GUERNSEY STATUTORY INSTRUMENT

2009 No. 62

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

Made	*1st October, 2009*
Coming into operation	*1st October, 2009*
Laid before the States	*, 2009*

ARRANGEMENT OF REGULATIONS

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

THE HEALTH AND SOCIAL SERVICES DEPARTMENT, in exercise of the powers conferred on it by sections 7(3), 18, and 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:-

Automatic recognition of United Kingdom licences.

1. (1) Subject to the conditions specified in these Regulations, every United Kingdom licence, other than one which relates to premises in the Bailiwick, is automatically recognised in the Bailiwick.

(2) Neither Schedule 2 nor Schedule 3 to the Law applies to this recognition.

Application for recognition of Bailiwick-based United Kingdom licences.

2. (1) A United Kingdom licence which relates to premises in the Bailiwick is recognised in the Bailiwick only if the Department recognises the licence under this regulation.

(2) An application for recognition under this regulation must be in a form and contain the documents, samples and other materials that the Department thinks fit.

(3) On receiving an application made in accordance with paragraph (2), the Department, acting on the advice of the Committee, shall recognise the licence if it is satisfied that –

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[a] Order in Council No. V of 2009.

(a) the applicant holds a United Kingdom licence which relates to premises in the Bailiwick,

(b) the applicant has supplied full details of that United Kingdom licence to the Department, and

(c) the applicant has supplied all further information that the Department thinks fit.

(4) Schedule 2 (except paragraphs 9 and 10) does not apply to a recognition under this regulation.

(5) A recognition under this regulation is subject to regulation 3(1).

Terms and conditions of United Kingdom licences.

3. (1) The terms and conditions of a United Kingdom licence recognised in the Bailiwick under regulation 1 or 2, including any standard provisions incorporated into a United Kingdom licence by virtue of the UK Regulations or any other enactment, have effect in the Bailiwick with any modifications necessary to reflect the recognition in the Bailiwick.

(2) In the case of a licence recognised under regulation 1, any renewal, expiry, variation, suspension, invalidation, revocation or restriction of a licence shall immediately and automatically have the same effect in the Bailiwick, without the need for any procedure set out in Schedule 2 or 3 to the Law.

Confirmation of licence.

4. (1) Where the Department is not satisfied that a person holds a United Kingdom licence, regulation 1 does not apply in relation to that person until the Department is so satisfied.

(2) Where the Department is not satisfied that a person who requires a licence has a United Kingdom licence, it may –

(a) publish notice of this in a manner and for a period it thinks fit,

(b) give notice of this to the persons it thinks fit, and

(c) require any person claiming to have such a licence to prove it to the satisfaction of the Department.

Meaning of United Kingdom licence.

5. (1) In these Regulations "**United Kingdom licence**" means –

(a) a United Kingdom wholesale dealer's licence, or

(b) a United Kingdom manufacturer's licence.

(2) In paragraph (1), "**United Kingdom wholesale dealer's licence**" means a licence for an action specified in paragraph (3) granted or recognised by the MHRA under and in accordance with –

(a) the Medicines Act,

(b) the UK Regulations or any other subordinate legislation made under that Act, or

(c) any other enactment -

and includes a wholesale dealer's licence within the meaning of the Medicines Act.

(3) The actions referred to in paragraph (2) are, in the course of a business, –

(a) to sell or offer for sale any medicinal product by way of wholesale dealing, or

(b) to distribute, otherwise than by way of sale, any proprietary medicinal product, or industrially produced medicinal product which has been imported but was not consigned from a Member State of the European Union.

(4) In paragraph (1), "**United Kingdom manufacturer's licence**" means a licence to manufacture or assemble any medicinal product, in the course of a business, granted or recognised by the MHRA under and in accordance with –

(a) the Medicines Act,

(b) the UK Regulations or any other subordinate legislation made under that Act, or

(c) any other enactment -

and includes a manufacturer's licence within the meaning of the Medicines Act.

Interpretation.

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

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

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[b] Order in Council No. V of 2009.

"**Medicines Act**" means the Medicines Act 1968[c];

"**UK Regulations**" means the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005[d]; and

"**United Kingdom licence**" has the meaning given by regulation 5.

(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[e] 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.

(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.

7. These Regulations have effect throughout the Bailiwick.

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c An Act of Parliament, Chapter 67 of 1968.

d United Kingdom S.I. 2005 No. 2789.

e Ordres en Conseil Vol. XIII, p. 355.

Citation and commencement.

8. These Regulations may be cited as the Medicines (Human) (Recognition 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. Hunter

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*)

Under the Medicines Law, a licence is needed to manufacture or sell by wholesale medicinal products. These Regulations provide that a wholesale dealer's licence or manufacturer's licence, granted by the Medicines and Healthcare products Regulatory Agency in the United Kingdom, shall be automatically recognised in the Bailiwick. If the licence relates to premises in the Bailiwick, the licence holder must formally apply to the Department for recognition.