STATUTORY INSTRUMENTS

1974 No. 498

MEDICINES

The Medicines (Exemption from Licences) (Clinical Trials) Order 1974

Made - - - -	19*th March* 1974
Laid before Parliament	28*th March* 1974
Coming into Operation	18*th April* 1974

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Head of the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 13(2), 15(1) and 35(8)(*a*) 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) (Clinical Trials) Order 1974 and shall come into operation on 18th April 1974.

(2) In this order, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"control products", in relation to a clinical trial the primary object of which is to assess what, if any, are the effects of medicinal products of a particular description, means substances or articles that are administered by way of such a trial, in order that the effects, if any, of those substances or articles may be compared with the effects, if any, of those medicinal products;

"medicinal product" shall not include substances or articles specified in orders made under sections 104 or 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;

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

(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 Head of the Department of Health and Social Services for Northern Ireland by virtue of the provisions of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c.36).

(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 amended or extended by any other enactment, regulation or order.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) 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.

Exemptions in respect of clinical trials

2.—(1) The following provision of this Article may have effect in relation only to the following medicinal products, that is to say—

(*a*) medicinal products in respect of which there is in force a product licence and which are manufactured in accordance with that product licence, or

(*b*) medicinal products which but for a change in a process carried out in the course of making the products would be products that are manufactured in accordance with a product licence, where such change has been approved by the licensing authority, or

(*c*) without prejudice to the generality of (*b*) above, medicinal products which but for their shape or colour or for the omission of distinctive marks displayed on them would be products that are manufactured in accordance with a product licence, where such change in shape or colour or such omission of distinctive marks has been made by or to the order of the holder of that product licence, or

(*d*) medicinal products in respect of which there is in force a product licence and which, for the purposes of their administration in the course of a clinical trial, are enclosed in or surrounded by inert substances by or to the order of the holder of that product licence or with the approval of the licensing authority,

and, hereinafter in this Article, any such product licence as is mentioned in (*a*), (*b*), (*c*) or (*d*) above as the case may be is referred to as "the relevant product licence".

(2) Subject to Article 4 of this order, the restrictions imposed by sections 7 and 31 of the Act (restrictions as to dealings with medicinal products) shall not apply to anything done in relation to medicinal products of a particular description which consists of selling or supplying, or procuring the sale, supply, manufacture or assembly of, or importing, medicinal products of that description for the purposes of a clinical trial, if the conditions specified in either paragraph (3) or paragraph (4) of this Article are satisfied.

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

(*a*) the medicinal products are to be administered in accordance with those particulars of the relevant product licence which relate to indications for which the products are to be administered, the dosage, and the method or routes of administration and, with regard to any directions, contra-indications or warnings contained in the relevant product licence,

(a) 1889 c. 63.

(*b*) the provisions of the relevant product licence, in so far as such provisions relate to manufacture (except to the extent set out in paragraph (1)(*c*) above), testing, maintenance of records or adverse reactions or effects, are complied with by the person so selling or supplying, so procuring or so importing, and

(*c*) where the clinical trial in question is to be carried out under arrangements made by, or at the request of, a person who is not the holder of the relevant product licence, that person notifies the licensing authority of that trial and makes such arrangements as in the opinion of the licensing authority are adequate for notifying the licensing authority of any adverse reactions or effects or of any unexplained or unexpected absence of any effects associated with the administration of the medicinal products in relation to which the exemption conferred by this Article applies.

(4) The alternative conditions referred to in paragraph (2) of this Article are that—

(*a*) the person proposing to sell or supply, to procure or to import as aforesaid, the medicinal product in question notifies the licensing authority of such proposed activity and furnishes details of the clinical trial in question, and

(*b*) the licensing authority have directed that this Article shall apply to the activity in question.

Exemptions in respect of control products in clinical trials

3.—(1) Without prejudice to the exemptions conferred by the preceding Article and subject to paragraph (2) below and to Article 4 of this order, the restrictions imposed by sections 7 and 31 of the Act shall not apply to anything done in relation to medicinal products of a particular description being control products, which consists of selling or supplying, or procuring the sale, supply, manufacture or assembly of, or importing control products of that description for the purposes of a clinical trial if any one of the following conditions is satisfied, that is to say that—

(*a*) the specification of the said control products has been included in a clinical trial certificate (whether or not any such certificate is in force) issued in respect of a trial other than the trial in question and which relates to medicinal products of the same description as the medicinal products that are to be administered in the course of the trial in question, and either—

(i) that the control products are to be administered in accordance with that certificate, or

(ii) that the licensing authority have been notified of the proposed administration of the control products and have not directed that the provisions of this Article shall not apply to the control products in question,

or

(*b*) the composition and specification of the said control products and the other medicinal products to be administered in the course of the trial in question are identical except for the omission from the control products of any active ingredient or ingredients, or

(*c*) the said control products consist only of ingredients that are not active ingredients being such ingredients as have been approved by the licensing authority for the purposes of this order, or such ingredients as correspond to ingredients contained in the other medicinal products to be administered in the course of the trial in question, or

(*d*) the person proposing to sell or supply, to procure or to import as aforesaid the control products in question notifies the licensing authority of such proposed activity and furnishes details of the clinical trial in question, and the licensing authority have directed that this Article shall apply to the activity in question.

(2) The exemption conferred by the preceding paragraph shall apply if (and only if) the medicinal products, other than the control products, that are to be administered in the course of the trial in question, are either—

(*a*) products in relation to which the exemption conferred by Article 2 of this order applies, or

(*b*) products in relation to which the condition set out in section 31(3)(*a*) of the Act (product licence which authorises a trial) is satisfied.

Further conditions

4.—(1) The exemptions conferred by Article 2 or 3 of this order shall not apply to any vaccine, plasma or serum unless the licensing authority have been notified of the clinical trial in question.

(2) The said exemptions shall not apply 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 so notified such persons 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 paragaph, and so long as such notification has not been withdrawn by the licensing authority.

Variation of Article 4 of the Medicines (Exemption from Licences) (Special and Miscellaneous Provisions) Order 1972

5. The exemptions conferred by Article 4(1) and (3) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(a), in so far as those exemptions apply to clinical trials shall not apply if, and so long as, the licensing authority are of the opinion that in the interests of safety the said exemptions shall not apply and if the licensing authority have so notified such person whose activities in relation to the medicinal products 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.

(a) S.I. 1972/1200 (1972 II, p. 3553).

Barbara Castle,
Secretary of State for Social Services.

14th March 1974.

John Morris,
Secretary of State for Wales.

14th March 1974.

William Ross,
Secretary of State for Scotland.

15th March 1974.

Patrick J. Devlin,
Head of the Department of Health and Social Services for Northern Ireland.

19th March 1974.

EXPLANATORY NOTE

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

This Order exempts from those restrictions imposed by Part II of the Medicines Act 1968 concerning clinical trials, certain dealings and activities involving medicinal products in respect of which there is in force a product licence including such products as are enclosed in or surrounded by inert substances. The exemptions conferred also cover medicinal products that do not correspond with the relevant product licence because of a change in a manufacturing process or in the shape or colour of the product or because of the omission of distinctive markings. Medicinal products that are used as control products, as defined in the Order are also exempt. The exemptions apply only if certain specified conditions are satisfied or complied with.

The Order also amends Article 4 of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 so as to provide that when, in the interests of safety, the licensing authority have notified the person concerned, the exemptions conferred by that Article shall not apply in relation to clinical trials.

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