STATUTORY INSTRUMENTS

1994 No. 3016

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

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.”.