

GUERNSEY STATUTORY INSTRUMENT

2009 No. 68

**The Medicines (Human) (Terms of Licences) (Bailiwick of
Guernsey) Regulations, 2009**

<i>Made</i>	<i>1st October, 2009</i>
<i>Coming into operation</i>	<i>1st October, 2009</i>
<i>Laid before the States</i>	<i>, 2009</i>

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The Medicines (Human) (Terms of Licences) (Bailiwick of Guernsey) Regulations, 2009

THE HEALTH AND SOCIAL SERVICES DEPARTMENT, in exercise of the powers conferred on it by section 8(6), (6A), and (11) and section 132 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008^a and all other powers enabling it in that behalf, hereby makes the following Regulations:-

Requirements in respect of manufacturer's licences

Obligations in relation to the manufacture and assembly of medicinal products.

1. (1) In relation to the manufacture and assembly of medicinal products, every holder of a manufacturer's licence shall –

- (a) comply with the principles of good manufacturing practice,
- (b) comply with the requirements of paragraph (3), and
- (c) subject to paragraph (2), use active substances as starting materials, within the meaning of Article 46a and 47 of the 2001 Directive, only where those active substances have been manufactured or assembled in accordance with the principles of good manufacturing practice applicable to starting materials.

(2) Paragraph (1)(c) does not apply in relation to the manufacture or assembly of exempt medicinal products under a manufacturer's licence.

^a Order in Council No. V of 2009.

- (3) The requirements of this paragraph are that the holder shall –
- (a) maintain the staff, premises, equipment and facilities necessary for the stages of the manufacture and assembly of medicinal products that are undertaken by him in accordance with the requirements of –
 - (i) his licence, and
 - (ii) any marketing authorisation in force in respect of the medicinal products in question,
 - (b) maintain the staff, premises, equipment and facilities for the handling, control, storage and distribution of the medicinal product that he handles, stores and distributes under his licence, necessary to maintain the quality of those medicinal products,
 - (c) ensure that any arrangements he makes with any person for the control, storage and distribution of the medicinal products are adequate to maintain the quality of those products,
 - (d) not carry out any manufacture or assembly of medicinal products other than –
 - (i) the manufacture or assembly of those classes of medicinal products specified in his licence, and
 - (ii) at the premises specified in his licence,
 - (e) not use any premises for the handling, control, storage or distribution of medicinal products other than those

specified in his licence as approved by the licensing authority for that purpose from time to time,

- (f) inform the licensing authority and the regulatory authority before making any material alteration to the premises or facilities used under his licence, or in the operations for which they are used,
- (g) inform the licensing authority and the regulatory authority of any change that he proposes to make to any personnel named in his licence as responsible for quality control of the medicinal products being manufactured or assembled by him, including the person named as the qualified person for the purposes of regulation 3,
- (h) for the purpose of enabling the licensing authority or the regulatory authority to ascertain whether there are any grounds for suspending, revoking, terminating or varying any licence, permit and provide all necessary facilities to enable any person duly authorised by the regulatory authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as that person thinks fit,
- (i) ensure that any blood or blood component imported into the Bailiwick and used by him as a starting material or raw material in the manufacture of a medicinal product meets standards of quality and safety equivalent to those laid down in Commission Directive 2004/33/EC of 22 March 2004,

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards technical requirements for blood and blood components, and

- (j) where he distributes by way of wholesale dealing any medicinal product manufactured or assembled pursuant to his licence, comply with the requirements of regulations 6(1)(a) and (b) and (2), and 7(2) and (3), as if he is the holder of a wholesale dealer's licence.

Obligations in respect of import from a third country of medicinal products.

2. In respect of the import from a third country of any medicinal product, every holder of a manufacturer's licence shall –

- (a) comply with the principles of good manufacturing practice so far as they relate to the import of medicinal products,
- (b) comply with the principles of good distribution practice,
- (c) ensure that any medicinal products (other than exempt medicinal products) imported by him from a third country use active substances as starting materials only where those active substances have been manufactured in accordance with the principles of good manufacturing practice applicable to starting materials,
- (d) maintain the staff, premises, equipment and facilities for the handling, control, storage and distribution of the medicinal products that he handles, stores and distributes under his licence, necessary to maintain the quality of those medicinal products,

- (e) ensure that any arrangements he makes with any person for the storage and distribution of the medicinal products are adequate to maintain the quality of those products,
- (f) not use any premises for the handling, control, storage or distribution of medicinal products other than those specified in his licence as approved by the licensing authority for that purpose from time to time,
- (g) inform the licensing authority and the regulatory authority before making any material alteration to the premises or facilities used under his licence, or in the operations for which they are used,
- (h) inform the licensing authority and the regulatory authority of any change that he proposes to make to any personnel named in his licence as responsible for quality control of the medicinal products being imported by him including the person named as the qualified person for the purposes of regulation 3,
- (i) for the purposes of enabling the licensing authority or the regulatory authority to ascertain whether there are grounds for suspending, revoking, terminating or varying any licence, permit and provide all necessary facilities to enable any person duly authorised in writing by the regulatory authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as that person thinks fit, and

- (j) where he distributes by way of wholesale dealing any medicinal product manufactured or assembled pursuant to his licence, comply with the requirements of regulations 6(1)(a) and (b) and (2) and 7(2) and (3), as if he is the holder of a wholesale dealer's licence.

Qualified persons.

3. (1) Subject to paragraphs (7) and (8), where a manufacturer's licence relates to the manufacture, assembly or importation of medicinal products, the licence holder shall ensure that he has at all times at his disposal the services of at least one qualified person who is responsible for carrying out, in relation to those products, the duties specified in Article 51 of the 2001 Directive.

(2) For the purposes of paragraph (1), the licence holder may act as the qualified person to the extent that he satisfies the requirements specified in the definition of qualified person in regulation 10(1).

(3) For the purposes of paragraph (1), but without prejudice to paragraph (4), the licence holder may regard a person as satisfying the provisions of Article 49 or 50 of the 2001 Directive as respects formal qualifications if he produces evidence that –

- (a) he is a member of –
 - (i) the Institute of Biology,
 - (ii) the Pharmaceutical Society,
 - (iii) the Royal Society of Chemistry, or
 - (iv) any other body that appears to the licensing authority to be an appropriate body for the

purposes of this paragraph, and

- (b) he is regarded by the body of which he is a member as so satisfying these provisions.

(4) The licence holder –

- (a) shall notify the licensing authority and the regulatory authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of qualified person,

- (b) shall notify the licensing authority and the regulatory authority of any change to the qualified person,

- (c) shall not permit any person to act as qualified person other than –

- (i) the person named in his licence as qualified person, or

- (ii) subject to paragraph (5), any other qualified person whose name is notified to the licensing authority and the regulatory authority.

(5) Where, after giving the licence holder and the person acting as a qualified person the opportunity of making representations to it (orally or in writing), the regulatory authority is of the opinion that –

- (a) the person so acting does not qualify to be a qualified person, in terms of the requirements specified in the definition of “qualified person” in regulation 10(1), or

- (b) the person so acting is failing to carry out the duties referred to in paragraph (1) adequately or at all, -

and has notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a qualified person.

(6) Subject to paragraph (7), the licence holder shall at all times provide and maintain the staff, premises, equipment and facilities necessary to enable the qualified person at his disposal to carry out the duties referred to in paragraph (1).

(7) A licence holder is not required to meet the requirements of this regulation in relation to any activity carried out under his licence which consists of the manufacture, assembly, or import from a third country, of medicinal products under a manufacturer's licence to the extent that the activity is limited to the manufacture, assembly or importation of -

- (a) exempt medicinal products, or
- (b) products which may be placed on the market without a marketing authorisation in the Bailiwick or an EEA State by virtue of legislation adopted by the Bailiwick or (as the case may be) that State under Article 5(2) of the 2001 Directive (medicinal products during emergencies).

(8) Where the conditions specified in paragraph 2 of Article 51 of the 2001 Directive are satisfied, a qualified person is not required to meet the requirements of point (b) of the first sub-paragraph of paragraph 1 of Article 51 of the 2001 Directive in respect of the import of any medicinal product from a third country.

Special provisions as to effect of recognised manufacturer's licence.

4. Paragraph 7 of Schedule 2 to the Law shall apply to a manufacturer's licence recognised in accordance with regulations made under section 7(3) of the Law as it applies to a manufacturer's licence.

Obligations of sellers or suppliers of starting materials

Offence relating to sale or supply of starting materials for use in manufacture of medicinal products.

5. (1) A person is guilty of an offence who, in the course of a business carried on by him, sells or supplies any active substance in circumstances where the active substance –

- (a) has not been manufactured in accordance with the principles of good manufacturing practice applicable to starting materials, and
- (b) is intended to be used, by the person to whom it is sold or supplied, in the manufacture of a medicinal product other than an exempt medicinal product.

(2) It is a defence to an offence under paragraph (1) for the person who sells or supplies the active substance to show that he could not, by reasonable diligence, have discovered that it was not manufactured in accordance with the principles of good manufacturing practice applicable to starting materials.

(3) A person guilty of an offence under paragraph (1) is liable –

- (a) on summary conviction, to a fine not exceeding level 5 on the uniform scale, imprisonment for a term not exceeding 3 months, or both, or

- (b) on conviction on indictment, to a fine, imprisonment for a term not exceeding 2 years, or both.

Requirements in respect of wholesale dealer's licences

Obligations in relation to wholesale dealings of medicinal products.

- 6. (1) The holder of a wholesale dealer's licence shall –
 - (a) comply with the principles of good distribution practice,
 - (b) ensure, within the limits of his responsibility as a distributor of medicinal products, the appropriate and continued supply of such medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstances corresponding to retail sale, that the needs of patients in the Bailiwick are covered,
 - (c) provide and maintain the staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under his licence, necessary to maintain the quality of, and ensure proper distribution of those medicinal products,
 - (d) inform the licensing authority and the regulatory authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or premises which have been approved from time to time by the licensing authority.

(2) Subject to paragraph (3) the holder of a wholesale dealer's licence shall not sell, offer for sale or supply any medicinal product unless –

- (a) there is a recognised marketing authorisation in force in respect of that product, and
- (b) the sale or offer for sale is in conformity with the provisions of that recognised marketing authorisation.

(3) The restriction in paragraph (2) does not apply to –

- (a) the sale, offer for sale or supply of an exempt medicinal product,
- (b) the sale, offer for sale or supply of a medicinal product which may be placed on the market without a marketing authorisation by virtue of Article 5(2) of the 2001 Directive (medicinal products during emergencies), or
- (c) the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation by virtue of legislation adopted by that State under Article 5(2) of the Directive.

(4) The holder of a wholesale dealer's licence shall –

- (a) keep all documents, relating to the sale of medicinal products to which his licence relates, necessary to facilitate the withdrawal or recall from sale of medicinal products in accordance with sub-paragraph

- (b),
- (b) have in place an emergency plan which will ensure effective implementation of the recall from the market of any medicinal products where such recall is –
- (i) ordered by the regulatory authority, the Agency, the MHRA, or by the competent authority of any EEA State, or
 - (ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation for, the product in question, and
- (c) keep such records, which may be in the form of purchases and sales invoices or on a computer or in any other form, which give, as a minimum, where any medicinal products are received and dispatched, the following information –
- (i) the date of receipt or, as the case may be, dispatch,
 - (ii) the name of the medicinal product,
 - (iii) the quantity of the medicinal product received, or as the case may be, dispatched, and
 - (iv) the name and address of, as may be applicable in each case, the person from whom the products are received or to whom they are sold or supplied.

(5) Where the holder of a wholesale dealer's licence imports from an EEA State any medicinal product in respect of which he is neither –

- (a) the holder of the recognised marketing authorisation in respect of that product,
- (b) nor acting on behalf of the holder referred to in subparagraph (a) in importing that product, -

he shall notify the holder referred to in subparagraph (a) and the licensing authority of his intention to import it.

(6) The licence holder, for the purpose of enabling the licensing authority or the regulatory authority to ascertain whether there are any grounds for suspending, revoking, terminating or varying any licence, shall permit, and provide all necessary facilities to enable any person duly authorised in writing by the regulatory authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the licence, as that person thinks fit.

Wholesale dealers to deal only with specified persons.

7. (1) The holder of a wholesale dealer's licence shall obtain supplies of medicinal product only from one or more of the following –

- (a) a holder of a manufacturer's licence or wholesale dealer's licence in respect of these products,
- (b) a holder of an authorisation granted by an EEA State authorising the manufacture of these products or their distribution by way of wholesale dealing, or
- (c) the Department.

(2) The holder of a wholesale dealer's licence shall distribute medicinal products by way of wholesale dealing only to –

- (a) a holder of a wholesale dealer's licence relating to these products,
- (b) a holder of an authorisation granted by the competent authority of an EEA State authorising the supply of these products by way of wholesale dealing,
- (c) any person who may lawfully sell those products by retail or who may lawfully supply them in circumstances corresponding to retail sale,
- (d) the Department, or
- (e) any person who may lawfully administer these products.

(3) Where any medicinal product is supplied to any person under paragraph (2)(c), the holder of the wholesale dealer's licence shall enclose with the product a document which makes it possible to ascertain –

- (a) the date on which the supply took place,
- (b) the name and pharmaceutical form of the product supplied,
- (c) the quantity of the product supplied, and
- (d) the names and addresses of the persons from whom the products were supplied to that licence holder.

- (4) The holder of the wholesale dealer's licence shall –
 - (a) keep a record of the information supplied under paragraph (3) for a minimum period of 5 years after the date on which it was supplied, and
 - (b) ensure, during that period, that the record is available to the regulatory authority for inspection.

Responsible persons.

8. (1) Every holder of a wholesale dealer's licence shall at all times have at his disposal the services of a person ("a **responsible person**") who, in the opinion of the regulatory authority –

- (a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate for performing the functions of the responsible person, and
 - (b) has experience in those procedures and activities which is adequate for those purposes.
- (2) The functions of the responsible person are to ensure that –
- (a) the conditions under which the licence has been granted have been, and are being complied with, and
 - (b) the quality of each medicinal product handled by the wholesale dealer's licence holder is being maintained in accordance with the requirements of each marketing authorisation applicable to the product.
- (3) The licence holder shall –

- (a) notify the regulatory authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of the responsible person,
- (b) notify the regulatory authority of any change to the responsible person,
- (c) not permit any person to act as responsible person other than –
 - (i) the person named in his licence as responsible person, or
 - (ii) subject to paragraph (4), any other responsible person whose name is notified to the regulatory authority.

(4) Where, after giving the licence holder and the person acting as a responsible person the opportunity of making representations to them (orally or in writing), the regulatory authority is of the opinion that –

- (a) the person so acting does not satisfy the provisions of paragraph (1) as respects qualifications and experience, or
- (b) the person so acting is failing to carry out the duties referred to in paragraph (2) adequately or at all, -

and has notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a responsible person.

General

Requirements to have effect as if provisions of licence

9. Each requirement set out in regulation 1, 2, 3, or 4, with which the holder of a manufacturer's licence must comply, and each requirement set out in regulation 6, 7, or 8, with which the holder of a wholesale dealer's licence must comply, has effect as if it is a provision of the licence concerned.

Interpretation.

10. (1) In these Regulations, unless the context requires otherwise -

"**exempt medicinal product**" means a medicinal product to which Article 5(1) of the 2001 Directive (special needs of specific patients under supervision of medical professionals) applies;

"**the Law**" means the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008^b;

"**licensing authority**", in relation to any licence, -

- (a) in the case of a licence issued or granted by the MHRA, means the MHRA, and
- (b) in any other case, means the person or authority that issued or granted the licence;

"**manufacturer's licence**" (except in regulation 4) includes a manufacturer's licence recognised in accordance with regulations made under section 7(3) of the Law, and a reference to a holder of a

^b Order in Council No. V of 2009.

manufacturer's licence shall be construed accordingly;

"the principles of good distribution practice" means the Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C63/03) published by the European Commission pursuant to Article 84 of the 2001 Directive;

"the principles of good manufacturing practice" means the principles and guidelines of good manufacturing practice set out in Commission Directive 2003/94/EC;

"qualified person" means –

- (a) a person whose qualifications and experience satisfy the requirements of Article 49 or 50 of the 2001 Directive, or
- (b) insofar as the activities of the qualified person are limited to traditional herbal medicinal products, a person who, without satisfying the requirements referred to in paragraph (a) –
 - (i) has been engaged in activities equivalent to those to be performed in accordance with Article 51 of the 2001 Directive in respect of traditional herbal medicinal products on or before 30th April 2011, and
 - (ii) has, whilst he continues to be engaged in activities equivalent to those to be performed in accordance with Article 51 of the 2001 Directive, been named as a qualified person in an application for a United Kingdom

manufacturer's licence which is made in accordance with the requirements of the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971^c before 30th April 2013;

"third country" means any country other than an EEA State;

"traditional herbal medicinal product" has the same meaning as in the 2001 Directive; and

"wholesale dealer's licence" includes a wholesale dealer's licence recognised in accordance with regulations made under section 7(3) of the Law, and a reference to a holder of a wholesale dealer's licence shall be construed accordingly.

(2) A reference in these Regulations to an enactment, or any provision or part of it, is a reference to it as amended, or re-enacted or re-made (with or without modification), or extended or applied by or under any enactment.

(3) The Interpretation (Guernsey) Law, 1948^d applies to the interpretation of these Regulations –

(a) throughout the Bailiwick, and

(b) for the avoidance of doubt, as it applies to the interpretation of an enactment.

^c United Kingdom S.I. 1971 No. 1448.

^d Ordres en Conseil Vol. XIII, p. 355.

(4) For the avoidance of doubt, unless paragraph (1) or the context otherwise requires, an expression used in these Regulations has the same meaning as in the Law.

Extent.

11. These Regulations have effect throughout the Bailiwick.

Citation and commencement.

12. These Regulations may be cited as the Medicines (Human) (Terms of Licences) (Bailiwick of Guernsey) Regulations, 2009 and come into force on the 1st October, 2009.

Dated this 1st day of October, 2009



A. H. Adam

Minister of the States Health and Social Services Department

For and on behalf of the Department

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set out the requirements which the holder of a manufacturer's or wholesale dealer's licence, in respect of medicinal products, must comply with. They reflect the requirements set out in Title IV of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.