STATUTORY INSTRUMENTS

1971 No. 1450

MEDICINES

The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

Made - - - -	*27th August* 1971
Laid before Parliament	*2nd September* 1971
Coming into Operation	*1st September* 1971

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 Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, acting jointly, in exercise of their powers under sections 15(1) and 23(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 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) (Special and Transitional Cases) Order 1971 and shall come into operation on 1st September 1971.

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

(4) The Interpretation Act 1889(c) 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.
(b) S.I. 1969/388 (1969 I p. 1070).
(c) 1889 c. 63.

Exemption from product licences for certain special manufactured products

2.—(1) The restrictions imposed by section 7 of the Act (restriction as to dealing with medicinal products) shall not apply to the sale or supply of any medicinal product if the conditions specified in paragraph (2) of this Article as to sale, supply and manufacture of that product are satisfied.

(2) The conditions referred to in the preceding paragraph are—

(i) that the medicinal product is sold or supplied,

(*a*) to a doctor or dentist for use by him in circumstances to which section 9(1) of the Act relates, or

(*b*) to a veterinary surgeon or veterinary practitioner for use by him in circumstances to which section 9(2) of the Act relates, or

(*c*) for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist in circumstances to which section 10 of the Act (as modified by the Medicines (Retail Pharmacists—Exemptions from Licensing Requirements) Order 1971(a)) relates, or

(*d*) to a person, in the course of whose business herbal remedies are sold, where that medicinal product, being a herbal remedy is to be sold or supplied in circumstances to which section 12(1)(*b*) of the Act relates, or

(*e*) to a person for administration to himself or to a member of his household, where that medicinal product is a product which may lawfully be sold by retail otherwise than in accordance with a practitioner's prescription or from premises other than a registered pharmacy within the meaning of the Act (as modified for the purposes of section 10 of the Act as aforesaid),

or, if sold or supplied through a person lawfully carrying on a retail pharmacy business or a holder of a wholesale dealer's licence (including a person entitled to such a licence by virtue of that person's entitlement to a licence of right), that the medicinal product is sold or supplied for the uses and in the circumstances specified in the foregoing provisions of this sub-paragraph;

(ii) that no advertisement or representation (within the meaning of section 92 of the Act) relating to the medicinal product is issued and that the sale or supply as aforesaid is in response to a bona fide unsolicited order;

(iii) that the manufacture of the medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that that product is of the character and specification required by the person specified in sub-paragraph (i) of this paragraph; and

(iv) that written records as to manufacture in accordance with the preceeding sub-paragraph and as to sale or supply to persons specified in sub-paragraph (i) of this paragraph of the medicinal product are made and maintained, and are available to the licensing authority or the enforcement authority on request of either authority;

(v) that the medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of medicinal products to which this Article relates.

(a) S.I. 1971/1445 (1971 III, p. 4078).

(3) In respect of the medicinal products to which the preceding paragraphs of this Article relate the provisions of subsection (1) of section 23 of the Act (special provisions as to effect of manufacturer's licences) shall have effect as if the holder of the manufacturer's licence in respect of any such products was also the holder of a product licence in respect of such products or as if such products were manufactured or assembled to the order of a person who is the holder of such a product licence.

Exemption from manufacturer's licences for products manufactured in certain circumstances

3.—(1) The restrictions imposed by section 8(2) of the Act (restriction as to manufacture and assembly) shall not apply to the manufacture or assembly of any medicinal product in any of the circumstances specified in paragraph (2) of this Article provided that the person who so manufactures or so assembles—

(*a*) is the holder of a manufacturer's licence in respect of the manufacture or assembly of medicinal products in circumstances other than those specified in the said paragraph (2), and

(*b*) has notified the licensing authority of his intention to manufacture or assemble as the case may be, medicinal products in circumstances specified in the said paragraph (2) and has supplied that authority with such information as to the medicinal products and their manufacture or assembly as that authority may from time to time require,

and provided that the licensing authority has directed that the provision of this Article may apply to such manufacture or assembly.

(2) The circumstances referred to in the preceding paragraph in relation to the manufacture or assembly of any medicinal product are circumstances in which—

(*a*) a medicinal product is assembled in accordance with a product licence in respect of that medicinal product, where that licence has not been granted to the person who so assembles nor to the person to whose order the medicinal product is assembled, but has been granted to some other person, or

(*b*) the manufacture or assembly of the medicinal product is—

(i) to the order of the Crown, or

(ii) under the supervision of a pharmacist to the order of any person for administration to that person or any person under his care in circumstances where that product may lawfully be supplied otherwise than to a practitioner's prescription,

and in which the person who so manufactures or assembles that medicinal product is not required to be the holder of a product licence in respect of that product under the provisions of the Act.

Transitional exemption from manufacturer's licences

4.—(1) Until such day as section 16(4) of the Act (transitional examption from manufacturer's licence) ceases to have effect by an order for that purpose under section 17 of the Act (termination of transitional exemption) the restrictions imposed by section 8(2) of the Act shall not apply to the manufacture or assembly of any medicinal product in respect of which a product licence other than a licence granted under section 26 of the Act (licence of right) has been granted if the person who so manufactures or so assembles is a person to whom the provisions of the said section 16(4), as having effect subject to the proviso thereto

(operations which were included in manufacture or assembly during 12 month period prior to first appointed day), apply and have effect in relation to his manufacture or assembly of other medicinal products in the course of a business carried on by him, provided that that medicinal product is manufactured or assembled in accordance with that product licence.

(2) Until such day as section 16(2) of the Act (transitional exemption from product licence) ceases to have effect by an order for that purpose under section 17 of the Act, the restrictions imposed by section 8(2) of the Act shall not apply to the manufacture or assembly of any medicinal product to the order of a person who is not the holder of a product licence in respect of that product provided the provisions of section 16(2) of the Act apply to that person in relation to that product and provided the licensing authority has not signified its disapproval of such manufacture or assembly.

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.

Signed by authority of the Secretary of State for Wales.

David Gibson-Watt,
Minister of State, Welsh Office.

27th August 1971.

Gordon Campbell,
Secretary of State for Scotland.

25th August 1971.

W. K. Fitzsimmons,
Minister of Health and Social Services
for Northern Ireland.

16th August 1971.

In witness whereof the official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th August 1971.

(L.S.)

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

H. W. West,
Minister of Agriculture for Northern Ireland.

17th August 1971.

EXPLANATORY NOTE

(This Note is not part of the Order.)

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 under that Act, certain medicinal products manufactured in certain circumstances, provided specified conditions are satisfied, and in the case of products which this order exempts from the need for a product licence, enables the manufacture of such products under a manufacturer's licence. The order also provides for exemptions from the need to hold manufacturer's licences in certain cases where the relevant product licence is held by someone other than the manufacturer or where no product licence is required or in certain circumstances during the transitional period immediately following the first appointed day.