STATUTORY INSTRUMENTS

1994 No. 3016

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1994

Made - - - -	*25th November 1994*
Laid before Parliament	*5th December 1994*
Coming into force - -	*30th December 1994*

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 (No. 2) Order 1994 and shall come into force on 30th December 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 (1P)" there is substituted "Article 4(1) to (1V)".

(**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; section 58(1), (4) and (5) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 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.

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 (1P):—

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

(a) the maximum strength of the diclofenac diethylammonium in the medicinal product does not exceed 1.16 per cent. calculated in terms of weight in weight;

(b) the medicinal product is indicated for external application for the local symptomatic relief of pain and inflammation in trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism, in adults and in children of not less than the age of 12 years;

(c) it is sold or supplied in a container or package containing not more than 30 grams of the medicinal product; and

(d) its container or package is labelled to show a maximum period of use of 7 days.

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

(a) the maximum strength of the felbinac in the medicinal product does not exceed 3.17 per cent. calculated in terms of weight in weight;

(b) the medicinal product is indicated for external application for the relief of symptoms associated with soft tissue injury such as strains, sprains and contusions, in adults and in children of not less than the age of 12 years;

(c) it is sold or supplied in a container or package containing not more than 30 grams of the medicinal product; and

(d) the container or package is labelled to show a maximum period of use of 7 days.

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

(a) the medicinal product is in the form of a non-pressurised nasal spray;

(b) the maximum strength of the flunisolide in the medicinal product does not exceed 0.025 per cent. calculated in terms of weight in volume;

(c) the medicinal product is indicated for the prevention and treatment of seasonal allergic rhinitis, including hayfever, in adults and children of not less than the age of 12 years;

(d) it is sold or supplied in a container or package containing not more than 240 metered doses of the medicinal product; and

(e) the container or package is labelled to show a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril of flunisolide in the case of adults and children over the age of 16 years and a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in the case of other children of not less than the age of 12 years.

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

(a) it is sold or supplied in a container or package containing not more than 400 milligrams of oxethazaine; and

(b) its container or package is labelled to show a maximum dose of 10 milligrams and a maximum daily dose of 30 milligrams of oxethazaine.

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

(a) the maximum strength of the piroxicam in the medicinal product does not exceed 0.5 per cent. calculated in terms of weight in weight;

(b) the medicinal product is indicated for external application for the relief of rheumatic pain and muscular aches, pains and swellings such as strains, sprains and sports injuries, in adults and in children of not less than the age of 12 years;

(c) it is sold or supplied in a container or package containing not more than 30 grams of the medicinal product; and

(d) its container or package is labelled to show a maximum period of use of 7 days.

(1V) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance ranitidine hydrochloride 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 equivalent to 75 milligrams of ranitidine and a maximum daily dose equivalent to 300 milligrams of ranitidine for a maximum period of use of 14 days.".

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:

Azelaic Acid

Diclofenac Diethylammonium

Nicotinic Acid

Oxethazaine

Pyrimethamine

Terbinafine;

(b) in relation to the substance Minoxidil, there are inserted in column 2 the entry "2 per cent." and in column 3 the entry "External";

(c) for the entries relating to "Nandrolone Laureate" and "Pizotifen Maleate" in column 1, there are substituted the entries "Nandrolone Laurate" and "Pizotifen Malate" respectively;

(d) in relation to the substance Nicotinic Acid, there are inserted in column 3 the entry "any use, except for the treatment of hyperlipidaemia" and in column 4 the entry "600mg (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 entry "Mucaine 0011/5014" is omitted.

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), there are inserted at the appropriate points in the alphabetical order of the names listed the following entries:

Adcortyl in Orabase for Mouth Ulcers (0034/0321)

Anusol Plus HC Ointment (0018/0223)

Anusol Plus HC Suppositories (0018/0224).

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
22nd November 1994 Department of Health

John Redwood
25th November 1994 Secretary of State for Wales

Fraser of Carmyllie
23rd November 1994 Minister of State The Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 25th November 1994.

L.S.

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 exclude from the categories of prescription only medicines certain products containing diclofenac diethylammonium, felbinac, flunisolide, oxethazaine, piroxicam and ranitidine hydrochloride;

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;

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.