



Jersey

**MEDICINES (APPLICATIONS FOR
CLINICAL TRIAL CERTIFICATES) (JERSEY)
ORDER 1997**

Official Consolidated Version

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MEDICINES (APPLICATIONS FOR CLINICAL TRIAL CERTIFICATES) (JERSEY) ORDER 1997

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Jersey

MEDICINES (APPLICATIONS FOR CLINICAL TRIAL CERTIFICATES) (JERSEY) ORDER 1997¹

THE HEALTH AND SOCIAL SERVICES COMMITTEE after consultation with the Medicines Advisory Council, in pursuance of Articles 37 and 110 of the [Medicines \(Jersey\) Law 1995](#), orders as follows –

Commencement [[see endnotes](#)]

1 Interpretation

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

“approved name”, in respect of a constituent, means –

- (a) the name of the substance or article that appears in the current edition of the list prepared in accordance with section 100 of the Medicines Act and published under that section by the Ministers (within the meaning of subsection (1) of section 1 of the Act); or
- (b) the international non-proprietary name recommended by the World Health Organisation;

“Law” means the [Medicines \(Jersey\) Law 1995](#);

“monograph” means a monograph, in the current edition of–

- (a) the European Pharmacopoeia;
- (b) any compendium published under section 99 of the Medicines Act by the Health Ministers or the Agriculture Ministers (within the meaning of subsection (1) of section 1 of the Act);
- (c) the British Pharmacopoeia; or
- (d) the British Pharmaceutical Codex;

“monograph name” means the name that appears at the head of a monograph;

“standard provisions” means the standard provisions that are for the time being prescribed by the [Medicines \(Standard Provisions for Licences and Certificates\) \(Jersey\) Order 1997](#) in respect of the clinical trial certificate for which application is made.

- (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 Scope of Order

This Order does not apply to an application to renew a clinical trial certificate.

3 Applications for certificates

- (1) An application for a clinical trial certificate shall be in writing.
- (2) The application shall include the information in the Schedule to this Order.
- (3) A separate application shall be made for each description of medicinal product.
- (4) Notwithstanding paragraph (3), one application may be made for any medicinal products that are to be administered in the course of the same clinical trial.

4 Standard provisions

The application shall specify –

- (a) each of the standard provisions that it is desired to exclude or modify; and
- (b) in the latter case, the ways in which modification is sought.

5 Explanation of omissions

Where the application omits information that is required by Article 3 –

- (a) if the information is not applicable, it shall state that it is not applicable; and
- (b) if the information is applicable, it shall explain the reason for the omission.

6 Layout

- (1) The application shall be laid out so that those parts relating to –
 - (a) chemical and pharmaceutical studies;
 - (b) experimental and biological studies;
 - (c) clinical studies; and
 - (d) precautions and contra-indications,are each appended, in sequence, in a separate section or volume.
- (2) The pages of the application shall be numbered in sequence, except that each appendix –
 - (a) shall have on its first page a reference that identifies the application of which it forms part; and
 - (b) shall have its own pages numbered separately, in their own sequence.

- (3) The body of the application shall itself identify the appendices, in sequence, by their references.

7 Signature

- (1) The applicant shall sign the application.
- (2) Where the proposed holder of the certificate is not the applicant, the proposed holder shall also sign the application.

8 Copies

The applicant shall supply to the Minister –

- (a) 10 copies of the application, or such lesser number as the Minister may require, in the English language; and
- (b) where it has been translated from another language, one copy in that language.

9 Samples

If so requested by the Minister, the applicant shall provide a sample of any medicinal product to which the application relates.

10 Citation

This Order may be cited as the Medicines (Applications for Clinical Trial Certificates) (Jersey) Order 1997.

SCHEDULE

(Article 3(2))

INFORMATION REQUIRED ON APPLICATION FOR CLINICAL TRIAL CERTIFICATE

- 1 (1) The name and address of the applicant.
- (2) The name and address of the proposed holder of the certificate (if the proposed holder is not the applicant).
- 2 The period for which the certificate is desired (if less than 2 years).
- 3 (1) A statement of the activities to which the certificate is to relate.
- (2) In respect of each medicinal product to which the certificate is to relate, whether it is for one or more of the following purposes, namely –
 - (a) the sale or supply of the medicinal product for the purposes of a clinical trial;
 - (b) the procurement of its sale or supply, for the purposes of a clinical trial;
 - (c) the procurement of its manufacture or assembly, for sale or supply, for the purposes of a clinical trial; or
 - (d) its importation into Jersey for the purposes of a clinical trial.
- 4 Where any medicinal product is to be sold or supplied, for the purposes of the trial –
 - (a) to practitioners;
 - (b) to persons providing hospital services; or
 - (c) in any other way,a statement of each of those ways in which it is to be sold or supplied.
- 5 A statement of –
 - (a) the name and address of each person in the United Kingdom or Jersey (other than the proposed holder of the certificate) who will take part in the manufacture or assembly of each medicinal product;
 - (b) the manufacturing and assembling operations;
 - (c) the address of each place of manufacture or assembly; and
 - (d) in the case of an imported medicinal product, the name and address of each person who manufactures or assembles the medicinal product in the form in which it is to be imported.
- 6 Where the activity is to procure the sale or supply of any medicinal product, the name and address of the person selling or supplying the medicinal product for the purposes of the clinical trial.
- 7 The name of each medicinal product or, if it does not have a name, the code designation that the proposed holder of the certificate has given to it.

- 8 A statement of the specification of each medicinal product (apart from the information required under paragraphs 9, 10 and 12 of this Schedule).
- 9 A description of the pharmaceutical form in which each medicinal product is to be administered to human beings.
- 10 A statement of the qualitative and quantitative composition of each medicinal product, dealing with –
 - (a) its constituents (whether active or not); and
 - (b) all colouring matter, flavouring agents and perfumes.
- 11 In respect of each constituent (whether active or not) –
 - (a) its approved name or monograph name;
 - (b) if it does not have an approved name or monograph name, the non-proprietary designation or other descriptive appellation by which it can be readily identified; or
 - (c) if there is no such name, designation or descriptive appellation, the proprietary designation.
- 12 The specification of all constituents (whether active or not) or, at the option of the applicant in respect of a constituent that is the subject of a monograph, a reference to the monograph name instead of the specification.
- 13 The chemical structural formula for each active constituent (where known) or, at the option of the applicant in the case of an active constituent that is the subject of a monograph, a reference to the monograph name instead of the formula.
- 14 A description in detail of the method of manufacture of each medicinal product.
- 15 A description of the method of manufacture of each active constituent or, at the option of the applicant in the case of an active constituent that is the subject of a monograph, a reference to the monograph name instead of a description.
- 16 In the case of every constituent (whether active or not), a description of the procedures and methods, for the control of its quality, that are to be applied to ensure compliance with the specification.
- 17 A description of the procedures and methods to be used to ensure the uniformity of each medicinal product in the processes of manufacture and assembly, and evidence of the stability of the product.
- 18 A description of the methods to be employed during manufacture for determining the identity, purity and potency of each medicinal product, and the address of the premises where the procedures for those purposes are to be carried out.
- 19 A description of the containers to be used for each description of medicinal product, and a statement of any special directions that are necessary for storage and transport.
- 20 A description of the clinical use to be investigated and an outline of the proposed trial.
- 21 The proposed dosage, duration of dosage and methods and routes of administration of each medicinal product.
- 22 A statement of the directions, contra-indications and warnings proposed by the applicant in relation to the trial of each medicinal product.

- 23 Copies of the reports and evaluations of experimental and biological studies and other preclinical, clinical and laboratory studies carried out with each medicinal product or its constituents, where, in the view of the applicant, they are relevant to the assessment of the safety, quality or efficacy of the medicinal product.
- 24 References to all relevant publications and other clinical trials.

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement
Medicines (Applications for Clinical Trial Certificates) (Jersey) Order 1997	R&O.9127	1 January 1998
States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005	R&O.45/2005	9 December 2005

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