STATUTORY INSTRUMENTS

1993 No. 3256

The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No. 2) Order 1993

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 1993, and shall come into force on 21st January 1994.

(2) In this Order "the principal Order" means the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(**1**).

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 (1J)" there is substituted "Article 4(1) to (1P)".

Amendment of article 4 of the principal Order

3.—(1) In article 4 of the principal Order (medicinal products that are not prescription only), for paragraph (1C), there is substituted the following paragraph:—

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

(a) the medicinal product is indicated for oral use in the treatment of enterobiasis in adults and in children over the age of 2 years;

(b) its container or package is labelled to show a maximum dose of 100 milligrams of mebendazole; and

(c) it is sold or supplied in a container or package containing not more than 400 milligrams of mebendazole.".

(2) In article 4 of the principal Order the following paragraphs are inserted after paragraph (1J):—

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

(a) the medicinal product is indicated only for the treatment of seasonal allergic rhinitis by non-aerosol nasal administration, in adults and in children over the age of 12 years;

(b) it is sold or supplied in a container or package containing not more than 200 doses; and

(c) its container or package is labelled to show a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril of beclomethasone dipropionate.

(**1**) 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 2937 and 1993/1890.

(1L) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance cimetidine 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 of 200 milligrams and a maximum daily dose of 800 milligrams of cimetidine for a maximum period of 14 days.

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

(a) the medicinal product is for the prophylactic management of nocturnal heartburn; and

(b) its container or package is labelled to show a maximum dose of 100 milligrams of cimetidine to be taken once daily at night for a maximum period of 14 days.

(1N) Notwithstanding article 3(1)(a), a medicinal product shall not be a prescription only medicine by reason that it contains the substance famotidine 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 of 10 milligrams and a maximum daily dose of 20 milligrams of famotidine for a maximum period of 14 days.

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

(a) the medicinal product is indicated for the treatment of acute seasonal allergic conjunctivitis;

(b) it is in the form of aqueous eye drops;

(c) the maximum strength of the sodium cromoglycate in the medicinal product does not exceed two per cent. calculated in terms of weight in volume; and

(d) it is sold or supplied in a container containing not more than 10 millilitres of the medicinal product.

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

(a) the medicinal product is indicated for the treatment of acute seasonal allergic rhinitis;

(b) it is in the form of an eye ointment;

(c) the maximum strength of the sodium cromoglycate in the medicinal product is four per cent. calculated in terms of weight in weight; and

(d) it is sold or supplied in a container or package containing not more than 5 grams of the medicinal product.”.

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)—

(a) the following substance is inserted at the appropriate point in the alphabetical order of the substances listed in Column 1:—

Naftifine Hydrochloride;

(b) for the entries relating to pseudoephedrine hydrochloride and tioconazole respectively there are substituted the entries relating to those substances set out in the Schedule to this Order.

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, which are prescription only medicines), the entries relating to "Anhydrol Forte 0173/0030" and "Nicorette Plus 0458/0021" are deleted.

Amendment to 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) immediately before the entry relating to Cortaid Cream 1% 0032/0126 there are inserted the following entries:

(i) "Calacort Cream 12650/0001",

(ii) "Corlan Pellets 0039/0397"; and

(b) immediately before the entry relating to Efcortelan P Cream 1% 0004/0327 there is inserted the entry "Dioderm Hydrocortisone Cream 0173/0153".

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
23rd December 1993 Department of Health

Sir Wyn Roberts
31st December 1993 Minister of State, Welsh Office

Fraser of Carmyllie
23rd December 1993 Minister of State, The Scottish Office

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

L.S.

F. A. Elliott
23rd day of December 1993. Permanent Secretary