STATUTORY INSTRUMENTS

1996 No. 1514

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1996

Made - - - -	*10th June 1996*
Laid before Parliament	*12th June 1996*
Coming into force - -	*5th July 1996*

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) 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 1996 and shall come into force on 5th July 1996.

(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) of the principal Order (medicinal products on prescription only)—

(a) in sub-paragraph (a), for "Article 4(1) to (1AA)" there is substituted "Article 4(1) to (1AC)";

(**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, 1994/558, 3016 and 3050 and 1995/1384 and 3174.

(b) after sub-paragraph (g) there is inserted the following sub-paragraph—

"(h) radioactive medicinal products, as defined in regulation 1(2) of the Medicines (Administration of Radioactive Substances) Regulations 1978(**4**), other than products which fall within that definition only because they are substances or articles specified in the Medicines (Dental Filling Substances) Order 1975(**5**) or in the Medicines (Radioactive Substances) Order 1978(**6**).".

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 (1AA)—

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

(a) the medicinal product is indicated only for the treatment of seasonal allergic rhinitis in adults and in children aged not less than 12 years;

(b) it is in non-aerosol, aqueous form for nasal administration;

(c) it is sold or supplied in a container or package containing not more than 36 doses, each of which contains not more than 140 micrograms of azelastine hydrochloride; and

(d) the container or package is labelled to show a maximum dose of 140 micrograms per nostril of azelastine hydrochloride and a maximum daily dose of 280 micrograms per nostril of azelastine hydrochloride.

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

(a) the medicinal product is indicated only for the prevention of the symptoms of food-related heartburn in persons aged not less than 16 years; and

(b) the container or package is labelled to show a maximum dose of 75 milligrams of nizatidine and a maximum of 4 such doses in any period of 14 days.".

Amendment of Part I to 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), in Column 1—

(a) after the entry "Fenoterol Hydrobromide" there is inserted the entry "Fenticonazole Nitrate";

(b) after the entry "Tolmetin Sodium" there is inserted the entry "Tramadol Hydrochloride";

(c) in the entry for Vaccines, after "Bacillus Calmette-Guerin Vaccine" there is inserted"Bacillus Salmonella Typhi Vaccine".

Amendment of Part II of Schedule 1 to the principal Order

5. In Part II of Schedule 1 to the principal Order (which lists circumstances which exclude specified controlled drugs from the class of prescription only medicines), in the entries in columns 2 and 4 appearing against the entry in column 1 which relates to "Codeine; its salts", for the word"Codeine" in both places in which it appears there are substituted the words "Codeine Monohydrate".

(**4**) S.I. 1978/1006, to which there are amendments not relevant to this Order.
(**5**) S.I. 1975/533 amended by S.I. 1994/3119.
(**6**) S.I. 1978/1004.

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 (name and product licence number of medicinal products that are not prescription only medicines), after the entry for Lanacort Ointment there is inserted the following entry—

"Perinal Spray	0173/0049".

Signed by authority of the Secretary of State for Health.

Gerald Malone
Minister of State,
7th June 1996 Department of Health

William Hague
10th June 1996 Secretary of State for Wales

James Douglas-Hamilton
10th June 1996 Minister of State, The Scottish Office

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

L.S.

F A Elliott
10th June 1996. 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 (i.e. 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). Under the principal Order products are included in a class of such medicines by reason of the substances contained in them, subject to their being excluded in specified circumstances.

The amendments made by this Order are as follows—

the inclusion of radioactive medicinal products and products containing bacillus salmonella typhi vaccine, fenticonazole nitrate and tramadol hydrochloride (articles 2 and 4);

exclusions for certain products containing azelastine hydrochloride and nizatidine (article 3) and an exclusion for Perinal Spray (marketing authorization number 0173/0049) (article 6);

clarification of the exclusion for products containing codeine and its salts (article 5).