Jersey

# MEDICINES (APPLICATIONS FOR MANUFACTURER'S AND WHOLESALE DEALER'S LICENCES) (JERSEY) ORDER 1997

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# MEDICINES (APPLICATIONS FOR MANUFACTURER'S AND WHOLESALE DEALER'S LICENCES) (JERSEY) ORDER 1997

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### Article

Jersey

# MEDICINES (APPLICATIONS FOR MANUFACTURER'S AND WHOLESALE DEALER'S LICENCES) (JERSEY) ORDER 1997[1]

**THE HEALTH AND SOCIAL SERVICES COMMITTEE** in pursuance of Articles 19 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 –

"imported proprietary product" means a proprietary medicinal product that is imported from a place other than a member State of the European Communities and other than Guernsey;

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

"licence" means a manufacturer's licence or a wholesale dealer's licence;

"product to which Chapters II to V of the 1965 Directive apply" means a medicinal product to which Chapters II to V of Council Directive 65/65/EEC apply, in accordance with Article 2 of Council Directive 65/65/EEC as amended, Article 34 of Council Directive 75/319/EEC, Article 1 of Council Directive 89/342/EEC, Article 1 of Council Directive 89/343/EEC; and Article 1 of Council Directive 89/381/EEC;

"proprietary medicinal product" has the same meaning as it has in Article 8(7)(a) of the Law;

"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 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 to an application to renew a licence.

## 3 Applications for licences

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

(2) An application for a manufacturer's licence shall include the information in Schedule 1.

(3) An application for a wholesale dealer's licence shall include the information in Schedule 2.

## 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

The pages of the application shall be numbered in sequence.

## 7 Signature

(1) The applicant shall sign the application.

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

## 8 Copies

The applicant shall supply to the Minister –

(a) 6 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 Citation

This Order may be cited as the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Jersey) Order 1997.

# SCHEDULE 1[2]

(Article 3(2))

## INFORMATION REQUIRED ON APPLICATION FOR MANUFACTURER'S LICENCE

**1**

(1) The name and address of the applicant.

(2) The name and address of the proposed holder of the licence (if he or she is not the applicant).

**2** The period for which the licence is desired (if less than 5 years).

**3** A statement of the manufacturing or assembling operations to which the licence is to relate.

**4** A statement of the uses for which the medicinal products are to be manufactured or assembled, and whether they are any of the following uses –

(a) by being administered to human beings;

(b) by being administered to animals;

(c) in the form of an ingredient in the preparation of a substance, or of an article, that is to be administered for a medicinal purpose to human beings or animals; or

(d) by incorporation in any animal feeding stuff.

**5**

(1) The address of each of the premises where the manufacturing or assembling operations (including any testing that is associated with manufacture or assembly) are to be carried out.

(2) The address of each of the premises where the medicinal products will be stored, and each of the premises from where they will be distributed.

(3) A statement describing the facilities and equipment available at each of the premises for storing the medicinal products, and for distributing them from those premises and between those premises.

(4) A separate statement, in respect of each of the premises, of the manufacturing and the assembling operations that are capable of being carried out at those premises with their existing facilities. (Each statement shall specify the kinds of medicinal products to which the operations are relevant.)

(5) A separate statement, in respect of each of the premises, of the equipment that is available at those premises for carrying out each stage of the manufacturing operations and the assembling operations described in sub-paragraph (4).

**6** A statement of –

(a) the manufacturing operations (other than those to which the licence is to relate) that are carried on by the proposed holder of the licence on or near each of the premises to which paragraph 5 refers; and

(b) the substances and articles that are the subject of such operations.

**7**

(1) The following information about the person who will be responsible for supervising production operations at each of the premises to which paragraph 5 refers –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas);

(c) his or her designation; and

(d) the name and function of the person to whom he or she will be responsible.

(2) The following information about the person who will be responsible for the control of quality in respect of all of the premises to which paragraph 5 refers –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas);

(c) his or her designation;

(d) the extent of the authority to be delegated to him or her to reject unsatisfactory batches of medicinal products; and

(e) the name and function of the person to whom that person will be responsible,

and where the holder of the product licence is to be responsible ultimately for the control of quality, a statement to that effect.

(3) The following information about each person who will be responsible for the culture of living tissue to be used in the manufacture of medicinal products –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas); and

(c) his or her designation.

(4) The following information about the person who is to carry out the functions specified in paragraph 21(1) of Schedule 3 to the Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997 –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas); and

(c) his or her designation.

**8** If the applicant, the proposed holder of the licence or any person to whom paragraph 7 refers –

(a) has been convicted in Jersey or elsewhere of any offence for which a person is liable to imprisonment (whether or not a person is also liable to any other penalty); or

(b) has been found guilty of professional misconduct in Jersey or elsewhere, by a professional body to whose disciplinary control he or she was subject at the time of the conduct on which the finding was based,

the details of that conviction or finding.

**9** A description, in summary, of the arrangements –

(a) for the identification and storage of materials and ingredients before and during manufacture; and

(b) for the storage of medicinal products after manufacture, and after assembly.

**10** A description, in summary, of the arrangements (whether by maintaining records or by other means) for ensuring as far as practicable a satisfactory turn-over of stocks of medicinal products at each of the premises where they will be stored.

**11** A description, in summary, of the arrangements –

(a) for maintaining production records;

(b) for maintaining records of analytical and other testing procedures that are applied in the course of manufacture and of assembly, to ensure that materials used comply with the specifications of those materials and the medicinal products; and

(c) for keeping samples, for purposes of reference, of –

(i) the materials used in manufacture, and

(ii) the medicinal products.

# SCHEDULE 2[3]

(Article 3(3))

## INFORMATION REQUIRED ON APPLICATION FOR WHOLESALE DEALER'S LICENCE

**1**

(1) The name and address of the applicant.

(2) The name and address of the proposed holder of the licence (if he or she is not the applicant).

**2** The period for which the licence is desired (if less than 5 years).

**3** A statement of the wholesale dealings to which the licence is to relate, including (*inter alia*) the following matters –

(a) in respect of the kinds of medicinal products involved –

(i) whether there will be more than one kind and, if so, whether they will include herbal remedies,

(ii) whether they will consist only of herbal remedies,

(iii) whether they will consist only of medicinal products that may be sold otherwise than at a registered pharmacy, or otherwise than by a practitioner or otherwise than at a hospital,

(iv) whether they will include imported proprietary products, and

(v) where they consist only of medicinal products that are not referred to in any of clauses (i), (ii) and (iii), descriptions of the medicinal products; and

(b) whether any medicinal product is for any of the following uses –

(i) by being administered to human beings,

(ii) by being administered to animals,

(iii) in the form of an ingredient in the preparation of a substance, or of an article, that is to be administered for a medicinal purpose to human beings or animals, or

(iv) by incorporation in any animal feeding stuff,

a statement of each of those uses that it is for.

**4** The address of each of the premises where the medicinal products will be stored, and each of the premises from where they will be distributed.

**5** A statement describing the general range of medicinal products to be stored at each of the premises (including, where the licence is to relate to imported proprietary products, the description of each medicinal product).

**6** A statement describing the facilities and equipment available at each of the premises for storing the medicinal products, and for distributing them from those premises and between those premises.

**7** Where the licence is to relate to products to which Chapters II to V of the 1965 Directive apply –

(a) the following information about the person who is to carry out the functions specified in paragraph 10(1) of Schedule 4 to the Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997 –

(i) his or her name and address,

(ii) his or her qualifications and experience (including any degrees and diplomas), and

(iii) his or her designation; and

(b) the details of an emergency plan that fulfills the requirements of paragraph 5 of that Schedule.

**8** Where the licence is to relate to a product to which Chapters II to V of the 1965 Directive apply, a statement of the arrangements for keeping records (in the form of invoices or on computer or in any other form) in respect of the receipt and despatch of the product.

**9** Where the licence is to relate to an imported proprietary product and is to be subject to the provisions of paragraph 13 of Schedule 4 to the Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997, the following information about the person who is to carry out the functions specified in sub-paragraph (1) of that paragraph –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas); and

(c) his or her designation.

**10** Where the licence is to relate to any dealing in a controlled drug (as defined in Article 3 of the Misuse of Drugs (Jersey) Law 1978), the following information about each person who is to handle the drug on behalf of the proposed holder of the licence in the course of that dealing –

(a) his or her name and address;

(b) his or her qualifications and experience (including any degrees and diplomas); and

(c) his or her designation.

**11** If the applicant, the proposed holder of the licence or any person to whom any of paragraphs 7, 9 and 10 refers –

(a) has been convicted in Jersey or elsewhere of any offence for which a person is liable to imprisonment (whether or not a person is also liable to any other penalty); or

(b) has been found guilty of professional misconduct in Jersey or elsewhere, by a professional body to whose disciplinary control he or she was subject at the time of the conduct on which the finding was based,

the details of that conviction or finding.

**12** A description, in summary, of the arrangements (whether by maintaining records or by other means), for ensuring as far as practicable a satisfactory turn-over of stocks of medicinal products at each of the premises where they will be stored.

# ENDNOTES

## Table of Legislation History

| Legislation | Year and No | Commencement |
|---|---|---|
| Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Jersey) Order 1997 | R&O.9129 | 1 January 1998 |
| Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Amendment) (Jersey) Order 2000 | R&O.76/2000 | 14 September 2000 |
| States of Jersey (Amendments and Construction Provisions No. 12) (Jersey) Regulations 2005 | R&O.133/2005 | 9 December 2005 |

## Table of Renumbered Provisions

| Original | Current |
|---|---|
| FIRST SCHEDULE | SCHEDULE 1 |
| paragraph 7A | paragraph 8 |
| 8 | 9 |
| 9 | 10 |
| 10 | 11 |
| SECOND SCHEDULE | SCHEDULE 2 |
| paragraph 10A | paragraph 11 |
| 11 | 12 |

## Table of Endnote References

[1] *This Order has been amended by the States of Jersey (Amendments and Construction Provisions No. 12) (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] *Schedule 1 amended by R&O.76/2000*

[3] *Schedule 2 amended by R&O.76/2000*