Jersey

MEDICINES (STANDARD PROVISIONS FOR LICENCES AND CERTIFICATES) (JERSEY) ORDER 1997

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MEDICINES (STANDARD PROVISIONS FOR LICENCES AND CERTIFICATES) (JERSEY) ORDER 1997

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Article

Jersey

MEDICINES (STANDARD PROVISIONS FOR LICENCES AND CERTIFICATES) (JERSEY) ORDER 1997[1]

THE HEALTH AND SOCIAL SERVICES COMMITTEE, in pursuance of Articles 46, 90 and 110 of the Medicines (Jersey) Law 1995, and 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 –

"advertisement" has the same meaning as it has in Article 87 of the Law;

"allergen product" means a product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergenising agent;

"blood product" –

(a) means a medicinal product for human use that is prepared industrially and is derived from human blood or human plasma; and

(b) also means albumin, coagulating factors and immunoglobulins of human origin,

but does not mean whole human blood, human plasma or blood cells of human origin;

"clinical trial certificate of right" means a certificate to which an applicant is entitled if the applicant fulfils the requirements of Article 38(4) of the Law;

"Council Directive" means Council Directive 81/851/EEC;

"expiry date", in relation to a medicinal product, means the date after which the medicinal product should not be used;

"good manufacturing practice" means that aspect of the assurance of quality that ensures that medicinal products are consistently produced and controlled to the standards of quality that are appropriate to their intended use, the principles and guidelines of which are specified in Chapter II of Commission Directive 91/356/EEC;

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

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

"member State" means a member State of the European Communities;

"parenteral administration" means administration by breach of the skin or mucous membrane;

"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, Article 1 of Council Directive 89/381/EEC and Article 9(1) of Council Directive 92/73/EEC;

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

"relevant period", in relation to a medicinal product, means –

(a) the period of 5 years from the date of certification, under paragraph 21(1)(b) of Schedule 3 to this Order, of the batch of which it forms part; or

(b) the period of one year from the expiry date of the batch,

whichever expires later;

"Second Council Directive" means Second Council Directive 75/319/EEC;

"serum" means a fluid fraction of coagulated blood;

"toxins" means substances that –

(a) consist wholly or partly of poisonous substances derived from specific micro-organisms, plants or animals; and

(b) are used in the diagnosis, prevention or treatment of disease;

"vaccines" means antigenic substances that consist wholly or partly of –

(a) any micro-organisms, viruses or other organisms in any state;

(b) any toxoids (that is to say, any toxins of microbial origin that have been detoxified); or

(c) any extracts or derivatives of any micro-organisms or of any viruses,

being substances that, when administered to human beings or animals, are used for the prevention or treatment of specific diseases.

(2) In this Order, unless the context otherwise requires, a reference to a Directive is to that 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 Standard provisions for licences and certificates

The standard provisions for the purposes of Part 3 of the Law shall be –

(a) for product licences (including product licences of right), the provisions in Schedule 1 to this Order;

(b) for clinical trial certificates (including clinical trial certificates of right), the provisions in Schedule 2 to this Order;

(c) for manufacturer's licences (including manufacturer's licences of right), the provisions in Schedule 3 to this Order; and

(d) for wholesale dealer's licences (including wholesale dealer's licences of right), the provisions in Schedule 4 to this Order.

3 Standard provisions for product licences for blood products and immunological products for human use

In addition to the standard provisions in Schedule 1 to this Order, and for the purposes of Part 3 of the Law –

(a) the standard provisions for product licences (including product licences of right), in relation to blood products, shall be the provisions in paragraphs 1 and 2 of Schedule 5 to this Order; and

(b) the standard provisions for product licences (including product licences of right), in relation to vaccines, toxins, serums or allergen products for human use, shall be the provisions in paragraph 3 of Schedule 5 to this Order.

4 Citation

This Order may be cited as the Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997.

SCHEDULE 1

(Article 2(a))

STANDARD PROVISIONS FOR PRODUCT LICENCES

1. The holder of the licence shall inform the Minister forthwith of each change –

   (a) in his or her name or address; or

   (b) in any address at which there is carried on a business to which the licence relates.

2.

(1) Where there is a change or proposed change, of a material nature, in the information that has been provided with the application in respect of a medicinal product to which the licence relates, being a change –

   (a) in the specification of the medicinal product or of any of its constituents;

   (b) in the composition of the medicinal product, or of any of its constituents;

   (c) in any method of manufacture or assembly of the medicinal product, or of any of its constituents;

   (d) in any method or procedure for ensuring compliance with the specification of the medicinal product; or

   (e) in the arrangements described, in the application, for storage of the medicinal product,

   the holder of the licence shall inform the Minister forthwith.

(2) Where –

   (a) the particulars of any matter mentioned in the licence differ from those provided, in respect of that matter, with the application for the licence; and

   (b) it is proposed to change, to a material extent, any matter mentioned in the licence,

   the holder of the licence shall inform the Minister forthwith of the proposed change.

3. The holder of the licence shall inform the Minister forthwith of information received by him or her that casts doubt on the continuing reliability of any data provided with the application for the product licence for the purposes of being taken into account in assessing the safety, quality or efficacy of any medicinal product.

4.

(1) The holder of the licence shall maintain a record of reports of which he or she is aware of adverse effects, in any human beings or animals that are associated in those reports with the use of any medicinal product to which the licence relates.

(2) The holder of the licence shall keep the record readily available for inspection by a person authorized by the Minister.

(3) If the Minister so directs, the holder of the licence shall furnish the Minister with a copy of any such report of which he or she has a record, or of which he or she is or subsequently becomes aware.

(4) The holder of the licence shall permit the authorized person to take copies and make extracts from the record and reports.

5.

(1) The holder of the licence shall keep readily available, for inspection by a person authorized by the Minister, durable records of his or her arrangements –

(a) for procuring the sale, supply, manufacture, assembly and importation of each medicinal product to which the licence relates;

(b) for obtaining materials for the purposes of the manufacture and assembly of the medicinal product; and

(c) for tests to be carried out –

(i) on the materials used for the manufacture and assembly of the medicinal product; and

(ii) on the medicinal product itself.

(2) The holder of the licence shall permit the authorized person to take copies of and make extracts from those records.

(3) The records shall not be destroyed, without the prior consent of the Minister, for a period of 5 years from the date when (as the case may be) the sale, supply or exportation of the batch of which the medicinal product forms part was authorized by or on behalf of the holder of the licence.

6. The holder of the licence shall keep documents that will facilitate the withdrawal or recall from sale, supply and exportation of medicinal products to which the licence relates.

7. Where –

(a) the holder of the licence has been informed by the Minister that any batch of a medicinal product to which the licence relates has been found not to conform in strength, quality or purity with the specification of the medicinal product, or with the Law or any subordinate legislation made under the Law that is applicable to the medicinal product; and

(b) the Minister so directs,

he or she shall withhold the batch from sale, supply or exportation, so far as may be reasonably practicable, for such a period not exceeding 6 weeks as the Minister shall specify.

8. The holder of the licence –

(a) shall inform the Minister forthwith of any decision to withdraw from sale, supply or exportation any medicinal product to which the licence relates; and

(b) in so informing the Minister, shall state the reason for that decision.

9.

(1) Except as permitted by sub-paragraphs (3), (4) and (6) of this paragraph, the holder of the licence shall not –

(a) issue an advertisement to which this paragraph applies;

(b) consent to its issue; or

(c) cause another person to issue it.

(2) This paragraph applies to an advertisement of a medicinal product to which the licence relates, where –

(a) the advertisement contains particulars as to the uses, nature or effects of the medicinal product, or warnings about the medicinal product; and

(b) the Minister has served notice in writing on the holder of the licence that this paragraph applies to advertisements of its kind.

(3) An advertisement may be issued if its terms, in respect of the particulars or warnings, do not differ materially from the terms of that nature in the licence.

(4) Where no such terms are contained in the licence an advertisement may (subject to sub-paragraph (5) of this paragraph) be issued if its terms, in respect of the particulars or warnings, do not differ materially from those stated –

(a) in the application for the licence; or

(b) in a notice in writing served by the holder of the licence on the Minister, not less than 42 days before the first issue of the advertisement, or not less than such shorter time before its first issue as the Minister may allow.

(5) An advertisement may not be issued by reason of sub-paragraph (4) of this paragraph, without the prior written consent of the Minister, if he or she has served notice in writing on the holder of the licence –

(a) by the date on which the application for the licence was granted; or

(b) within 21 days after the service of a notice under that sub-paragraph by the holder of the licence,

(whichever is the later date) that, for any of the purposes specified in Article 90(4) of the Law, the terms of the advertisement relating to the particulars or warnings should not be included in the advertisement, or that they should only be included in it in a modified form specified by the Minister in his or her notice under this paragraph.

(6) An advertisement may be issued in any modified form specified in a notice served by the Minister under sub-paragraph (5) of this paragraph.

10.

(1) If the Minister so directs, the holder of the licence shall give to the Minister particulars of any advertisement that it is proposed to issue in respect of a medicinal product to which the licence relates.

(2) The particulars shall include –

(a) the contents and form of the proposed advertisement;

(b) every means and every medium by which it is to be issued; and

(c) the times and manner of its issue.

11. As soon as reasonably possible, the holder of the licence shall comply with any direction in writing given to him or her by the Minister that, for any of the purposes specified in Article 90(4) of the Law –

(a) advertisements of any kind specified in the direction in respect of a medicinal product should not be issued or re-issued, except in such circumstances (if any) as are specified in the direction;

(b) the contents or form of those advertisements or the manner in which they are issued should be modified in a way specified in the direction; or

(c) precautions as to the use of the medicinal product, or warnings as to its effect, should be included in those advertisements.

12. Where –

(a) the licence relates to a medicinal product that has been or is to be imported; and

(b) the Minister has required the production of an undertaking by the manufacturer of the medicinal product under Article 20(4)(a) of the Law,

the holder of the licence shall ensure that the medicinal product is not sold or supplied unless the medicinal product has been manufactured or assembled in the premises in respect of which the undertaking has been given.

13.

(1) Subject to Article 46(5) of the Law, where –

(a) the licence is a licence of right that has been renewed by the Minister; and

(b) at any time after its renewal, an Order is made under the Law, amending this Order by inserting additional standard provisions in this Schedule,

the holder of the licence shall apply to vary the provisions of the licence to incorporate provisions having the same effect as the provisions so inserted in this Schedule.

(2) The application shall be made before the expiry of the period of 3 months immediately following the date on which the amending Order comes into force.

SCHEDULE 2

(Article 2(b))

STANDARD PROVISIONS FOR CLINICAL TRIAL CERTIFICATES

1. The holder of the certificate shall inform the Minister forthwith of each change –

   (a) in his or her name or address; or

   (b) in any address at which there is carried on a business to which the clinical trial certificate relates.

2. The holder of the certificate shall inform the Minister forthwith of information received by him or her that casts doubt on the continuing reliability of any data provided with the application for the clinical trial certificate for the purposes of being taken into account in assessing the safety, quality or efficacy of any medicinal product.

3. The holder of the certificate –

   (a) shall inform the Minister forthwith of any decision to discontinue the trial of any medicinal product to which the certificate relates; and

   (b) in so informing the Minister, shall state the reason for that decision.

4. The clinical trial to which the clinical trial certificate relates shall be carried out in accordance with the description of the clinical trial in the application for that certificate, subject to any changes that the Minister may from time to time approve.

5.

(1) The medicinal product to which the clinical trial certificate relates shall be administered only by or under the direction of a doctor or dentist –

   (a) who is named in the application for that certificate; or

   (b) who is approved by the Minister for the purpose.

(2) Where –

   (a) the medicinal product to which the clinical trial certificate relates is to be administered by or under the direction of a doctor or dentist who has not been named in the application for the certificate; or

   (b) it is proposed that there shall be a change of the doctor or dentist so named,

   the holder of the certificate –

      (i) shall apply to the Minister for his or her approval of the doctor or dentist who is to administer or to direct the administration of the medicinal product, and

      (ii) in so applying, shall inform the Minister of the holder's name, address and qualifications.

(3) Where any doctor or dentist ceases to participate in the clinical trial to which the clinical trial certificate relates, the holder of the certificate –

   (a) shall inform the Minister as soon as reasonably possible; and

(b) in so informing the Minister, shall state the reason.

6.

(1) The holder of the certificate shall inform each doctor or dentist who is to administer or to direct the administration of any medicinal product to which the clinical trial certificate relates of the provisions of the certificate.

(2) The holder of the certificate shall do so before the doctor or dentist administers or directs the administration of the medicinal product.

SCHEDULE 3

(Article 2(c))

STANDARD PROVISIONS FOR MANUFACTURER'S LICENCES

1.

(1) The holder of the licence shall maintain the staff, premises and plant that are necessary to carry out, in accordance with the licence and any relevant product licences, the stages of the manufacture and assembly of the medicinal products that are undertaken by him or her under the manufacturer's licence.

(2) The holder of the licence shall not manufacture or assemble any medicinal products except at the premises specified in the manufacturer's licence.

2.

(1) For the handling, storage and distribution of medicinal products under the licence, the holder of the licence shall maintain the staff, premises, equipment and facilities that are necessary to avoid deterioration of the medicinal products.

(2) The holder of the licence shall not use for those purposes any premises except those –

(a) specified in the licence; or

(b) approved by the Minister.

3. The holder of the licence shall conduct all manufacturing and assembly operations in such a way as to ensure that the medicinal products conform with the standards of strength, quality and purity applicable to them under the relevant product licences.

4. The holder of the licence shall, in relation to medicinal products for human use, conduct all manufacturing and assembly operations in accordance with the principles and guidelines of good manufacturing practice.

5. In relation to medicinal products for human use, the licence holder shall establish and implement an effective system for assuring their pharmaceutical quality.

6.

(1) In relation to medicinal products for human use –

(a) the holder of the licence shall maintain a department that –

(i) has authority to control their quality,

(ii) is independent of all other departments in the exercise of that authority, and

(iii) is designated as the quality control department; and

(b) the holder shall place the quality control department under the authority of the person named in the application for the licence, in accordance with paragraph 7(2) of Schedule 1 to the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Jersey) Order 1997 as being responsible for the control of quality.

(2) To support the quality control department, the holder of the licence shall provide and maintain the staff, premises and plant that are necessary to carry out –

(a) the tests required by the relevant product licences of the strength, quality and purity of the medicinal products that he or she manufactures for human use under the manufacturer's licence; and

(b) the test and controls that relate to the conditions and processes of production.

(3) The holder of the licence shall ensure that the quality control department, in determining whether finished medicinal products for human use are to be released for sale or distribution, takes into account –

(a) the conditions of production;

(b) the results of controls of the processes used;

(c) the examination of documents relating to production; and

(d) the conformity of products to the specifications in the relevant product licences,

in addition to analytical results.

7. The holder of the licence need not himself or herself maintain the staff, premises and plant that are necessary to carry out the tests specified in paragraph 6(2) of this Schedule if a person approved by the Minister carries out those tests on his or her behalf.

8. The holder of the licence shall provide such information as may be requested by the Minister, for the purposes of the Law, about –

(a) any medicinal product that is being manufactured or assembled under the licence; and

(b) any operation that is being carried out in relation to manufacture or assembly.

9.

(1) The holder of the licence shall inform the Minister before making any material alteration –

(a) of the premises or plant used under the licence; or

(b) in any operations for which they are used.

(2) The holder of the licence shall inform the Minister of each change that it is proposed to make of any person named in the licence (including any person named for the purposes of paragraph 21 of this Schedule) as being –

(a) responsible for supervising the production operations;

(b) responsible for the control of quality of medicinal products; or

(c) responsible for the culture of any living tissue used in the manufacture of medicinal products.

10.

(1) The holder of the licence shall keep readily available, for inspection by a person authorized by the Minister, durable records of –

(a) the details of manufacture and assembly of each batch of medicinal products that is being manufactured or assembled under the licence; and

(b) the tests carried out on each batch,

including any register or other record to which paragraph 21(1)(b) of this Schedule refers.

(2) The records shall be kept in such a form that, in relation to each batch, they will be easily identifiable from its number as shown on each container in which medicinal products in that batch are sold, supplied or exported.

(3) The holder of the licence shall permit the authorized person to take copies of or make extracts from those records.

(4) The records shall not be destroyed –

(a) in relation to a medicinal product for human use, for the relevant period; and

(b) in any other case, for a period of 5 years from the date when the manufacture or assembly of the batch to which they relate was completed,

without the prior consent of the Minister.

11.

(1) The holder of the licence –

(a) shall keep samples of each batch of finished medicinal products for human use readily available for one year after their expiry dates; and

(b) shall keep samples of starting materials (except solvents, gases and water) readily available for 2 years after the date of release of the batch of which they formed part,

for examination by a person authorized by the Minister.

(2) Notwithstanding sub-paragraph (1) of this paragraph, the Minister may authorize the holder of the licence to destroy a sample sooner.

12. The holder of the licence shall make suitable arrangements to ensure that each record or sample to which paragraph 10 or paragraph 11 of this Schedule refers, relating to a medicinal product for human use, is kept for the period required under that paragraph.

13. The holder of the licence shall keep documents that will facilitate the withdrawal or recall from sale, supply or exportation of medicinal products to which the licence relates that are not for human use.

14.

(1) The holder of the licence shall implement –

(a) an effective system for recording and reviewing complaints relating to medicinal products for human use that are manufactured or assembled under the licence; and

(b) an effective system for recalling promptly at any time any of those medicinal products that are in the distribution network.

(2) The holder of the licence –

(a) shall record and investigate all such complaints; and

(b) shall inform the Minister forthwith of any defect that could result in –

(i) a recall from sale, supply or exportation, or

(ii) an abnormal restriction on the sale, supply or exportation,

of any medicinal product.

15. Where –

(a) the holder of the licence has been informed by the Minister that any batch of a medicinal product to which the licence relates has been found not to conform in strength, quality or purity with the specification of the medicinal product, or with the Law or any subordinate legislation made under the Law that is applicable to the medicinal product; and

(b) the Minister so directs,

the holder shall withhold the batch from sale, supply or exportation, so far as may be reasonably practicable, for such a period not exceeding 6 weeks as the Minister shall specify.

16. The holder of the licence shall ensure that the tests for determining conformity with the standards and specifications applying to any particular product that is used in the manufacturing of a medicinal product are applied to samples taken from the medicinal product –

(a) after all manufacturing processes have been completed; or

(b) at such earlier stage in manufacture as may be approved by the Minister,

except to the extent that any relevant product licence provides otherwise.

17.

(1) Where the holder of the licence is not the holder of a product licence in respect of a medicinal product to which the manufacturer's licence relates –

(a) he or she shall comply with the provisions of the product licence that relates to the sale of the medicinal product; and

(b) by a label or by some other means, he or she shall inform each person to whom he or she sells or supplies the medicinal product of the particulars of the provisions of the product licence that relate to the mode of sale or to restrictions as to the sale of the medicinal product.

(2) Where –

(a) the manufacturer's licence relates to the assembly of a medicinal product; and

(b) the holder of the licence sells or supplies the medicinal product at a stage of assembly at which the provisions of any relevant product licence as to labelling have not been complied with fully,

the holder of the manufacturer's licence shall inform the person to whom the medicinal product has been sold or supplied by him or her of the particulars of those provisions.

18. Where –

(a) the holder of the licence –

(i) has specified in his or her application for a manufacturer's licence a general classification of medicinal products in respect of which the licence was required, or

(ii) has given in the application particulars of manufacturing operations, and of substances or articles, in accordance with paragraph 6 of Schedule 1 to the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) (Jersey) Order 1997; and

(b) there has been a change, or it is proposed that there shall be a change, in that general classification or in those particulars,

the holder of the licence shall inform the Minister forthwith of the change or proposed change.

19. Where –

(a) the licence relates to the assembly of a medicinal product that is not manufactured by the holder of the licence; and

(b) the name and address of the manufacturer or the person who imports the medicinal product have been given by the holder of the licence to the Minister,

the holder of the licence shall inform the Minister forthwith of any change in the name or address of that manufacturer or person.

20.

(1) For the purpose of enabling the Minister to ascertain whether there are any grounds for varying, suspending or revoking any licence or certificate under Part 3 of the Law, the holder of the licence –

(a) shall permit any person who is authorized in writing to do so by the Minister to inspect and take samples, to the extent described in sub-paragraph (2) of this paragraph, of anything relating to the business of the holder of the licence; and

(b) shall provide the facilities that are necessary to enable the person to do so.

(2) The authority conferred by the Minister under sub-paragraph (1) of this paragraph extends only to those things that the Minister, under the Law, may authorize a person to do to verify a statement in an application for a licence or certificate.

(3) The holder of the licence need not comply with sub-paragraph (1) of this paragraph if the authorized person does not produce his or her written authority on request.

21.

(1) The holder of the licence shall have at his or her disposal the services of a person whose functions shall be –

(a) to ensure that each batch of each medicinal product to which the licence relates has been manufactured and assembled, and checked, in compliance with the Law, the provisions of the manufacturer's licence and the provisions of any product licence that relates to the medicinal product;

(b) to certify in a register, or in any other record that is appropriate for the purpose, whether each production batch of the medicinal product fulfils the requirements in clause (a) of this sub-paragraph; and

(c) to ensure that the register or other record is maintained regularly, and in particular that the appropriate entries in it are made as soon as practicable after each batch has been manufactured.

(2) The person must fulfil the requirements of Articles 23 and 24 of the Second Council Directive as to qualifications and experience.

(3) A person may be regarded as fulfilling the requirements of Article 24 of the Second Council Directive as to formal qualifications if he or she produces evidence –

(a) that he or she is a member of the Royal Pharmaceutical Society of Great Britain or of the Royal Society of Chemistry or of any other body that the Minister considers appropriate for the purpose; and

(b) that he or she is regarded by the body of which he or she is a member as fulfilling those requirements.

(4) The holder of the licence shall maintain the staff, premises, equipment and facilities that are necessary to enable the person to carry out his or her functions.

(5) The holder of the licence shall inform the Minister in writing forthwith of each material change in the information provided in relation to the person who carries out or is to carry out the functions in sub-paragraph (1) of this paragraph.

(6) Where, after giving the holder of the licence and the person concerned the opportunity of making oral or written representations, and taking those representations (if any) into consideration, the Minister is of the opinion –

(a) that a person having the functions in sub-paragraph (1) of this paragraph, or a person proposed for that purpose, does not fulfil the requirements of Articles 23 and 24 of the Second Council Directive in respect of his or her qualifications and experience; or

(b) in the case of a person having those functions, that he or she is not carrying them out,

and the Minister serves notice in writing accordingly on the holder of the licence and the person, the latter shall cease to be a person who fulfils the requirements of sub-paragraph (1) of this paragraph, unless the notice is withdrawn.

(7) The Minister may withdraw any notice under sub-paragraph (6) of this paragraph.

(8) The holder of the licence shall not permit any person to carry out the functions in sub-paragraph (1) of this paragraph unless –

(a) that person is named in the licence as the person who will do so; or

(b) the Minister has been informed in accordance with sub-paragraph (5) of this paragraph that he or she is to be the person who will do so,

and in either case the Minister has not served any notice under sub-paragraph (6) in respect of the person, or has withdrawn any such notice.

SCHEDULE 4

(Article 2(d))

STANDARD PROVISIONS FOR WHOLESALE DEALER'S LICENCES

1.

(1) For the handling, storage and distribution of medicinal products under the licence, the holder of the licence shall maintain the staff, premises, equipment and facilities that are necessary to avoid deterioration of the medicinal products.

(2) The holder of the licence shall not use for those purposes any premises except those –

(a) specified in the licence; or

(b) approved by the Minister.

2. The holder of the licence shall provide such information as the Minister may request as to the type and quantity of any medicinal product that he or she handles, stores or distributes.

3. The holder of the licence shall inform the Minister before altering structurally or discontinuing the use of any of his or her premises.

4. The licence holder shall keep documents that will facilitate the withdrawal or recall from sale or exportation of medicinal products to which the licence relates.

5. Where the licence relates to a product to which Chapters II to V of the 1965 Directive apply, the holder of the licence shall institute an emergency plan that ensures effective implementation of any recall from the market that –

(a) is ordered by the licensing authority or the competent authority of a member State; or

(b) is carried out in co-operation with the manufacturer or the holder of any product licence or of the marketing authorization granted by the competent authority of a member State in respect of the product.

6.

(1) Where the licence relates to a product to which Chapters II to V of the 1965 Directive apply, the holder of the licence shall keep a record (in the form of invoices or on computer or in any other form) giving the following information in respect of the receipt and dispatch of the product –

(a) the dates of receipt and of dispatch;

(b) the name of the product;

(c) the quantities of the product received and dispatched; and

(d) the name and address of each person from whom or to whom the product is sold or supplied.

(2) The holder of the licence shall keep the record readily available for inspection by a person authorized by the Minister.

(3) The record in respect of each product shall not be destroyed, without the prior consent of the Minister, for a period of 5 years from the date of receipt or despatch of the product, whichever is the later.

7. Where –

(a) the holder of the licence has been informed by the Minister, or by the holder of any product licence relating to a medicinal product to which the wholesale dealer's licence also relates, that any batch of the medicinal product has been found not to conform in strength, quality or purity with the specification of the medicinal product, or with the Law or any subordinate legislation made under the Law that is applicable to the medicinal product; and

(b) the Minister so directs,

the holder of the wholesale dealer's licence shall withhold the batch from sale or exportation, so far as may be reasonably practicable, for such a period not exceeding 6 weeks as the Minister shall specify.

8.

(1) Subject to sub-paragraph (2) of this paragraph –

(a) no medicinal product to which the wholesale dealer's licence relates shall be sold or offered for sale by way of wholesale dealing by virtue of that licence unless there has been granted in respect of that medicinal product a product licence that is for the time being in force; and

(b) every sale or offer for sale of the medicinal product shall be in conformity with the provisions of the product licence.

(2) Sub-paragraph (1) of this paragraph shall not apply where –

(a) the sale of the medicinal product to which the wholesale dealer's licence relates is otherwise than by way of wholesale dealing and is not subject to the restrictions in Article 8(2) of the Law;

(b) the sale or offer for sale is by way of wholesale dealing and is of a medicinal product in respect of which, at the time of its acquisition by the holder of the licence, such dealings were not subject to the restrictions in Article 8(2) of the Law; or

(c) at the time of the sale or offer for sale, the holder of the licence –

(i) does not know and could not by reasonable diligence and care know that the sale or offer is of a medicinal product, or

(ii) believes, on reasonable grounds, that the provisions of clause (a) or clause (b) of this sub-paragraph apply in relation to the sale or offer.

9.

(1) For the purpose of enabling the Minister to ascertain whether there are any grounds for varying, suspending or revoking any licence or certificate under Part 3 of the Law, the holder of the licence –

(a) shall permit any person who is authorized in writing to do so by the Minister to inspect and take samples, to the extent described in sub-paragraph (2) of this paragraph, of anything relating to the business of the holder of the licence; and

(b) shall provide the facilities that are necessary to enable the person to do so.

(2) The authority conferred by the Minister under sub-paragraph (1) of this paragraph extends only to those things that the Minister, under the Law, may authorize a person to do to verify a statement in an application for a licence or certificate.

(3) The holder of the licence need not comply with sub-paragraph (1) of this paragraph if the authorized person does not produce the authorized person's written authority on request.

10.

(1) Where the licence relates to a product to which Chapters II to V of the 1965 Directive apply, the licence holder shall have at his or her disposal the services of a responsible person whose functions shall be to ensure –

(a) that the conditions on which the licence has been granted are complied with; and

(b) that the quality of the product is maintained in accordance with the requirements of each product licence that relates to the medicinal product.

(2) The responsible person must be a person who, in the opinion of the Minister, possesses –

(a) adequate knowledge of the activities to be carried out and the procedures to be performed under the wholesale dealer's licence; and

(b) adequate experience in those activities,

to carry out his or her functions.

(3) The holder of the licence shall maintain the staff, premises, equipment and facilities that are necessary to enable the responsible person to carry out his or her functions.

(4) The holder of the licence shall inform the Minister in writing forthwith of each material change in the information provided in relation to the person who is or is to be the responsible person for the purposes of this paragraph.

(5) Where, after giving the holder of the licence and the person concerned the opportunity of making oral or written representations, and taking those representations (if any) into consideration, the Minister is of the opinion –

(a) that a responsible person for the purposes of this paragraph, or a person who is proposed for those purposes, does not fulfil the requirements of sub-paragraph (2) of this paragraph; or

(b) that a responsible person is not carrying out his or her functions under this paragraph,

and the Minister serves notice in writing accordingly on the holder of the licence and the person, the latter shall cease to be a person who fulfils the requirements of sub-paragraph (2) of this paragraph, unless the notice is withdrawn.

(6) The Minister may withdraw any notice under sub-paragraph (5) of this paragraph.

(7) The holder of the licence shall not permit any person to carry out the functions in sub-paragraph (1) of this paragraph unless –

(a) that person is named in the licence as the responsible person who will do so; or

(b) the Minister has been informed in accordance with sub-paragraph (4) of this paragraph that he or she is to be the responsible person,

and in either case the Minister has not served any notice under sub-paragraph (5) in respect of him or her, or has withdrawn any such notice.

11. Where the licence relates to a product to which Chapters II to V of the 1965 Directive apply, the holder of the licence shall obtain supplies of the product only from –

(a) a person who is the holder of a manufacturer's licence, or a wholesale dealer's licence, that relates to the product; or

(b) a person who holds an authorization, granted by a competent authority of a member State, for the manufacture of the product or the distribution by way of wholesale dealing of the product.

12.

(1) Where the licence relates to a product to which Chapters II to V of the 1965 Directive apply, the holder of the licence shall distribute it only by way of wholesale dealing to –

(a) a holder of a wholesale dealer's licence that relates to the product;

(b) a holder of an authorization, granted by the competent authority of a member State, for the supply of the product by way of wholesale distribution;

(c) a person who may lawfully sell the product by retail or may lawfully supply it in circumstances corresponding to retail sale; or

(d) a person who may lawfully administer the product.

(2) Where supply is made to a person to whom sub-paragraph (1)(c) of this paragraph refers, the holder of the licence shall enclose with the product a document that makes it possible to ascertain –

(a) the date on which the transaction took place;

(b) the name and pharmaceutical form of the product;

(c) the quantity of the product supplied; and

(d) the name and address of the person from whom the product was supplied.

13.

(1) Where the licence relates to an imported proprietary product, the holder of the licence shall have at his or her disposal the services of a person whose functions shall be –

(a) to ensure that each production batch of the product has undergone a full qualitative analysis, a qualitative analysis of at least all the active ingredients and all other tests or checks that are necessary to ensure that the quality of the product fulfils the requirements of the product licence that relates to the product;

(b) to certify in a register, or in any other record that is appropriate for the purpose, whether each batch of the product fulfils the requirements in clause (a) of this sub-paragraph; and

(c) to ensure that the register or other record is maintained regularly.

(2) The person must fulfil the requirements of Articles 23 and 24 of the Second Council Directive as to qualifications and experience.

(3) A person may be regarded as fulfilling the requirements of Article 24 of the Second Council Directive as to formal qualifications if he or she produces evidence –

(a) that he or she is a member of the Royal Pharmaceutical Society of Great Britain or of the Royal Society of Chemistry or of any other body that the Minister considers appropriate for the purpose; and

(b) that he or she is regarded by the body of which he or she is a member as fulfilling those requirements.

(4) The holder of the licence shall maintain the staff, premises, equipment and facilities that are necessary to enable him or her to carry out his or her functions.

(5) The functions in sub-paragraph (1) of this paragraph need not be carried out in respect of a batch that had entered the territory of another member State prior to its importation, if –

(a) evidence in writing is available that the batch in question fulfils the requirements in clause (a) of that sub-paragraph; and

(b) that evidence is given by a person carrying out those functions in that member State.

(6) The holder of the licence shall keep the register or other record readily available for inspection by a person authorized by the Minister.

(7) The register or other record in respect of each batch shall not be destroyed, without the prior consent of the Minister, for a period of 5 years from the date of the certification of the batch under sub-paragraph (1)(b) of this paragraph.

(8) The holder of the licence shall inform the Minister in writing forthwith of each material change in the information provided in relation to the person who carries out or is to carry out the functions in sub-paragraph (1) of this paragraph.

(9) Where, after giving the holder of the licence and the person concerned the opportunity of making oral or written representations, and taking those representations (if any) into consideration, the Minister is of the opinion –

(a) that a person having the functions in sub-paragraph (1) of this paragraph, or a person proposed for that purpose, does not fulfil the requirements of Articles 23 and 24 of the Second Council Directive in respect of qualifications and experience; or

(b) in the case of a person having those functions, that he or she is not carrying them out,

and the Minister serves notice in writing accordingly on the holder of the licence and the person, the latter shall cease to be a person who fulfils the requirements of sub-paragraph (2) of this paragraph unless the notice is withdrawn.

(10) The Minister may withdraw any notice under sub-paragraph (9) of this paragraph.

(11) The holder of the licence shall not permit any person to carry out the functions in sub-paragraph (1) of this paragraph unless –

(a) that person is named in the licence as the person who will do so; or

(b) the Minister has been notified in accordance with sub-paragraph (8) of this paragraph that he or she is to be the person who will do so,

and in either case the Minister has not served any notice under sub-paragraph (9) in respect of the person, or has withdrawn any such notice.

(12) The provisions of this paragraph shall not apply where the imported proprietary product that is to be sold or offered for sale or in any other way distributed has been in the possession, in the course of his or her business, of a person who is the holder of a wholesale dealer's licence relating to imported proprietary products of the same description, in circumstances by virtue of which that holder is required to comply with the provisions of this paragraph.

(13) The provisions of this paragraph shall not apply where the holder of the licence handles the imported proprietary product –

(a) in the course of the provision of facilities solely for the transport of the product; or

(b) in the course of a business carried on by him or her as an import agent, where he or she imports the product solely to the order of another person who –

(i) intends, in the course of a business carried on by that other person, to sell or offer for sale the product by way of wholesale dealing, or

(ii) in any other way intends to distribute the product.

14. Where the licence relates to imported proprietary products, the holder of the licence shall in relation to medicinal products for human use –

(a) ensure that all manufacturing and assembly operations have been carried out by a manufacturer or assembler who has done so lawfully;

(b) ensure that the products have been manufactured or assembled in accordance with the principles and guidelines of good manufacturing practice;

(c) keep readily available for a period of at least one year after their expiry dates, for examination by a person authorized by the Minister, samples of each batch of finished medicinal products, except where the holder of the licence is authorized by the Minister to destroy any such samples sooner;

(d) implement –

(i) an effective system for recording and reviewing complaints relating to the medicinal products to which the licence relates, and

(ii) an effective system for recalling promptly at any time any of those medicinal products that are in the distribution network; and

(e) record and investigate all such complaints and inform the Minister immediately of any defect that could result in –

(i) a recall from sale, supply or exportation, or

(ii) an abnormal restriction on the sale, supply or exportation,

of any medicinal product.

SCHEDULE 5

(Article 3)

ADDITIONAL STANDARD PROVISIONS FOR PRODUCT LICENCES FOR BLOOD PRODUCTS AND IMMUNOLOGICAL MEDICINAL PRODUCTS FOR HUMAN USE

Blood products

1. The holder of the licence shall ensure that the manufacturing and purifying processes used in the preparation of each blood product to which the licence relates –

   (a) are properly validated;

   (b) attain batch-to-batch consistency; and

   (c) guarantee, as far as the state of technology permits, the absence of specific viral contamination,

   and shall ensure that appropriate records relating to relevant control measures are –

   (i) signed by the person who is to carry out the functions in paragraph 21(1) of Schedule 3;

   (ii) kept for the relevant period; and

   (iii) if so requested by the Minister, submitted to the Minister.

2. The holder of the licence shall ensure that the manufacturer of each blood product to which the product licence relates notifies the Minister of the method or methods used to reduce or eliminate pathogenic viruses that are liable to be transmitted by the blood product.

Immunological products

3. The holder of the licence shall take all necessary measures to ensure that the processes used in the production of each vaccine, toxin, serum or allergen product to which the licence relates –

   (a) are properly validated; and

   (b) attain batch-to-batch consistency,

   and shall ensure that appropriate records relating to control measures are–

   (i) signed by the person who is to carry out the functions in paragraph 21(1) of Schedule 3;

   (ii) kept for the relevant period; and

   (iii) if so requested by the Minister, submitted to the Minister.

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement
Medicines (Standard Provisions for Licences and Certificates) (Jersey) Order 1997	R&O.9138	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*