STATUTORY INSTRUMENTS

1973 No. 2079

MEDICINES

The Medicines (Exemption from Licences) (Foods and Cosmetics) Amendment Order 1973

Made - - -	10*th December* 1973
Laid before Parliament	18*th December* 1973
Coming into Operation	8*th January* 1974

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland, and the Secretary of State for Northern Ireland, acting jointly, in exercise of powers conferred by section 15(1) of the Medicines Act 1968(**a**) and now vested in them(**b**) 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, interpretation and commencement

1. This order, which may be cited as the Medicines (Exemption from Licences) (Foods and Cosmetics) Amendment Order 1973, shall be read as one with the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971(**c**) (hereinafter referred to as "the principal order"), and shall come into operation on 8th January 1974.

Amendment of Article 2 of the principal order

2.—(1) Article 2 of the principal order (exemption from licences for certain foods and cosmetics) shall be amended in accordance with the following paragraphs of this Article and shall accordingly have effect as set out in the Schedule to this order.

(2) In Article 2(1) for the words "provisions of paragraph (2)" there shall be substituted the words "other provisions".

(3) In Article 2(2) for sub-paragraph (*c*) there shall be substituted the following sub-paragraph—

"(*c*) being a product for external use as a cosmetic as aforesaid contains—

(i) any antibiotic, or

(ii) hexachlorophane, except where the product is exempted from the prohibition imposed by the Medicines (Hexachlorophane Prohibi-

(**a**) 1968 c. 67.

(**b**) 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 (1969 I, p. 1070)), and in the case of the Secretary of State for Northern Ireland by virtue of the provisions of Section 1(1)(*a*) of the Northern Ireland (Temporary Provisions) Act 1972 (c. 22).

(**c**) S.I. 1971/1410 (1971 III, p. 3945).

tion) Order 1973(a) under paragraphs (2)(i)(*a*) or (2)(ii) of Article 2 of that order, or

(iii) any hormone in a proportion (calculated on the weight of the medicinal product) in excess of 0.004 per cent, or

(iv) resorcinol in a proportion (calculated as aforesaid) in excess of 1 per cent, or".

(4) After Article 2(2) there shall be added the following paragraph—

"(3) Without prejudice to paragraph (2) of this Article, the exemption from section 7 of the Act (product licences) conferred by paragraph (1) of this Article does not apply to a medicinal product as aforesaid in respect of which there are, or are to be directed to practitioners advertisements or representations of the nature and in the manner described in section 96(1) and (2) of the Act.".

Temporary provisions

3.—(1) Notwithstanding the provisions of paragraphs (2)(*c*)(ii) and (3) of Article 2 of the principal order, as amended by this order, during the periods set out in paragraph (2) below, the exemption conferred by Article 2(1) of the principal order shall apply to a medicinal product to which the said paragraphs (2)(*c*)(ii) or (3) apply, if—

(*a*) that product was effectively on the market in the United Kingdom immediately before the date of the coming into operation of this order, and

(*b*) dealings in or manufacture of that product would have been subject to the restrictions imposed by sections 7 or 8 of the Act as from that date but for the provisions of this Article.

(2) The periods referred to in the preceding paragraph are as follows:—

(*a*) the period of 28 days, or such extended period as the licensing authority may in a particular case allow, from the date of the coming into operation of this order;

(*b*) the period of 3 months or such extended period as aforesaid from that date, if during the period under (*a*) above the licensing authority have been notified of the intention to apply for a product licence in respect of the medicinal product to which paragraph (1) above relates;

(*c*) the period until the application for such product licence has been finally disposed of, if the licensing authority have been notified in accordance with (*b*) above and the application for such product licence is made during the period under the said sub-paragraph.

(3) For the purposes of this Article an application shall be taken as finally disposed of on (but not before) the occurrence of whichever of the events specified in paragraphs (*a*) to (*e*) of section 27(7) of the Act last occurs.

6th December 1973. *Keith Joseph,*
Secretary of State for Social Services.

6th December 1973. *Peter Thomas,*
Secretary of State for Wales.

7th December 1973. *Gordon Campbell,*
Secretary of State for Scotland.

10th December 1973. *Francis Pym,*
Secretary of State for Northern Ireland.

(a) S.I. 1973/1120 (1973 II, p.3453).

SCHEDULE

Article 2(1)

Containing Article 2 of the Principal Order
as amended by this Order*

2.—(1) Subject to the *other provisions* 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*—

(i) *any antibiotic, or*

(ii) *hexachlorophane, except where the product is exempted from the prohibition imposed by the Medicines (Hexachlorophane Prohibition) Order* 1973(*a*) *under paragraphs* (2)(*i*)(*a*) *or* (2)(*ii*) *of Article* 2 *of that order, or*

(iii) *any hormone in a proportion (calculated on the weight of the medicinal product) in excess of* 0.004 *per cent. or*

(iv) *resorcinol in a proportion (calculated as aforesaid) in excess of* 1 *per cent, 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.

(3) *Without prejudice to paragraph* (2) *of this Article, the exemption from section* 7 *of the Act (product licences) conferred by paragraph* (1) *of this Article does not apply to a medicinal product in respect of which there are, or are to be, directed to practitioners advertisements or representations of the nature and in the manner described in section* 96(1) *and* (2) *of the Act.*

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*The words substituted or added by this order are shown in italics.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order amends the Medicines (Exemption from Licences) (Foods and Cosmetics) Order 1971 by adding to the cases to which the exemptions from licensing conferred by the Order of 1971 do not apply, the cases where the medicinal product is being advertised in a certain way to practitioners and cases where the medicinal product, being a cosmetic within the meaning of the Order of 1971, contains hexachlorophane. The Order provides for certain periods during which the exemptions from licensing will continue to apply after the coming into operation of the Order.

The Order also amends the proportion of hormone specified in Article 2(2)(*c*) of the Order of 1971 from 0·4 per cent to 0·004 per cent.

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