STATUTORY INSTRUMENTS

1971 No. 1410

MEDICINES

The Medicines (Exemption From Licences) (Foods and Cosmetics) Order 1971

Made - - - -	*23rd August 1971*
Laid before Parliament	*3rd September 1971*
Coming into Operation	*6th September 1971*

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Minister of Health and Social Services for Northern Ireland, acting jointly, in exercise of their powers under section 15(1) of the Medicines Act 1968 (as having effect subject to the provisions of Article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(**1**)) 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 the following order, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971 and shall come into operation on 6th September 1971.

(2) In this order, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"cosmetic" means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration;

"food" includes beverages, confectionery and articles and substances as ingredients in the preparation of food and includes any manufactured substance to which there has been added any vitamin and which is advertised (within the meaning of Section 92 of the Act) as available and for sale to the general public as a dietary supplement;

(**1**) (1969 I, p. 1070).

"medicinal product" includes articles or substance specified in orders made under section 104 or section 105 of the Act which are for the time being in force and which direct that Part II of the Act shall have effect in relation to such articles or substances as that Part has effect in relation to medicinal products within the meaning of the Act;

"mineral salts" means salts of any one or more of the following, iron, iodine, calcium, phosphorus, fluorine, copper, potassium, manganese, magnesium or zinc;

"vitamin preparation" means any medicinal product the active ingredients of which consist only of vitamins or vitamins and mineral salts;

"vitamins" means any one or more of the following, vitamins A, B1, B2, B6, C, D and E, biotin, nicotinamide, nicotinic acid, pantothenic acid and its salts, biflavonoids, inositol, choline, para-aminobenzoic acid, cyanocobalamin or folic acid;

and other expressions have the same meaning as in the Act.

(3) Except in so far as the context otherwise requires, any reference in this order to any enactment shall be construed as a reference to that enactment as amended, extended or re-enacted by any other enactment.

(4) The Interpretation Act 1889 applies for the purpose of the interpretation of this order as it applies for the purpose of the interpretation of an Act of Parliament.

Exemption from licences for certain foods and cosmetics

2.—(1) Subject to the provisions of paragraph (2) of this Article, the restrictions imposed by sections 7 and 8 of the Act (licences for dealings in and manufacture of medicinal products) shall not apply to anything done in relation to a medicinal product which is wholly or mainly for use by being administered to one or more human beings and which is or is to be for sale either for oral administration as a food or for external use as a cosmetic.

(2) The exemption conferred by the preceding paragraph of this Article does not apply to a medicinal product as aforesaid which—

(a) is or is to be sold with, accompanied by or having in relation to it, any particulars in writing specifying that product's curative or remedial function in relation to a disease specified or the use of that product for such curative or remedial purposes, or

(b) being a product for oral administration as a food as aforesaid, comes within any of the descriptions contained in the Schedule to this order, or

(c) being a product for external use as a cosmetic as aforesaid contains any antibiotic or any hormone in a proportion in excess of 0.4 per cent or resorcinol in a proportion in excess of 1 per cent (the said proportions calculated on the weight of the medicinal product), or

(d) being neither a vitamin preparation nor a substance coming within the description in paragraph 3 of the said Schedule, is or is to be sold with, accompanied by or having in relation to it any particulars in writing specifying the dosage relevant to that product's medicinal purpose.

Signed by authority of the Secretary of State for Social Services.

Paul Dean
Parliamentary Under Secretary of State
Department of Health and Social Security

13th August 1971

Peter Thomas
18th August 1971 — Secretary of State for Wales

Gordon Campbell
23rd August 1971 — Secretary of State for Scotland

W. K. Fitzsimmons
Minister of Health and Social Services for
16th August 1971 — Northern Ireland

SCHEDULE

Article 2(2)(b)

Description of certain medicinal product foods which are not exempt from licences

1. Any vitamin preparation in relation to which there are no written particulars or directions as to dosage.

2. Any vitamin preparation in relation to which there are written particulars or directions as to dosage specifying a recommended daily dosage for adults which involves a daily intake in excess of—

(i) the equivalent of 2,500 Units (within the meaning of the 1968 edition of the British Pharmacopoeia) of vitamin A activity, or

(ii) the equivalent of 250 Units (within the meaning of the 1968 edition of the British Pharmacopoeia) of antirachitic activity, or

(iii) 25 micrograms of folic acid, or

(iv) 5 micrograms of cyanocobalamin.

3. Any medicinal product, not being a vitamin preparation, to which one or more of the ingredients vitamin A or D, folic acid or cyanocobalamin has been added and in relation to which product there are written particulars or directions as to recommended use of that substance which involves a daily intake in excess of the quantities and ingredients specified in the preceding paragraph.

EXPLANATORY NOTE

This Order exempts from the restrictions imposed by Part II of the Medicines Act 1968 as to dealings in and manufacture of medicinal products except in accordance with a licence granted under that Act, certain medicinal products which are for oral administration as foods or which are for external use as cosmetics.