Jersey

MEDICINES (CLINICAL TRIAL EXEMPTIONS) (No. 2) (JERSEY) ORDER 1997

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Article

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MEDICINES (CLINICAL TRIAL EXEMPTIONS) (No. 2) (JERSEY) ORDER 1997[1]

THE HEALTH AND SOCIAL SERVICES COMMITTEE in pursuance of Articles 14, 16, 36 and 110 of the Medicines (Jersey) Law 1995, after consultation with the Medicines Advisory Council and having otherwise complied with Article 110 of the Law, orders as follows –

Commencement [see endnotes]

1 Interpretation

(1) In this Order, unless the context otherwise requires –

"control product", in respect of a clinical trial of which the primary object is to assess the effects (if any) of a medicinal product, means a substance or article that is administered by way of the trial in order that any effects of the substance or article may be compared with any effects of the medicinal product;

"Law" means the Medicines (Jersey) Law 1995.

(2) Without prejudice to Article 10 of the Interpretation (Jersey) Law 1954, every provision in the Medicines (Jersey) Law 1995 that relates in any other way to its interpretation shall also apply in the same way to this Order, unless the context otherwise requires.

2 Exemption of medicinal products for clinical trials

(1) This Article applies only to the following medicinal products –

(a) a medicinal product that is manufactured in accordance with a product licence;

(b) a medicinal product that is manufactured in accordance with a product licence but for a change carried out in the course of manufacture, where that change has been approved by the Minister for the purposes of this Order;

(c) in particular, but without limiting the generality of sub-paragraph (b), a medicinal product that is manufactured in accordance with a product licence but for the shape or colour of the product or the omission from it of a

distinctive mark to be displayed on it, where the change in shape or colour or the omission of the mark –

(i) has been made by or to the order of the holder of the product licence, and

(ii) has been approved by the Minister for the purposes of this Order; and

(d) a medicinal product in respect of which there is in force a product licence, and which for the purposes of its administration in the course of a clinical trial is enclosed in or surrounded by inert substances –

(i) by or to the order of the holder of the product licence, and

(ii) with the approval of the Minister for the purposes of this Order.

(2) Subject to Article 6 of this Order, the restrictions in Articles 8 and 32 of the Law shall not apply to –

(a) the selling or supplying;

(b) the procuring of the sale, supply, manufacture or assembly; or

(c) the importing,

of a medicinal product for the purposes of a clinical trial, where the conditions in paragraph (3) or the alternative conditions in paragraph (4) are fulfilled.

(3) The conditions to which paragraph (2) refers are –

(a) the medicinal product is administered in accordance with the particulars of the product licence that relate –

(i) to indications for which the product is to be administered,

(ii) to the dosage, and the methods and routes of administration, and

(iii) in respect of any directions, to contra-indications or warnings contained in the product licence;

(b) the provisions of the product licence relating to manufacture, testing and maintenance of records of adverse reactions and effects are complied with (except, in respect of manufacture, to the extent described in paragraph (1)(c)); and

(c) where the clinical trial is to be carried out under arrangements made by or at the request of a person who is not the holder of the product licence, that person –

(i) informs the Minister of the trial, and

(ii) makes arrangements that are in the opinion of the Minister adequate for informing the Minister of any adverse reactions, adverse effects, unexplained absences of effects and unexpected absences of effects that are in any such case associated with the administration of the product.

(4) The alternative conditions to which paragraph (2) refers are –

(a) the person proposing to sell or supply the medicinal product, or to procure its sale, supply, manufacture or assembly, or to import it, has informed the Minister of the proposed activity, and has furnished details of the clinical trial; and

(b) the Minister has directed that this Article shall apply to the activity.

3 United Kingdom Exemption of medicinal products for clinical trials[2]

(1) The restrictions in Articles 8 and 32 of the Law shall not apply to the selling, supplying or importing, or the procuring of the sale, supply, manufacture or assembly, of a medicinal product for the purposes of a clinical trial where the restrictions imposed by sections 7 and 31 of the Medicines Act 1968 of the United Kingdom do not apply to the medicinal product by virtue of Article 2 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom.

(2) Any conditions applicable to the exemption conferred by Article 2 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom shall be applicable to the exemption conferred by paragraph 1 of this Article.

(3) If an exemption conferred by Article 2 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom shall cease to apply by virtue of a withdrawal of notification under Article 4(2) of that Order, the exemption conferred by paragraph (1) of this Article shall forthwith cease to have effect.

4 Exemption of control products for clinical trials

(1) This Article applies only where each medicinal product (other than a control product) that is to be administered in the course of a clinical trial is –

(a) a product in respect of which the exemption conferred by Article 2 of this Order applies; or

(b) a product in respect of which the condition in Article 32(3)(a) of the Law is fulfilled.

(2) Subject to Article 6 of this Order, the restrictions in Articles 8 and 32 of the Law shall not apply to –

(a) the selling or supplying;

(b) the procuring of the sale, supply, manufacture or assembly; or

(c) the importing,

of a medicinal product that is a control product, for the purposes of a clinical trial, where the conditions in any of sub-paragraphs (a), (b), (c) and (d) of paragraph (3) of this Article are fulfilled.

(3) The conditions to which paragraph (2) refers are –

(a) the specification of each control product has been included in a clinical trial certificate (whether or not the certificate is in force) issued in respect of a clinical trial other than the trial in question and relating to medicinal products of the same description as the medicinal product that is to be administered in the course of the trial in question, and –

(i) that control product is to be administered in accordance with that certificate, or

(ii) the Minister has been informed of the proposed administration of that control product and has not directed that the provisions of this Article shall not apply to it;

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

(c) each control product consists only of ingredients that are not active ingredients, and are ingredients –

(i) that have been approved by the Minister for the purposes of this Order, or

(ii) that 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 the control product, or to procure its sale, supply, manufacture or assembly, or to import it, has informed the Minister of the proposed activity and has furnished details of the clinical trial in question, and the Minister has directed that this Article shall apply to the activity.

5 United Kingdom Exemption of control products for clinical trials[3]

(1) The restrictions in Articles 8 and 32 of the Law shall not apply to the selling, supplying or importing, or the procuring of the sale, supply, manufacture or assembly of a medicinal product that is a control product, for the purposes of a clinical trial where the restrictions imposed by sections 7 and 31 of the Medicines Act 1968 of the United Kingdom do not apply to the medicinal product that is a control product by virtue of Article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom.

(2) Any conditions applicable to the exemption conferred by Article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom shall be applicable to the exemption conferred by paragraph (1) of this Article.

(3) If an exemption conferred by Article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974 of the United Kingdom shall cease to apply by virtue of a withdrawal of a notification under Article 4(2) of that Order, the exemption conferred by paragraph (1) of this Article shall forthwith cease to have effect.

6 Restrictions on exemptions of vaccine, plasma and serum

(1) An exemption conferred by Article 2 or 4 shall not apply to any vaccine, plasma or serum unless the Minister has been informed of the clinical trial in question.

(2) An exemption conferred by Article 2 or 4 shall not apply to any vaccine, plasma or serum if –

(a) the Minister is of the opinion that in the interests of safety the exemption should not apply to that vaccine, plasma or serum;

(b) the Minister has so notified the person seeking the benefit of the exemption; and

(c) the Minister has not withdrawn its notification.

7 Citation

This Order may be cited as the Medicines (Clinical Trial Exemptions) (No. 2) (Jersey) Order 1997.

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement
Medicines (Clinical Trial Exemptions) (No. 2) (Jersey) Order 1997	R&O.9132	1 January 1998
Medicines (Clinical Trial Exemptions) (No. 2) (Amendment) (Jersey) Order 2003	R&O.74/2003	13 August 2003
States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005	R&O.45/2005	9 December 2005

Table of Renumbered Provisions

Original	Current
2A	3
3	4
3A	5
4	6
5	7

Table of Endnote References

[1] *This Order has been amended by the States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005. The amendments replace all references to a Committee of the States of Jersey with a reference to a Minister of the States of Jersey, and remove and add defined terms appropriately, consequentially upon the move from a committee system of government to a ministerial system of government*

[2] *Article 3* *inserted by R&O.74/2003*

[3] *Article 5* *inserted by R&O.74/2003*