STATUTORY INSTRUMENTS

1995 No. 3174

MEDICINES

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1995

Made - - - -	*6th December 1995*
Laid before Parliament	*8th December 1995*
Coming into force - -	*29th December 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 (No. 2) Order 1995 and shall come into force on 29th December 1995.

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

Amendment of article 1 of the principal Order

2. In article 1(2) of the principal Order (interpretation), for the definition of "maximum strength" there is substituted the following definition—

(**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.

""maximum strength" means such of the following as may be specified—

(i) the maximum quantity of a substance by weight or volume contained in a dosage unit of a medicinal product;

(ii) the maximum number of units of activity contained in a dosage unit or a weight of a medicinal product; and

(iii) the maximum percentage of a substance contained in a medicinal product calculated in terms of weight in weight, weight in volume, volume in weight or volume in volume, as appropriate;".

Amendment of article 3 of the principal Order

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

Amendment of article 4 of the principal Order

4. In article 4 of the principal Order (medicinal products that are not prescription only)—

(a) in sub-paragraph (a) of paragraph (1K) before "treatment" there is inserted "prevention or";

(b) the following paragraph is inserted after paragraph (1Z)—

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

(a) the medicinal product is indicated only for the prevention or 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 10 milligrams of the medicinal product; and

(d) the container or package is labelled to show a maximum dose, and a maximum daily dose, of 200 micrograms per nostril of budesonide.".

Amendment of Part I of Schedule 1 to the principal Order

5. 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:

Amorolfine Hydrochloride

Calcipotriol

Carbaryl

Lodoxomide Trometamol

Pancreatin;

(b) in relation to the substance Pancreatin, there are inserted in Column 2 the entries—

"(1) 21,000 European Pharmacopoeia units of lipase per capsule

(2) 25,000 European Pharmacopoeia units of lipase per gram";

(c) in relation to the substance Pancreatin, there are inserted in Column 3 the entries—

"(1) capsules

(2) powder".

Signed by authority of the Secretary of State for Health

John Horam
Parliamentary under Secretary of State,
1st December 1995 Department of Health

William Hague
6th December 1995 Secretary of State for Wales

James Douglas Hamilton
6th December 1995 Minister of State, The Scottish Office

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

F. A. Elliot
5th December 1995. 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 certain specified circumstances.

The amendments made by this Order are as follows:—

an extension of the exclusion for products containing beclomethasone dipropionate (article 4(a));

a new exclusion for products containing budesonide (article 4(b));

the inclusion of products containing substances mentioned in article 5.