STATUTORY INSTRUMENTS

1993 No. 1890

MEDICINES

The Medicines (Products Other Than Veterinary Dmgs) (Prescription Only) Amendment Order 1993

Made - - - -	*23rd July 1993*
Laid before Parliament	*2nd August 1993*
Coming into force - -	*23rd August 1993*

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 the powers conferred upon them by sections 58(1), (4)(a) 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 1993, and shall come into force on 23rd August 1993.

(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), (1A), (1B), (1C), (1D) and (1E)"there is substituted "Article 4(1) to (1J)".

(**1**) 1968 c. 67; see the meaning assigned to "the appropriate Ministers" by section 1(1) as amended.
(**2**) In the case of Secretaries of State concerned with health in England and 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).
(**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 1992/2937.

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 (1E):

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

(a) the medicinal product is sold or supplied in a container or package containing not more than 240 milligrams of acrivastine;

(b) its container or package is labelled to show a maximum daily dose of 24 milligrams of acrivastine.

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

(a) the medicinal product is sold or supplied in a container or package containing not more than 100 milligrams of cetirizine;

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

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

(a) the maximum strength of the ketoprofen in the medicinal product does not exceed two point five per cent.calculated in terms of weight in weight;

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

(c) the medicinal product is indicated only for treatment by external topical application, for rheumatic and muscular pain in adults and in children over the age of 12 years, for a maximum period of 7 days.

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

(a) the medicinal product is sold or supplied in a container or package containing not more than 100 milligrams of loratadine;

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

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

(a) the medicinal product is sold or supplied in a container or package containing not more than 1200 milligrams of terfenadine;

(b) its container or package is labelled to show a maximum daily dose of 120 milligrams of terfenadine.".

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

Acemetacin

Acitretin

Aclarubicin Hydrochloride

Acrivastine

Adenosine
Albendazole
Aldesleukin
Alfuzosin Hydrochloride
Azithromycin
Bambuterol Hydrochloride
Cefixime
Cefodizime Sodium
Cefpodoxime Proxetil
Celiprolol Hydrochloride
Cetirizine
Cilastatin Sodium
Cilazapril
Ciprofibrate
Clarithromycin
Colfosceril Palmitate
Dalteparin Sodium
Dexfenfluramine Hydrochloride
Diclofenac Potassium
Eflornithine Hydrochloride
Enoxaparin Sodium
Epirubicin Hydrochloride
Epoetin Alfa
Epoetin Beta
Filgrastim
Finasteride
Flosequinan
Fluticasone Propionate
Formestane
Fosfomycin
Trometamol
Fosinopril Sodium
Gadoteridol
Gestrinone
Granisetron Hydrochloride
Guanfacine Hydrochloride
Halofantrine Hydrochloride
Imipenem Hydrochloride
Iomeprol
Iopentol

Iothalamic Acid
Ioversol
Ioxaglic Acid
Ketorolac Trometamol
Lacidipine
Lamotrigine
Lomefloxacin Hydrochloride
Loratadine
Mifepristone
Mivacurium Chloride
Moclobemide
Molgramostim
Mometasone Furoate
Moracizine Hydrochloride
Nafarelin Acetate
Nitrendipine
Norfloxacin
Norgestimate
Ofloxacin
Ondansetron Hydrochloride
Oxaprozin
Oxitropium Bromide
Oxybutynin Hydrochloride
Paroxetine Hydrochloride
Perfluamine
Pergolide Mesylate
Pravastatin Sodium
Remoxipride Hydrochloride
Risperidone
Salmeterol Hydroxynaphthoate
Sermorelin
Sertraline Hydrochloride
Sodium Clodronate
Somatorelin Acetate
Sultamicillin
Sumatriptan Succinate
Tazobactam Sodium
Terfenadine
Tibolone
Tinzaparin

Tolfenamic Acid

Tropisetron Hydrochloride

Tulobuterol

Tulobuterol Hydrochloride

Zuclopenthixol Acetate

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

5. 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), immediately after the entry Zenoxone Ointment 0181/0032 there is inserted the following entry:

"Zovirax Cold Sore Cream 0003/0304".

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
19th July 1993 Department of Health

John Redwood
21st July 1993 Secretary of State for Wales

Fraser of Carmyllie
20th July 1993 Minister of State Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereto affixed on the

Gillian Shephard
23rd July 1993. Minister of Agriculture, Fisheries and Food

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

J. Harbison
19th day of July 1993. Under Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

19th day of July 1993.

W. J. Hodges
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 consequentiaily on the changes made to article 4 of the principal Order;

article 3 amends article 4 of the principal Order sp as to exempt certain products containing Acrivastine, Cetirizine, Ketoprofen 2.5%, Loratadine and Terfenadine 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.