

1972 No. 1199

MEDICINES
**The Medicines (Exemption from Licences)
(Manufacture and Assembly Temporary Provisions) Order 1972**

<i>Made</i>	- - -	<i>4th August 1972</i>
<i>Laid before Parliament</i>		<i>11th August 1972</i>
<i>Coming into Operation</i>		<i>1st September 1972</i>

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 Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of their powers under sections 15(1) and 129(4) of the Medicines Act 1968(a) (as having effect subject to the provisions of Article 2(2) of, and Schedule 1 to the Transfer of Functions (Wales) Order 1969(b) and section 1(1)(a) of the Northern Ireland (Temporary Provisions) Act 1972(c)) 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) (Manufacture and Assembly Temporary Provisions) Order 1972 and shall come into operation on 1st September 1972.

(2) In this order, unless the context otherwise requires—
“the Act” means the Medicines Act 1968;

“medicinal product” includes substances or articles 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 substances or articles as that Part has effect in relation to medicinal products within the meaning of the Act;

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, regulation or order shall be construed as a reference to that enactment, regulation or order, as the case may be, amended or extended by any other enactment, regulation or order.

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

(a) 1968 c. 67.
(c) 1972 c. 22.

(b) S.I. 1969/388 (1969 I, p. 1070).
(d) 1889 c. 63.

Temporary exemption from manufacturer's licences

2.—(1) Subject to the provisions of paragraphs (3) (4) (5) and (6) of this Article the restrictions imposed by section 8(2) of the Act (restrictions as to manufacture and assembly) shall not apply to the manufacture or assembly of any medicinal product if and so long as the conditions specified in paragraph (2) of this Article are satisfied.

- (2) The conditions referred to in the preceding paragraph are—
- (i) that the person who manufactures or assembles the medicinal product (in this order referred to as “the manufacturer”) is, in respect of those activities, a person in relation to whom section 16(4) of the Act (transitional exemptions) has effect;
 - (ii) that in respect of such manufacture or assembly an application for the grant of a manufacturer's licence, other than a licence of right, has been made before 1st July 1972 and that application has not been determined by the licensing authority and its determination by the licensing authority has not been deferred;
 - (iii) that the whole or any instalment of any fees that are payable in connection with that application have been paid;
 - (iv) that the manufacturer manufactures or assembles the medicinal product in accordance with—
 - (a) the particulars contained in or which accompany that application,
 - (b) any product licence required under the provisions of the Act which is applicable to medicinal products of the same description, and
 - (c) such standard provisions, prescribed under section 47 of the Act, as are applicable to manufacturer's licences^(a);
 - (v) that the licensing authority has directed that the provisions of this Article may apply to such manufacture or assembly by the manufacturer and the manufacturer has been notified in writing of that direction;
 - (vi) that such manufacture is not the manufacture of a product to which Article 2 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971^(b) (exemption from product licences for certain special manufactured products) relates.

(3) For the purposes of this order an application 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 manufacturer's licence is unable to furnish that information and where the licensing authority has indicated in writing to the manufacturer that by virtue of that section that application is not being determined because of that failure to furnish that information.

(a) See Schedule 2 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, S.I. 1971/972 (1971 II, p. 2809).
(b) S.I. 1971/1450 (1971 III, p. 4118).

(4) 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 the order.

(5) Where the application for the manufacturer's licence has not been made before 1st July 1972 but has been made before such relevant day as is appointed under section 17 of the Act (termination of transitional exemptions), the licensing authority may direct that the provisions of this order may apply as if the application had been made before 1st July 1972.

(6) Where after a direction under sub-paragraph (v) of paragraph (2) of this Article has been notified, it appears to the licensing authority that in the interests of safety the provisions of this Article ought not to apply, the licensing authority may notify the manufacturer in writing that that direction is no longer effective, whereupon the provisions of this Article will cease to apply to the manufacturer.

Application of exemption orders under section 15 of the Act during temporary period of exemption from manufacturer's licences

3.—(1) For the purposes of Article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(a) the manufacturer shall be treated as the holder of a manufacturer's licence if and so long as the restrictions imposed by section 8(2) of the Act do not apply to him by virtue of the application to him of the preceding Article of this order.

(2) For the purposes of Article 2 of the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1972(b) the authorised premises, in relation to the manufacturer who is exempt from the need to be the holder of a manufacturer's licence by virtue of this order, shall be the premises specified in the application for a manufacturer's licence as being the premises which the manufacturer proposes to use for the manufacture, assembly, storage or distribution of the medicinal products to which the application relates.

28th July 1972.

Keith Joseph,
Secretary of State for Social Services.

1st August 1972.

Peter Thomas,
Secretary of State for Wales.

3rd August 1972.

Gordon Campbell,
Secretary of State for Scotland.

3rd August 1972.

W. S. I. Whitelaw,
Secretary of State for Northern Ireland.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th August 1972.

(L.S.)

J. M. L. Prior,
Minister of Agriculture, Fisheries and Food.

(a) S.I. 1971/1450 (1971 III, p. 4118).

(b) S.I. 1972/640 (1972 I, p. 2081).

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order exempts from the restrictions imposed by section 8(2) of the Medicines Act 1968 as to manufacture and assembly of medicinal products except in accordance with a manufacturer's licence granted under Part II of the Act, the manufacture or assembly of certain medicinal products by manufacturers who are entitled to manufacturer's licences of right but who have applied for ordinary licences before 1st July 1972.

The exemption only applies during the period until the application for ordinary licences has been determined.

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