STATUTORY INSTRUMENTS

1974 No. 1150

MEDICINES

The Medicines (Exemption from Licences) (Ingredients) Order 1974

Made - - -	*5th July* 1974
Laid before Parliament	*15th July* 1974
Coming into Operation	*5th August* 1974

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Head of the Department of Health and Social Services for Northern Ireland and the Head of the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 13(2) and 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, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Exemption from Licences) (Ingredients) Order 1974 and shall come into operation on 5th August 1974.

(2) In this order, unless the context otherwise requires, "the Act" means the Medicines Act 1968 and other expressions have the same meanings 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, regulation or order.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(**c**) shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

(**a**) 1968 c. 67.
(**b**) In tne 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 Heads of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c.36).
(**c**) 1889 c. 63.

Temporary exemptions from licences for ingredients

2. Notwithstanding the provisions of Article 3, and subject to the provisions of Article 4 of this order, the restrictions imposed by sections 7 and 8 of the Act (restrictions as to dealing with and manufacture of medicinal products) shall not apply to anything done, in the period commencing with the coming into operation of this order and ending with 31st December 1974, in relation to a substance or article which is a medicinal product by virtue only of the provisions of section 130(1)(*b*) of the Act (ingredients).

Exemptions from licences for ingredients

3.—(1) Subject to the provisions of Article 2, 4 and 5 of this order, the restrictions imposed by sections 7 and 8 of the Act shall not apply to anything done in relation to a substance or article which is a medicinal product by virtue only of the provisions of section 130(1)(*b*) of the Act if and so long as the conditions specified in paragraph (2) of this Article are satisfied.

(2) The conditions referred to in paragraph (1) of this Article are that any person proposing to carry on any activity to which that paragraph is applicable, either—

(*a*) notifies the licensing authority in writing of his intention to carry on such activity or has furnished particulars relating to such activity in response to such request as is referred to in Article 4(*b*) of this order, or

(*b*) makes or has made an application, which has not been withdrawn, for the grant of a licence under Part II of the Act relating to such activity and that application has not been determined by the licensing authority and its determination by the licensing authority has not been deferred.

Further conditions

4. The exemptions conferred by Article 2 or, as the case may be, Article 3 of this order shall not apply—

(*a*) if, and so long as, the licensing authority are of the opinion that in the interests of safety the said exemptions should not apply and if the licensing authority have, by notice in writing, so notified such person whose activities in relation to the medicinal product in question would have been exempt by virtue of the said exemptions but for the provisions of this paragraph, and so long as such notification has not been withdrawn by the licensing authority, or

(*b*) where a person whose activities in relation to the medicinal product in question would have been exempt by virtue of the exemptions conferred by Article 2 of this order but for the provisions of this paragraph or where a person who has notified the licensing authority in accordance with Article 3(2)(*a*) of this order, fails to comply with a request in writing from the licensing authority, within the time specified in such request, either to furnish the licensing authority with such particulars in writing relating to the activity in question as would be required if such person were making an application for the grant of a licence under Part II of the Act relating to such activity or to make an application such as is described in Article 3(2)(*b*) of this order, or

(*c*) where there has been a failure to inform the licensing authority that a material change of circumstances has occurred in relation to the particulars furnished in response to such request as is referred to in paragraph (*b*) of this Article or in the particulars contained in or furnished in connection with an application such as is described in Article 3(2)(*b*) of this order.

General provisions

5.—(1) For the purposes of this order an application for the grant of a licence under Part II of the Act shall be taken as deferred when any information requested by the licensing authority under section 44(1) of the Act has not been furnished and it has not been shown to the reasonable satisfaction of the licensing authority that the applicant for that licence is unable to furnish that information and where the licensing authority have indicated in writing to the applicant that by virtue of that section the application is not being determined because of that failure to furnish that information.

(2) If by an interim order made under section 107(3)(*a*) of the Act the operation of the decision of the licensing authority on that application is suspended, the provisions of this order shall apply as if that application has not been determined, so long as the operation of the decision continues to be suspended by such interim order.

Barbara Castle,
Secretary of State for Social Services.

27th June 1974.

John Morris,
Secretary of State for Wales.

27th June 1974.

William Ross,
Secretary of State for Scotland.

1st July 1974.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th July 1974.

(L.S.)

Frederick Peart,
Minister of Agriculture, Fisheries and Food.

Donaldson,
Head of the Department of Health and Social Services for Northern Ireland.

5th July 1974.

Donaldson,
Head of the Department of Agriculture
for Northern Ireland.

5th July 1974.

EXPLANATORY NOTE

(*This Note is not part of the Order.*)

This Order provides for exemption 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, in respect of substances or articles which are medicinal products by virtue only of the provisions of section 130(1)(*b*) of the Act (ingredients). The exemptions apply if certain conditions as to notification or making an appropriate licence application are complied with unless the activity in question takes place during the period specified before 1st January 1975 (Articles 2 and 3). Article 4 of the Order provides for the cessation of the exemptions in certain circumstances.

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