1968 c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by S.I.1969/388, Schedule 1.

(**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, amended by S.I. 1984/756, 1986/586, 1987/674 and 1250, 1988/2017, 1989/1852, 1991/962, 1992/1534 and 2937, 1993/1890 and 3256 and 1994/558, 3016 and 3050.

Amendment of article 4 of the principal Order

3. In article 4 of the principal Order (medicinal products that are not prescription only), the following paragraphs are inserted after paragraph (1V):—

"(1W) 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 fluconazole where—

(a) the medicinal product is indicated for oral administration for the treatment of vaginal candidiasis in persons aged not less than 16 nor more than 60 years;

(b) it is sold or supplied in a container or package containing not more than 150 milligrams of the medicinal product; and

(c) the container or package is labelled to show a maximum dose of 150 milligrams of fluconazole.

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

(a) the medicinal product is indicated for the management of pruritus associated with acute or chronic urticaria or atopic dermatitis or contact dermatitis, in adults and in children aged not less than 6 years;

(b) it is sold or supplied in a container or package containing not more than 750 milligrams of the medicinal product; and

(c) the container or package is labelled to show a maximum dose of 25 milligrams and a maximum daily dose of 75 milligrams in the case of adults and in children aged not less than 12 years and a maximum daily dose of 50 milligrams in the case of children aged not less than 6 nor more than 12 years.

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

(a) the medicinal product is in the form of a shampoo;

(b) the maximum strength of the ketoconazole in the medicinal product does not exceed 2 per cent. calculated in terms of weight in weight;

(c) the medicinal product is indicated for the prevention and treatment of dandruff and seborrhoeic dermatitis of the scalp;

(d) it is sold or supplied in a container or package containing not more than 120 millilitres of the medicinal product, containing not more than 2400 milligrams of ketoconazole; and

(e) the container or package is labelled to show a maximum frequency of application of once every 3 days.

(1Z) 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 pyrantel embonate where—

(a) the medicinal product is indicated for the treatment of enterobiasis, in adults and in children aged not less than 2 years;

(b) it is sold or supplied in a container or package containing not more than 750 milligrams of the medicinal product; and

(c) the container or package is labelled to show a maximum daily dose (to be taken as a single dose) of pyrantel embonate of 750 milligrams in the case of adults and children aged not less than 12 years, of 500 milligrams in the case of children aged not less than 6 nor more than 12 years and of 250 milligrams in the case of children aged not less than 2 nor more than 6 years."

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 the circumstances also listed)—

(a) the following substances are inserted at the appropriate points in the alphabetical order of the substances listed in Column 1:

Azelastine Hydrochloride Lithium Succinate;

(b) in relation to the substance Pseudoephedrine Hydrochloride, for the entry "180mg (MDD)" at (a) and at (b) in Column 4, there is substituted in both places the entry "240mg (MDD)".

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, that are prescription only medicines), the following entries are omitted:

Ancoloxin 0021/5060 Debendox 0027/5001 Perstorp Dextrinomer Iodine 3863/0001.

Amendment of 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) the following entries are omitted:

Anflam Cream 0142/0190 Anflam Cream 0.5% 0142/0263 Anflam Ointment 0142/0191 Anflam Ointment 0.5% 0142/0262 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 0129/0076 Efcortelan P Cream 0004/0327 Efcortelan P Ointment 0004/0326 Evacort Cream 0039/0198 Kerfoot Hydrocortisone Cream 1% 0058/0092 Medicort Cream 3920/0010 Wasp-Eze Hydrocortisone Cream 0232/0058 Wasp-Eze Hydrocortisone Ointment 0232/0059 Zenoxone Ointment 0181/0032;

(b) (b) the following entries are inserted at the appropriate points in the alphabetical order of the medicinal products listed:

Efcortelan Eczema Cream 10949/0234 Efcortelan Eczema Ointment 10949/0235 Proctocream HC 0036/0065.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
23rd May 1995 Department of Health

John Redwood
25th May 1995 Secretary of State for Wales

Fraser of Carmyllie
25th May 1995 Minister of State, The Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 23rd May 1995.

F. A. Elliott
Permanent Secretary

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 fluconazole, hydroxyzine hydrochloride, ketoconazole and pyrantel embonate 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 the 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 that are prescription only medicines (no such products are now so specified);

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.