

GUERNSEY STATUTORY INSTRUMENT

2009 No. 63

**The Medicines (Human) (Exemptions and Recognition of
Marketing Authorisations) (Bailiwick of Guernsey)
Regulations, 2009**

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SCHEDULE: Offences and Penalties

**The Medicines (Human) (Exemptions and Recognition of
Marketing Authorisations) (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>

THE HEALTH AND SOCIAL SERVICES DEPARTMENT, in exercise of the powers conferred on it by sections 7(3) and (3A), 12(3), 15, 18, 73(11), 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 marketing authorisations.

1. (1) Subject to these Regulations, a United Kingdom marketing authorisation is automatically recognised in the Bailiwick.

(2) For the avoidance of doubt, neither Schedule 2 nor Schedule 3 to the Law applies to this recognition.

Automatic recognition of European Union marketing authorisations.

2. (1) Subject to these Regulations, a European Union marketing authorisation is automatically recognised in the Bailiwick.

(2) For the avoidance of doubt, neither Schedule 2 nor Schedule 3 to the Law applies to this recognition.

^a Order in Council No. V of 2009.

Terms and conditions of recognised marketing authorisations.

3. (1) The terms and conditions of a United Kingdom or European Union marketing authorisation recognised under regulation 1 or 2, including any provisions incorporated into it by virtue of any enactment, have effect in the Bailiwick with any modifications necessary to reflect that recognition in the Bailiwick.

(2) Any renewal, expiry, variation, suspension, invalidation, revocation, restriction, or other thing done to that marketing authorisation shall immediately have the same effect in the Bailiwick.

(3) For the avoidance of doubt, any notice to the holder of a United Kingdom traditional herbal registration under regulation 7 of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005^b -

(a) suspending the use, supply or marketing of a product to which the registration relates, or

(b) revoking that suspension -

shall be regarded as falling within paragraph (2).

(4) For the avoidance of doubt, this regulation and regulations 4 to 10 have effect as conditions subject to which -

(a) a United Kingdom marketing authorisation is recognised, under regulation 1, and

(b) a European Union marketing authorisation is recognised, under regulation 2.

^b United Kingdom S.I. 2005 No. 2750.

Exception for abortifacients and contraceptives.

4. (1) This regulation applies to any United Kingdom or European Union marketing authorisation in respect of a medicinal product for human use whose purpose is –

(a) inducing an abortion in women, or

(b) contraception.

(2) If it thinks fit, the Department may determine –

(a) not to recognise that marketing authorisation in the Bailiwick, or

(b) to recognise that marketing authorisation in the Bailiwick subject to a variation of its terms and conditions (including any classification as prescription only medicine).

(3) Subject to regulation 5, a determination under paragraph (2) has effect notwithstanding any other provision of these Regulations to the contrary.

Procedure where marketing authorisation not recognised.

5. (1) Where the Department makes a determination under regulation 4(2) –

(a) neither Schedule 2 nor Schedule 3 to the Law applies to the marketing authorisation concerned,

(b) the Department shall publish notice of its determination in a manner and for a period it thinks fit, and

- (c) the Department shall give notice of its determination to the MHRA and the holder of the marketing authorisation within 2 weeks of the date of making its determination
- (2) The determination does not take effect until –
- (a) notice of it has been published in accordance with paragraph (1)(b), or
 - (b) any later time the Department stipulates in the notice.

Confirmation of marketing authorisation.

6. (1) Where the appropriate Department is not satisfied that a medicinal product has a United Kingdom or European Union marketing authorisation, regulation 1 or (as the case may be) 2 shall not apply to that medicinal product until the Department is so satisfied.

(2) Where the appropriate Department is not satisfied that a medicinal product has a United Kingdom or European Union marketing authorisation, it may –

- (a) publish notice of this in a manner and for a period it thinks fit,
- (b) give notice of this to such persons as it thinks fit, and
- (c) require any person marketing a medicinal product and claiming to have such an authorisation for the product to prove it to the satisfaction of that Department.

Obligations in respect of holders of recognised marketing authorisations.

7. (1) Each holder of a recognised marketing authorisation shall comply with all obligations which apply to him by virtue of the 1993 Regulation or the 2001 Directive.

(2) Where a person is required to provide any information or furnish any document to the regulatory authority or the MHRA, by or under any provision of the 1993 Regulation, the 2001 Directive, or these Regulations, and no time is specified in that provision within which that obligation is to be performed, it shall be performed within such time as may be specified in a written notice served on that person by the regulatory authority or (as the case may be) the MHRA.

Pharmacovigilance.

8. (1) The holder of a recognised marketing authorisation shall –

- (a) maintain a record of reports of suspected side-effects of which he is aware, in accordance with the 2001 Directive,
- (b) make the record available for inspection by any person authorised by the regulatory authority, and
- (c) allow that person to take copies of the record.

(2) If the regulatory authority so directs, the holder of the recognised marketing authorisation shall furnish the regulatory authority with a copy of any report referred to in paragraph (1) of which he has a record, or of which he is or subsequently becomes aware.

(3) The holder of a recognised marketing authorisation shall keep the documents necessary to facilitate the withdrawal or recall from sale or supply of any medicinal product to which the authorisation relates.

(4) On request from the regulatory authority, the holder of a recognised marketing authorisation shall provide that regulatory authority with data on the volume of sales of the product to which the authorisation relates.

Withdrawal from the market.

9. (1) If the holder of a recognised marketing authorisation is served a notice in respect of that authorisation which satisfies the conditions of paragraph (2), he shall take all reasonably practicable steps to –

- (a) withdraw from the market and recover possession of the products to which the notice relates, within the time and for the period specified in the notice, and
- (b) inform wholesalers, retailers, practitioners, patients and others who may be in possession of those products of the withdrawal, the reasons for it, and the actions (if any) to be taken to restrict or prevent further use, supply or marketing of those products.

(2) The conditions referred to in paragraph (1) are that the notice

- (a) is in writing,
- (b) is issued by the regulatory authority or the MHRA for the purpose of –
 - (i) this regulation,
 - (ii) regulation 6(5) of the Medicines for Human Use (Marketing Authorisations Etc.)

Regulations 1994^c,

(iii) regulation 10 of the Medicines (Homeopathic Medicinal Products for Human Use)

Regulations 1994^d,

(iv) regulation 7 of the Medicines (Traditional Herbal Medicinal Products for Human Use)

Regulations 2005^e, or

(v) any other provision of any enactment,

(c) is in accordance with the provisions of the 2001 Directive, and

(d) specifies the grounds for its issue.

(3) The notice need not be served in the Bailiwick.

(4) The notice may relate to all products to which that marketing authorisation relates or to specified batches of the products.

^c United Kingdom S.I. 1994 No. 3144.

^d United Kingdom S.I. 1994 No. 105.

^e United Kingdom S.I. 2005 No. 2750.

Urgent safety restrictions.

10. Where –

- (a) under regulation 6A of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994^f, regulation 8 of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005^g, or any other provision of any enactment, the MHRA, or
- (b) under the 2003 Regulation, the European Commission–

has imposed an urgent safety restriction, the holder of the recognised marketing authorisation in respect of which it is imposed shall implement the restriction within the period specified in the restriction.

Offences and penalties.

11. The provisions of the Schedule have effect.

Meaning of "United Kingdom marketing authorisation".

12. (1) In these Regulations, "United Kingdom marketing authorisation" means an authorisation to market in the United Kingdom –

- (a) a homoeopathic medicinal product for human use, to which the 2001 Directive applies and which fulfils the conditions laid down in Article 14(1) of that Directive, granted or recognised by the MHRA under and in accordance with –
 - (i) the Medicines (Homeopathic Medicinal

^f United Kingdom S.I. 1994 No. 3144.

^g United Kingdom S.I. 2005 No. 2750.

Products for Human Use) Regulations 1994^h,

(ii) the 2001 Directive, or

(iii) any other enactment, -

including a certificate of registration within the meaning of the regulations specified in subparagraph (i),

(b) a traditional herbal medicinal product for human use, granted or recognised by the MHRA under and in accordance with -

(i) the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005ⁱ,

(ii) the 2001 Directive, or

(iii) any other enactment, -

including a traditional herbal registration within the meaning of the regulations specified in subparagraph (i),

(c) a medicinal product for human use (including a national homoeopathic product, but excluding any product specified in paragraph (a) or (b)), granted or recognised by the MHRA under and in accordance with -

^h United Kingdom S.I. 1994 No. 105.

ⁱ United Kingdom S.I. 2005 No. 2750.

- (i) the Medicines Act or any subordinate legislation made under that Act,
 - (ii) the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994^j,
 - (iii) the Medicines for Human Use (National Rules for Homoeopathic Products) Regulations 2006^k,
 - (iv) the 2001 Directive, or
 - (v) any other enactment, or
- (d) a medicinal product for veterinary use, granted or recognised by the Secretary of State under and in accordance with –
- (i) the Medicines Act or any subordinate legislation made under that Act,
 - (ii) the Veterinary Medicines Regulations 2008^l, or
 - (iii) any other enactment.

(2) Without prejudice to the generality of paragraph (1), a United Kingdom marketing authorisation includes –

^j United Kingdom S.I. 1994 No. 3144.

^k United Kingdom S.I. 2006 No. 1952.

^l United Kingdom S.I. 2008 No. 2297.

- (a) a marketing authorisation (including a marketing authorisation in respect of a national homoeopathic product),
- (b) a product licence,
- (c) a licence of right, and
- (d) an authorisation under Article 126a of the 2001 Directive,

within the meaning of the relevant enactments specified in paragraph (1).

Interpretation.

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

"**the 1993 Regulation**" means Regulation (EEC) No. 2309/1993 of the European Parliament and Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products;

"**the 2003 Regulation**" means Regulation (EC) No. 1085/2003 of the European Parliament and Council concerning the examination of applications of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No. 2309/1993;

"**the 2004 Regulation**" means Regulation (EC) No. 726/2004 of the European Parliament and Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

“Bailiwick” means the Bailiwick of Guernsey;

"European Union marketing authorisation" means an authorisation to market a medicinal product for human or veterinary use in the European Union granted by the Agency under the 1993 Regulation or any other enactment;

"homoeopathic medicinal product" has the meaning given by section 7 of the Law;

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

"Medicines Act" means the Medicines Act 1968ⁿ;

"national homoeopathic product" means a homoeopathic medicinal product which –

- (a) does not satisfy the conditions set out in Article 14(1) of the 2001 Directive, and
- (b) is indicated for the relief or treatment of minor symptoms or minor conditions in humans –

and for the purposes of this definition, symptoms or conditions are minor if they can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor;

"prescription only medicine" means a medicinal product of a

^m Order in Council No. V of 2009.

ⁿ An Act of Parliament, Chapter 67 of 1968.

description or falling within a class specified in section 2 of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009;

"side-effect" includes adverse reaction;

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

"United Kingdom certificate of registration" means a United Kingdom marketing authorisation of the kind described by regulation 12(1)(a);

"United Kingdom marketing authorisation" has the meaning given by regulation 12; and

"United Kingdom traditional herbal registration" means a United Kingdom marketing authorisation of the kind described by regulation 12(1)(b).

(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^o 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.

^o 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.

Section 73 exemptions.

14. Neither subsection (2) nor (4) of section 73 of the Law applies in relation to any medicinal product for which there is a recognised marketing authorisation by virtue of –

- (a) a United Kingdom certificate of registration in force in respect of that product, or
- (b) a United Kingdom traditional herbal registration in force in respect of that product.

Transitional exemption for traditional herbal medicinal products.

15. (1) This regulation applies to a herbal remedy if –

- (a) in producing the remedy, the plant or plants are not subjected to any treatment or process other than drying, crushing or comminuting, and
- (b) the remedy is, or is to be, sold or supplied –
 - (i) under a designation which only specifies the plant or plants and the process and does not apply any other name to the remedy, and
 - (ii) without any written recommendation (whether by means of a labelled container or package or a leaflet or in any other way) as to the use of the remedy.

(2) None of the restrictions in section 7(2) or (4), or section 8(2), (7), or (8), apply in respect of a herbal remedy to which this regulation applies that was on the market in the Bailiwick as at the 30th April, 2004 without a marketing authorisation.

(3) This regulation expires on 1 May 2011.

(4) For the avoidance of doubt, despite the exemption in paragraph (2), where a recognised marketing authorisation is in force at any time in respect of a herbal remedy exempted under paragraph (2), every provision in the Law, or any Ordinance, regulation, or order made under the Law, applying in respect of recognised marketing authorisations or holders of such authorisations, applies to the recognised marketing authorisation in question and to the holder of that authorisation.

Extent.

16. These Regulations have effect throughout the Bailiwick.

Citation and commencement.

17. These Regulations may be cited as the Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009 and come into force on the 1st October, 2009.

Dated this 1st day of October, 2009

A handwritten signature in black ink, appearing to read 'A. H. Hunter'.

A. H. Hunter

Minister of the States Health and Social Services Department

For and on behalf of the Department

SCHEDULE

Regulation 11

OFFENCES AND PENALTIES

Offences

1. (1) Without prejudice to any other sanction which may be available for the enforcement of terms and conditions of marketing authorisations, any holder of a recognised marketing authorisation who contravenes any term or condition of the authorisation is guilty of an offence.

(2) For the avoidance of doubt, any suspension of the kind referred to in regulation 3(3) shall be regarded as a condition of the recognised marketing authorisation concerned.

2. Any person who contravenes regulation 9(1) or 10 is guilty of an offence.

3. Any holder of a recognised marketing authorisation who fails promptly to –

- (a) keep the MHRA updated in relation to information concerning the product or any connected matter as required by the 2001 Directive or the 2004 Regulation,
- (b) take any steps reasonably necessary to take account of technical and scientific progress for the purposes of making any changes or amendments as required by the 2004 Regulation or Article 23 or any other provision of the 2001 Directive,
- (c) introduce any changes or make any amendments that

may be required in accordance with Article 23 or any other provision of the 2001 Directive,

- (d) provide information to the MHRA as required by the third or fourth paragraph of Article 23, the first paragraph of Article 23a, or any other provision, of the 2001 Directive,
- (e) provide information to the Agency, the European Commission or the MHRA as required by the 2004 Regulation, or
- (f) submit any application to the MHRA or the European Community to make any changes or variation as required by the 2004 Regulation or Article 23 or any other provision of the 2001 Directive -

is guilty of an offence.

4. Any holder of a recognised marketing authorisation who fails to provide the regulatory authority or (as the case may be) the MHRA any data requested by it pursuant to the final paragraph of Article 23 or Article 23a of the 2001 Directive -

- (a) where it has served written notice on the holder under regulation 7(2) in relation to the request, within the time specified in that notice, or
- (b) where there is no such notice, promptly -

is guilty of an offence.

5. Any holder of a recognised marketing authorisation who fails to

provide the regulatory authority any data requested by it pursuant to regulation 8(4)

- (a) where it has served written notice on the holder under regulation 7(2) in relation the request, within the time specified in that notice, or
- (b) where there is no such notice, promptly -

is guilty of an offence.

6. Any holder of a recognised European Union marketing authorisation who fails to provide the Agency with any data requested pursuant to the final paragraph of Article 13(4) or the final paragraph of Article 26 of the 2004 Regulation -

- (a) within the time (if any) specified in the request, or
- (b) promptly, if no such time is specified -

is guilty of an offence.

Penalties

7. A person guilty of an offence under any of the preceding paragraphs is liable -

- (a) on summary conviction to a fine not exceeding level 3 on the uniform scale, or
- (b) on conviction on indictment, to a fine, or to imprisonment for a term not exceeding 2 years, or to both.

Miscellaneous

8. Where the holder of a recognised marketing authorisation is charged with an offence under these Regulations in respect of anything which has been manufactured or assembled to his order by another person and had been so manufactured or assembled as not to comply with a term or condition of that authorisation, it shall be a defence for him to prove –

- (a) that he had communicated the terms and conditions relating to the marketing authorisation to that other person, and
- (b) that he did not know, and could not by the exercise of reasonable care have known, that the term or condition had not been complied with.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Under the Medicines Law, all medicinal products must have a marketing authorisation. These Regulations provide for the automatic recognition of certain marketing authorisations. These include: authorisations in the United Kingdom for products for human use granted by the Medicines and Healthcare products Regulatory Agency, and authorisations in the European Union for products for human or veterinary use granted by the European Medicines Agency. There are exceptions for abortifacients and contraceptives. Holders of recognised marketing authorisations must comply with conditions attaching to those marketing authorisations, including those in respect of pharmacovigilance under Title IX of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use. There are transitional exemptions for traditional herbal medicinal products.