STATUTORY INSTRUMENTS

# 1972 No. 1200

# MEDICINES

## The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972

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| *Made* - - - | *4th August* 1972 |
| *Laid before Parliament* | *11th August* 1972 |
| *Coming into Operation* | *1st September* 1972 |

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 13(2), 15(1), 23(4), 35(8) 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) (Special Cases and Miscellaneous 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" shall not include substances or articles specified in orders made under section 104 or section 105(1)(*b*) of the Act which are for the time being in force unless such order specifically directs that this Order shall have effect in relation to such substances or articles as this Order has effect in relation to medicinal products within the meaning of the Act;

"the Special Cases Order" means the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971**(d)**;

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

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(a) 1968 c. 67.
(b) S.I. 1969/388 (1969 I, p. 1070).
(c) 1972 c. 22.
(d) S.I. 1971/1450 (1971 III, p. 4118).

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

(4) The Interpretation Act 1889**(a)** 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 procuring the manufacture of certain products for stock*

**2.**—(1) Subject to the following paragraphs of this Article, the restrictions imposed by section 7 of the Act (licences for dealings in medicinal products) shall not apply to anything done—

(*a*) by a doctor or dentist which relates to a medicinal product specially prepared by him, or to his order for administration to one or more patients of his or where that doctor or dentist is a member of a group of doctors or dentists working together to provide general medical or dental services, to one or more patients of any other doctor or dentist of that group, and consists of procuring the manufacture or assembly, of a stock of the product with a view to administering the product to such patients;

(*b*) by a veterinary surgeon or veterinary practitioner which relates to a medicinal product specially prepared by him or to his order for administration to one or more animals under his care or, where that veterinary surgeon or veterinary practitioner is a member of a group of veterinary surgeons or veterinary practitioners working together to provide general veterinary services, to one or more animals under the care of any other veterinary surgeon or veterinary practitioner of that group and consists of procuring the manufacture or assembly of a stock of the product with a view to administering it to such animals;

(*c*) in a registered pharmacy, a hospital or a health centre and is done there by or under the supervision of a pharmacist and consists of procuring the manufacture or assembly, of a stock of medicinal products with a view to dispensing them in accordance with a prescription given by—

(i) a particular doctor or dentist, or, where that particular doctor or dentist is a member of a group of doctors or dentists working together to provide general medical or dental services, or is a member of a particular group of doctors or dentists working together in a hospital in the treatment of the same patient or category of patients, any other doctor or dentist of that group, or

(ii) a particular veterinary surgeon or veterinary practitioner or, where that particular veterinary surgeon or veterinary practitioner is a member of a group of such veterinary surgeons or veterinary practitioners working together to provide general veterinary services, any other veterinary surgeon or veterinary practitioner of that group, or

(iii) a practitioner for administration to a particular patient of his, or as the case may be, to a particular animal or herd which is under his care.

**(a)** 1889 c. 63.

(2) The exemption conferred by the preceding paragraph shall not apply to procuring the manufacture of medicinal products unless the products are to be manufactured by the holder of a manufacturer's licence which staisfies the condition specified in Article 2(2)(v) of the Special Cases Order as amended by Article 5 of this Order.

(3) Paragraphs (1)(*a*) and (1)(*b*) of this Article shall not have effect so as to exempt from the restrictions imposed by section 7 of the Act anything done by a practitioner in relation to a stock held by him of such medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all medicinal products to which those paragraphs relate.

(4) Paragraph (1) of this Article shall not have effect so as to exempt from the restrictions imposed by section 7 of the Act anything done—

(*a*) in relation to a vaccine specially prepared for administration to poultry, or

(*b*) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived, or

(*c*) in relation to plasma, or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived.

(5) So long as section 12 of the Pharmacy and Poisons Act 1933**(a)** remains in force in its application to Great Britain, paragraph (1)(*c*) of this Article in so far as that paragraph relates to a registered pharmacy, shall apply to anything done in the premises of an authorised seller of poisons within the meaning of that Act, being premises that are entered in the register kept under the said section 12.

(6) So long as section 17 of the Pharmacy and Poisons Act (Northern Ireland) 1925**(b)** remains in force, paragraph (1)(*c*) of this Article, in so far as that paragraph relates to a registered pharmacy, shall apply to anything that is done on premises for which an annual licence is in force under the said section 17.

*Further exemptions from product licences for certain special manufactured products*

**3.**—(1) The restrictions imposed by section 7 of the Act (restriction as to dealings with medicinal products) shall not apply to the sale, supply, or procuring the manufacture or assembly of any medicinal product to which this Article relates if the conditions specified in paragraph (3) of this Article are satisfied.

(2) The medicinal products to which this Article relates are medicinal products which are for use by being administered to one or more human beings and which may be lawfully sold by retail or supplied in circumstances corresponding to retail sale, otherwise than in accordance with a prescription given by a doctor or dentist.

(3) The conditions referred to in paragraph (1) of this Article are—

(i) that the medicinal product is sold or supplied to a person exclusively for use by him in the course of a business carried on by him for the purpose of administering it or causing it to be administered to one or more human beings otherwise than by selling it;

**(a)** 1933 c. 25. **(b)** 1925 c. 8. (N.I.).

(ii) that, if sold or supplied through a holder of a wholesale dealer's licence or a person entitled to such a licence by virtue of that person's entitlement to a licence of right, the medicinal product is sold or supplied to such person, and for such use by him, as described in sub-paragraph (i) of this paragraph;

(iii) that, where the manufacture or assembly of the medicinal product is procured, it is procured by such person, and for such use by him, as described in sub-paragraph (i) of this paragraph;

(iv) that no advertisement or representation (within the meaning of section 92 of the Act) relating to the medicinal product is issued with a view to it being seen generally by the public in the United Kingdom, that no advertisement relating to that product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the sale or supply as aforesaid is in response to a bona fide unsolicited order;

(v) that the medicinal product is prepared by or under the supervision of a pharmacist; and

(vi) 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 Article 2 of the Special Cases Order and this Article relate, in the latter case by specifying the description of medicinal products in question or by way of an appropriate general classification (including classification by reference to the persons to whom the product is to be sold or supplied).

(4) In respect of 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.

*Exemptions in respect of clinical trials and medicinal tests on animals*

**4.**—(1) Subject to paragraph (4) of this Article, the restrictions imposed by sections 7, 31(2) and 32 of the Act (restrictions as to dealings with medicinal products for clinical trials or medicinal tests on animals) shall not apply to anything done in relation to a medicinal product when—

(*a*) it consists of selling or supplying, or procuring the sale or supply of, medicinal products for the purposes of a clinical trial or, as the case may be, a medicinal test on animals, or

(*b*) it is done by a person in the course of a business carried on by him and consists of administering a medicinal product to an animal by way of a medicinal test on animals, or procuring such medicinal product to be so administered,

provided the conditions specified in paragraph (2) of this Article are satisfied.

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

(i) that either (*a*) the person selling or supplying the medicinal product is selling or supplying that product exclusively for the purposes of a clinical trial or, as the case may be, for a medicinal test on animals, or (*b*) where he is not selling or supplying that product exclusively as aforesaid, that in so far as he is selling or supplying the product for other purposes, such sale or supply is in accordance with a product licence, or clinical trial or animal test certificate or in circumstances which enable such sale or supply to be carried out otherwise than in accordance with such licence or certificate,

(ii) that, in relation to medicinal tests on animals, the manufacture or assembly of the medicinal product in question is procured by a veterinary surgeon or a veterinary practitioner for the purpose of its being administered to one or more animals which are under his care,

(iii) that the clinical trial or, as the case may be, medicinal test on animals in question is not to be carried out under arrangements made by or on behalf of the person who manufactured that medicinal product, the person responsible for its composition (within the meaning of section 7(6) of the Act) or the person selling or supplying it unless such person is the doctor or dentist or one of the doctors or dentists, by whom, or under whose direction that medicinal product is to be administered in that trial or, as the case may be, the person by whom or under whose direction that medicinal product is to be administered in that test,

(iv) that the doctor or dentist or one of the doctors or dentists by whom or under whose direction the medicinal product is to be administered in the clinical trial or as the case may be, that the person by whom or under whose direction the medicinal product is to be administered in the medicinal test on animals has notified the licensing authority of the trial, or, as the case may be the test, in question, specifying the product and the use of the product that is to be administered and the name and address of the supplier of that product, and

(v) that the licensing authority has not, within the period of 21 days of the date of such notification, or within such extended period as the licensing authority may in a particular case allow, directed that the provisions of this Article shall not apply to the medicinal product in question.

(3) Without prejudice to the preceding paragraphs of this Article, the restrictions imposed by sections 7(3) and 31(4) of the Act (restrictions as to importation of medicinal products for clinical trials) shall not apply to the importation of a medicinal product, exclusively for the purpose of a clinical trial, provided that the conditions specified in sub-paragraph (ii), (iii), (iv) and (v) of the preceding paragraph are satisfied in relation to the medicinal product and the clinical trial in question.

(4) Paragraph (1) of this Article shall not have effect in relation to a veterinary surgeon or veterinary practitioner where the medicinal test in question is to be carried out under arrangements made by, or at the request of, another person, and (where the arrangements are made by the veterinary surgeon or veterinary practitioner and not at the request of any other person) shall not have effect so as to exempt from the restrictions in question anything done—

(*a*) in relation to a vaccine specially prepared for administration to poultry, or

(*b*) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived, or

(*c*) in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived.

*Variation of Article 2 of the Special Cases Order*

**5.** Article 2 of the Special Cases Order (exemption from product licences for certain special manufactured products) shall be varied as follows:—

(*a*) in paragraph (2)(i)(*a*) after the word "Act" there shall be inserted the words "or Article 2(1)(*a*) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972";

(*b*) in paragraph (2)(i)(*b*) after the word "Act" there shall be inserted the words "or Article 2(1)(*b*) of the said Order of 1972";

(*c*) for sub-paragraph (i)(c) of paragraph (2) there shall be substituted the following:—

"(*c*) for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist either in circumstances to which section 10 of the Act (as modified by the Medicines (Retail Pharmacists—Exemption from Licensing Requirements) Order 1971**(a)**) or Article 2(1)(*c*) of the said Order of 1972 relates, or, as respects a substance that is a medicinal product by virtue of its use as an ingredient in accordance with the provisions of section 130(1)(*b*) of the Act, where such substance is to be used only as such an ingredient in the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, being a prescription which relates to a medicinal product which is for administration to a particular patient of that practitioner or as the case may by to a particular animal or herd which is under his care.";

(*d*) for sub-paragraph (ii) of paragraph (2) there shall be substituted the following:—

"(ii) that no advertisement (within the meaning of section 92 of the Act) relating to the medicinal product is issued with a view to it being seen generally by the public in the United Kingdom, that no advertisement relating to that product by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding

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

to retail sale, or the person who manufactures it, and that the sale or supply as aforesaid is in response to a bona fide unsolicited order;".

*Keith Joseph*,
Secretary of State for Social Services.

28th July 1972.

*Peter Thomas*,
Secretary of State for Wales.

1st August 1972.

*Gordon Campbell*,
Secretary of State for Scotland.

3rd August 1972.

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

3rd August 1972.

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.

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## 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 certain dealings and activities concerned with medicinal products. Article 2 provides for procuring the manufacture of stocks of certain medicinal products by practitioners and pharmacists without the need of a product licence. Article 3 exempts from the requirements to hold a product licence in the case of the sale or supply of certain medicinal products the persons who in the course of their business will not resell those products but will use them exclusively for the purpose of administering them to other persons. Article 4 provides for certain exemptions from the need to hold certificates or product licences in relation to clinical trials or medicinal tests on animals. The Order (in Article 5) also varies the provisions of Article 2 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 consequential upon the exemptions conferred by Article 2 of this Order. The other variation in Article 5 is of a minor character.

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