Jersey

MEDICINES (APPLICATIONS FOR LICENCES FOR PRODUCTS FOR HUMAN USE) (JERSEY) ORDER 1997

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MEDICINES (APPLICATIONS FOR LICENCES FOR PRODUCTS FOR HUMAN USE) (JERSEY) ORDER 1997

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Jersey

MEDICINES (APPLICATIONS FOR LICENCES FOR PRODUCTS FOR HUMAN USE) (JERSEY) ORDER 1997[1]

THE HEALTH AND SOCIAL SERVICES COMMITTEE after consultation with the Medicines Advisory Council, in pursuance of Articles 19 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 –

"Directives" means Council Directives 75/318/EEC, 75/319/EEC, 89/342/EEC and 89/381/EEC;

"1965 Directive" means Council Directive 65/65 EEC of 26th January 1965 on the approximation of provision laid down by law, regulation or administrative action relating to medicinal products (as amended by Council Directive 89/341/EEC and as it applies in accordance with Council Directives 75/319/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC and Article 9(1) of Council Directive 92/73/EEC);

"expert" means an expert with suitable technical or professional qualifications and experience for the purposes of drawing up any description or particulars to which paragraph 7 or 8 of Schedule 1 refers, or of drawing up any report to which paragraph 12 of that Schedule refers;

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

"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 product licence for which application is made.

(2) In this Order, unless the context otherwise requires, a reference to a Directive is to a Directive as it was in force immediately before the date on which this Order is made.

(3) 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 –

(a) to an application to renew a licence; or

(b) to an application for a licence for a medicinal product that is not for human use.

3 Applications for licences

(1) An application for a product licence shall be in writing.

(2) Subject to Schedules 2 and 3 –

(a) the application shall, for each medicinal product, include the information, documents, samples and other material specified in Schedule 1; and

(b) they shall in every case be prepared and presented in accordance with the requirements of the Directives in respect of medicinal products to which Chapters II to V of the 1965 Directive apply.

4 Separate applications

A separate application shall be made for each description of medicinal product, except that one application may be made in any of the following cases –

(a) in respect of any medicinal products that have the same pharmaceutical form, and either consist of the same single active constituent in different strengths or consist of a mixture in different strengths of the same 2 or more active constituents in the same proportion;

(b) in respect of any substances or articles that have the same physical form, and either have the same single active constituent in different strengths or are a mixture in different strengths of the same 2 or more active constituents in the same proportion;

(c) in the case of homeopathic medicinal products and medicinal products using similar attenuations, in respect of–

(i) any attenuations of the same mother tincture or other solution or of the same trituration, or

(ii) any attenuations of any mother tincture or other solution or trituration having the same specification and pharmaceutical form apart from the tincture, other solution or trituration;

(d) in the case of medicinal products that are preparations of allergen extracts for the treatment of allergies, in respect of any attenuations of –

(i) the same allergen extract, or

(ii) the same mixture of allergen extracts; or

(e) in the case of medicinal products for testing for allergic responses to specific substances, in respect of any allergen extracts that are manufactured by one and the same method (if the application specifies the substances from which the extracts are prepared).

5 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.

6 Signature

(1) The applicant shall sign the application.

(2) Where the proposed holder of the licence is not the applicant, the proposed holder shall also sign the application.

7 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.

8 Citation

This Order may be cited as the Medicines (Applications for Licences for Products for Human Use) (Jersey) Order 1997.

SCHEDULE 1

(Articles 1(1) and 3(2)(a))

INFORMATION REQUIRED ON APPLICATION FOR PRODUCT LICENCE

1.

(1) The names or corporate names, and the permanent addresses, of –

(a) the person responsible for placing the medicinal product on the market in Jersey;

(b) the manufacturers and the sites involved in the different stages of manufacture (including the manufacturer of the finished medicinal product and the manufacturers of the active ingredients); and

(c) where relevant, the importer.

(2) Where the licence is required solely for the purpose of exporting a medicinal product the name or corporate name, and the permanent address, of the exporter.

(3) In relation to a substance or article in respect of which Article 8(2) of the Law has effect by virtue of Article 42 of the Law, where any seller, supplier or exporter of the medicinal product is not named under paragraph (1) of this paragraph, a description of the circumstances in which that person will sell, supply or export it.

2. The name of the medicinal product, that is to say –

(a) the brand name;

(b) the common name, together with a trade mark;

(c) the name of the manufacturer; or

(d) the scientific name, together with a trade mark or name of the manufacturer.

3. The qualitative and quantitative particulars of each constituent of the medicinal product, together with –

(a) details of any relevant data concerning its container and, where appropriate, its manner of closure; and

(b) details of each device, for its use or administration, that will be delivered with it.

4. A brief description of the method of preparation.

5. Particulars of the therapeutic indications, contraindications and side effects.

6. Particulars of the posology, pharmaceutical form, method and route of administration and expected shelf-life.

7. A description, drawn up and signed by experts, of the control methods employed by the manufacturer (indicating the qualitative and quantitative analysis of –

(a) each constituent;

(b) the finished medicinal product; and

(c) all special tests that have been carried out (including sterility tests, tests for the presence of pyrogenic substances and for the presence of heavy metals, stability tests, biological and toxicity tests, and controls carried out at any intermediate stages of the manufacturing process).

8. Particulars, drawn up and signed by experts, of the results of all –

(a) physico-chemical, biological and microbiological tests;

(b) pharmacological and toxicological tests; and

(c) clinical trials,

including all relevant details of each incomplete or abandoned pharmacotoxicological or clinical test or trial.

9. A summary of the characteristics of the medicinal product, containing the following information –

(a) its name;

(b) by reference to its international non-proprietary name or (where there is no such name) the usual common name or chemical description, the qualitative and quantitative composition of the medicinal product, in terms of the active ingredients of which knowledge is essential for its proper administration;

(c) its pharmaceutical form;

(d) clinical particulars in respect of –

(i) therapeutic indications,

(ii) posology and methods of administration for adults and, where necessary, for children,

(iii) contra-indications,

(iv) special warnings,

(v) special precautions for use and, in relation to an immunological medicinal product to which Council Directive 89/342/EEC applies, information regarding any special precautions to be taken by persons handling the medicinal product and persons administering it to patients, together with any precautions to be taken by the patient,

(vi) interaction with other medicaments and other forms of interaction,

(vii) use during pregnancy and lactation,

(viii) effects on the ability to drive and to use machines,

(ix) undesirable effects (including their frequency and seriousness), and

(x) overdoses (including symptoms, emergency procedures and antidotes);

(e) its pharmacological properties and, where such information is useful for therapeutic purposes, pharmacokinetic particulars;

(f) pharmaceutical particulars in respect of –

(i) qualitative composition in terms of the excipients used,

(ii) major incompatibilities,

(iii) shelf-life, where relevant after reconstitution of the medicinal product and after the container is opened for the first time,

(iv) special precautions for storage,

(v) the nature and composition of the container,

(vi) special precautions for the disposal of unused medicinal products and waste materials derived from the medicinal products, if appropriate, and

(vii) the name or style, and the permanent address or registered place of business, of the holder of the licence;

(g) in relation to any radiopharmaceutical to which Council Directive 89/343/EEC applies –

(i) full details of internal radiation dosimetry, and

(ii) additional detailed instructions for the extemporaneous preparation and control of the quality of the preparation and, where appropriate, details of the maximum storage time during which any intermediate preparation such as an eluate, or the pharmaceutical as it is ready to use, will conform with its specifications; and

(h) in relation to any indications to which paragraph 22 of this Schedule applies, a statement drawing to the attention of persons who may lawfully prescribe or supply the medicinal product the fact that the particulars available concerning the medicinal product are as yet inadequate in specified respects.

10. A copy of the manufacturing authorization as defined in Article 16 of Council Directive 75/319/EEC, and any other relevant document showing that the manufacturer is authorized in the manufacturer's own country to produce medicinal products.

11. Copies of the following documents –

(a) each authorization obtained in –

(i) a member State of the European Communities (other than the United Kingdom), or

(ii) a country that is not a member of the European Communities,

to place the relevant medicinal product on the market;

(b) each of the summaries of the characteristics of the medicinal product in accordance with Article 4a of the 1965 Directive as approved by member States; and

(c) a list of the countries in which an application has been submitted in respect of the medicinal product.

12.

(1) An expert's report on –

(a) the chemical, pharmaceutical and biological documentation;

(b) the pharmacotoxicological documentation; and

(c) the clinical documentation,

in respect of the medicinal product stating, where applicable, the grounds on which the applicant claims to be entitled to use published references in accordance with paragraphs 1, 2, 3 and 4 of Schedule 2.

(2) The report shall be signed and dated by the expert.

13. Brief information about the educational background, training and occupational experience of each expert, and a declaration as to the expert's professional relationship to the applicant.

14. One or more samples or mock-ups of the presentational material to be used for marketing, the outer packaging, the immediate packaging, the labels, and the package leaflet (if any).

15. A statement indicating the number of volumes of documentation submitted in support of the application.

16. A statement indicating any samples provided.

17. Where the applicant is required to provide, under paragraph 8 of this Schedule, particulars of the results of any safety test falling within Part 3, paragraph 1.1, second sub-paragraph of the Annex to Council Directive 75/318/EEC, a copy of any certificate issued by the laboratory that carried out the test to the effect that the test was carried out in conformity with the principles of good laboratory practice to which that sub-paragraph refers.

18. Where the applicant is required to provide, under paragraph 8 of this Schedule, particulars of the results of any clinical trial, a summary of the arrangements proposed for the keeping in archives of documentation of the trial in accordance with Part 4, paragraph B.2 of the Annex to Council Directive 75/318/EEC, including the arrangements proposed for ensuring that any change of ownership in the relevant data is recorded in writing and that all relevant data and documents will be made available to the Minister if required.

19. A statement indicating –

(a) whether the medicinal product should be available –

(i) on prescription only (that is to say, that it should be subject to the restrictions described in Article 57(2)(a) or 59(1) of the Law),

(ii) only from a pharmacy (that is to say, that it should be subject to a restriction under Article 51 or 52 of the Law to the effect that it may be sold only at a registered pharmacy, but not subject to the restrictions described in Article 57(2)(a) or 59(1) of the Law), or

(iii) on general sale (that is to say, that it should not be subject to any of the restrictions to which clauses (i) and (ii) of this sub-paragraph refer); and

(b) what provisions (if any) in the licence are proposed in respect of the methods of sale and supply of the medicinal product (including any proposed restrictions affecting the circumstances that relate to the promotion and use of the medicinal product).

20. If the medicinal product is in use lawfully in other countries –

(a) information in respect of adverse drug reactions to the medicinal product and to other medicinal products containing the same active ingredient (in each

case, where possible, in relation to the rates of usage) and information from worldwide studies that is relevant to the safety of the medicinal product;

(b) in the case of any vaccine, information on the monitoring of vaccinated subjects to evaluate the prevalence of the disease in question by comparison with non-vaccinated subjects, when that information is available; and

(c) in the case of allergen medicinal products, details of response in periods of increased antigen exposure.

21. In relation to each generator to which Article 3 of Council Directive 89/343/EEC applies –

(a) a general description of the system, together with a detailed description of each component of the system that may affect the composition or quality of the daughter nuclide preparation; and

(b) qualitative and quantitative particulars of each eluate and each sublimate.

22. Where the applicant, in relation to any particular therapeutic indications, omits any information by reason of paragraph 5 of Schedule 2 –

(a) detailed proposals for the programme of studies to which that paragraph refers (including a proposed period for carrying them out) for the purposes of a reassessment of the profile of benefits and risks in relation to those indications; and

(b) a statement as to each proposal that the medicinal product in question should be administered for those indications only under strict medical supervision or in a hospital or, for a radiopharmaceutical to which Council Directive 89/343/EEC applies, by an authorized person.

23. Where the licence is required solely for the purpose of exporting a medicinal product, a statement to that effect.

24. All other information that is relevant to the evaluation of the medicinal product, whether the information is favourable or unfavourable.

SCHEDULE 2

(Article 3(2))

EXCEPTIONS TO REQUIREMENTS OF PARAGRAPH 8 OF SCHEDULE 1

1. Subject to paragraphs 2, 3 and 4 of this Schedule, the applicant shall not be required under paragraph 8 of Schedule 1 to provide particulars of the results of pharmacological and toxicological tests, or of the results of clinical trials, where the applicant can demonstrate –

   (a) that the medicinal product is similar in all material respects to a medicinal product to which an existing product licence applies (not being a licence relating solely to importation), and that the person responsible for placing that medicinal product on the market in Jersey consents to the pharmacological, toxicological or clinical references (as the case may be) that are contained in the file on the original medicinal product being used for the purpose of examining the medicinal product in question; or

   (b) by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Council Directive 75/318/EEC, that each constituent of the medicinal product has a well-established medical use, with recognized efficacy and an acceptable level of safety.

2. The applicant shall provide particulars of the results of appropriate pharmacological and toxicological tests, and of clinical trials, where –

   (a) the medicinal product is intended for a different therapeutic use from that of the other medicinal products marketed; or

   (b) is to be administered by any different route or in any different dose than those other medicinal products.

3. Where the medicinal product is a new medicinal product containing known constituents that have not been used in combination for therapeutic purposes, the applicant shall provide particulars of the results of appropriate pharmacological and toxicological tests and of clinical trials in relation to that combination, but it shall not be necessary to provide references relating to each individual constituent.

4. The applicant shall not omit any particulars or results if, without them, proper consideration of the application could not be carried out without prejudicing any rights that –

   (a) arise under any law relating to the protection of industrial or commercial property; and

   (b) are enforceable in Jersey.

5. The applicant shall not be required under paragraph 8 of Schedule 1 to provide, in relation to particular therapeutic indications, the results of any tests or trials where –

(a) in respect of those indications the applicant can show that he or she is unable to provide comprehensive information as to quality, efficacy and safety under normal conditions of use because –

(i) the indications for which the medicinal product is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence,

(ii) in the present state of scientific knowledge, comprehensive information cannot be provided, or

(iii) it would be contrary to generally accepted principles of medical ethics to collect such information;

(b) if the applicant wishes the Minister to consider granting the licence on the basis that the applicant would be required to carry out a programme of studies for the purposes of reassessing the profile of benefits and risks, the applicant can show –

(i) that the medicinal product would be supplied on medical prescription only (and subject to any other relevant restrictions), and

(ii) that the applicant would be required to provide relevant information in the package leaflet and medical information; and

(c) the applicant provides a statement that complies with paragraph 19(a) of Schedule 1 and paragraph 22(a) and (b) of that Schedule.

6. The applicant shall not be required under paragraph 8 of Schedule 1 to provide any material that –

(a) has been or is provided in connection with another application made by the applicant previously or at the same time (whether or not that other application is made under this Order);

(b) is identified in the application, or in any document accompanying it, by reference to its provision in connection with that other application; and

(c) would meet the requirements of this Order if it had been provided in connection with the application that is under consideration.

SCHEDULE 3

(Article 3(2))

INFORMATION THAT MAY BE PROVIDED BY MANUFACTURER

1. In the case of an active ingredient that is manufactured by a person other than the applicant, and –

   (a) is not described in the European Pharmacopoeia or in the pharmacopoeia of a member State of the European Communities; or

   (b) although described in the European Pharmacopoeia or in the pharmacopoeia of a member State, is an ingredient prepared by a method liable to leave impurities that are not mentioned in the pharmacopoeial monograph and for which the monograph is inappropriate to control its quality adequately,

   the applicant may arrange for the detailed descriptions of the manufacturing method, control of quality during manufacture and validation of the processes used to be supplied directly to the Minister by the manufacturer of the active ingredient.

2. Paragraph 1 shall not apply unless –

   (a) the manufacturer provides the applicant with the data that is necessary to enable the latter to take responsibility for the medicinal product;

   (b) the manufacturer confirms in writing to the applicant that the manufacturer will ensure batch to batch consistency and will not modify the manufacturing process or specifications without informing the applicant; and

   (c) the application is accompanied by –

      (i) the documents and other material that are reasonably necessary to enable the Minister to be satisfied that the manufacturer has complied with sub-paragraph (a),

      (ii) a copy of the confirmation required by sub-paragraph (b), and

      (iii) the other documents and material that are reasonably necessary to enable the Minister to be satisfied that the applicant has made adequate arrangements, with the manufacturer, for the provision to the Minister of appropriate documents and particulars supporting any application to make any modification to which sub-paragraph (b) refers.

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement
Medicines (Applications for Licences for Products for Human Use) (Jersey) Order 1997	R&O.9128	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*