GUERNSEY STATUTORY INSTRUMENT

2019 No. 39

The Medicines (Human and Veterinary) (Brexit) (Bailiwick of Guernsey) Regulations, 2019

Made	*26th March, 2019*
Coming into operation	*See Regulation 10*
Laid before the States	*, 2019*

THE POLICY & RESOURCES COMMITTEE, in exercise of the powers conferred on it by sections 5(1) and 11 of the European Union (Brexit) (Bailiwick of Guernsey) Law, 2018[a], and upon receipt of the certificate required under section 5(3) of that Law, hereby makes the following Regulations:-

Amendments to Medicines Law.

1. The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 ("**the principal Law**") is amended as follows.

2. In section 7(6) of the principal Law, in the definition of "**homoeopathic medicinal product**", immediately after "member State,", insert "the United Kingdom,".

3. In section 8 of the principal Law –

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a Order in Council No. I of 2019.

b Order in Council No. V of 2019; as amended by Ordinance No. XXIV of 2009; No. XLI of 2013; and No. IX of 2016.

(a) immediately after subsection (2)(a), insert the following paragraph –

"(aa) the United Kingdom, or",

(b) immediately after subsection (7)(b)(i), insert the following subparagraph –

"(ia) from the United Kingdom, or", and

(c) in subsection (7)(b)(ii), immediately before "any", insert "from".

4. In section 35(5) of the principal Law, immediately before paragraph (a), insert the following paragraph –

"(aa) in the circumstances specified in section 35A(1),".

5. Immediately after section 35 of the principal Law, insert the following section –

"**Sale etc. by a pharmacist in accordance with a serious shortage protocol.**

35A. (1) Section 35(4)(a) does not apply to the sale or supply of a medicinal product by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the medicinal product is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol ("**SSP**").

(3) Condition B is that the requirements of the SSP are satisfied in respect of to whom, and subject to what conditions, the medicinal product may be sold or supplied for the purpose of being administered.

(4) Condition C is that the sale or supply of the medicinal product is by or under the supervision of a pharmacist who is of the opinion, in the exercise of the pharmacist's professional skill and judgement, that –

(a) in a case to which subsection (5)(b)(i) applies, the sale or supply of a different strength, quantity or pharmaceutical form of the medicinal product to the strength, quantity or pharmaceutical form of the medicinal product ordered by the prescriber is reasonable and appropriate, or

(b) in a case to which subsection (5)(b)(ii) applies, the sale or supply of –

(i) a medicinal product other than the medicinal product ordered by the prescriber is reasonable, and

(ii) the substituted medicinal product, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this section, a SSP is a written protocol that–

(a) is issued by an office-holder in circumstances where the United Kingdom, the Bailiwick of Guernsey or any part of the United Kingdom or the Bailiwick of Guernsey is, in the opinion of the office-holder, experiencing or may experience a serious shortage of any medicinal products of a description, or falling within a class, specified in an Ordinance under section 35,

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP –

(i) of a different strength, quantity or pharmaceutical form of the medicinal products to the strength, quantity or pharmaceutical form ordered by the prescriber, or

(ii) of a medicinal product other than the medicinal product ordered by the prescriber,

(c) provides, in a case to which paragraph (b)(ii) applies, that the other medicinal product is to be–

(i) a generic version of the medicinal product being substituted, or that both

products are generic versions of another medicinal product,

(ii) in the case of a biological medicinal product, a similar medicinal product to the medicinal product being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii) a medicinal product that has a similar therapeutic effect to the medicinal product being substituted,

(d) specifies the period for which, and the parts of the Bailiwick of Guernsey (which may be all of the Bailiwick) in which, the protocol is to have effect, and

(e) is published by the office-holder in any manner the office-holder considers appropriate.

(6) A SSP expires at the close of the day which is twenty-eight days after the day on which it is issued, unless prior to this the SSP is endorsed by the Committee for Health & Social Care.

(7) As soon as is reasonably practicable after the end of one year beginning on the day on which the first protocol issued under this section has effect, the Committee for Health & Social Care must —

(a) review the operation of this section with a view to evaluating whether there have been any

adverse consequences (including adverse consequences for patient safety) as a consequence of the operation of this section,

(b) set out the conclusions of the review in a report, and

(c) publish the report in any manner the committee considers appropriate.

(8) In subsection (5) –

"**biological medicinal product**" has the meaning given in the third indent of paragraph 3.2.1.1.(b) of Annex I to the 2001 Directive, and

"**office-holder**" means –

(a) the Chief Pharmacist,

(b) the Director of Public Health, or

(c) the person who is for the time being the Medical Director appointed by the Committee for Health & Social Care.".

6. Immediately after section 136(1) of the principal Law, insert the following subsections –

"(1A) Unless the context requires otherwise, any reference in this Law to the 2001 Directive or any other Community provision (within the meaning

given by section 3(1) of the European Communities (Implementation) (Bailiwick of Guernsey) Law, 1994[c])), or any policy, guideline or other document made or issued under any Community provision, has effect as if in that Community provision, policy, guideline or other document –

(a) a reference to the Community, the European Union or a Member State or Member States of the European Union includes a reference to the United Kingdom and the Bailiwick of Guernsey,

(b) a reference to placing any thing on the market includes a reference to placing the thing on the market in the United Kingdom or the Bailiwick of Guernsey, and

(c) a reference to a competent authority or regulatory authority includes a reference to the MHRA and the Committee for Health & Social Care.

(1B) Nothing in subsection (1A) limits the effect of section 2 of the European Union (Brexit) (Bailiwick of Guernsey) Law, 2018.".

Amendments to the 2009 Regulations.

7. The Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009[d] are amended as set out in the Schedule.

Extent.

8. These Regulations have effect in the Bailiwick of Guernsey.

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c Ordres en Conseil Vol. XXXV(1), p. 65.

d G.S.I. No. 63 of 2009.

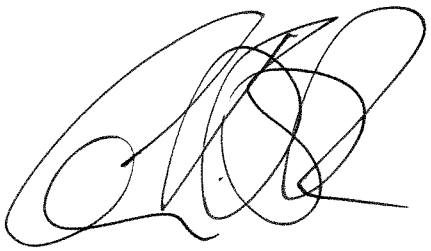
Citation.

9. These Regulations may be cited as the Medicines (Human and Veterinary) (Brexit) (Bailiwick of Guernsey) Regulations, 2019.

Commencement.

10. These Regulations come into force on exit day, and for this purpose "exit day" has the meaning given by section 12(1) of the European Union (Brexit) (Bailiwick of Guernsey) Law, 2018.

Dated this 26th day of March, 2019



G. A. ST PIER

President of the Policy & Resources Committee

For and on behalf of the Committee

SCHEDULE

AMENDMENTS TO THE MEDICINES (HUMAN) (EXEMPTIONS AND RECOGNITION OF MARKETING AUTHORISATIONS) (BAILIWICK OF GUERNSEY) REGULATIONS, 2009 ("**THE 2009 REGULATIONS**")

Provision	**Amendment**
New regulation 2A	In the 2009 Regulations, immediately after regulation 2, insert the following regulation – "**Automatic recognition of Member State marketing authorisations.** **2A.** (1) Subject to these Regulations, a Member State 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.".
Regulation 3(1)	For "or European Union", substitute ", European Union or Member State". For "or 2", substitute ", 2 or 2A"
Regulation 3(4)	For the full stop at the end of paragraph (b), substitute ", and". Immediately after paragraph (b), insert the following paragraph – "(c) a Member State marketing authorisation is recognised, under regulation 2A.".
Regulation 4(1)	For "or European Union", substitute ", European Union or Member State".
Regulation 6(1)	For "or European Union", substitute ", European Union or Member State". For "or (as the case may be) 2", substitute ", 2 or (as the case may be) 2A".
Regulation 6(2)	For "or European Union", substitute ", European Union or Member State".
Regulation 7(1)	For "or the 2001 Directive", substitute ", the 2001 Directive or any enactment".
Regulation 7(2)	Immediately after "the 2001 Directive,", insert "any enactment".
Regulation	Immediately after "the 2001 Directive", insert "and any applicable

8(1)(a)	enactment".
Regulation 9(2)(c)	Immediately after "the 2001 Directive", insert "and any applicable enactment".
Regulation 10	At the end of paragraph (b), substitute "-" with ", or". Immediately after paragraph (b), insert the following paragraph – "(c) under any enactment in force in a Member State, the regulatory authority of the Member State concerned –".
Regulation 13(1)	Insert the following definitions in the appropriate alphabetical order– ""**enactment**" – (a) in relation to a United Kingdom marketing authorisation, includes any enactment in force in the United Kingdom, and (b) in relation to a Member State marketing authorisation, includes any enactment in force in the Member State,", ""**Member State**" means a Member State of the European Union,", ""**Member State marketing authorisation**" means an authorisation to market a medicinal product for human use in a Member State, granted or recognised by the competent authority of the Member State concerned under any enactment in force in that Member State,", ""**regulatory authority**" – (a) in relation to a United Kingdom marketing authorisation, means the MHRA, (b) in relation to a European Union marketing authorisation, means the European Medicines Agency, and (c) in relation to a Member State marketing authorisation, means the competent authority which has the function of regulating medicinal products under any enactment of the Member State concerned,".
Regulation 14	For the full stop at the end of paragraph (b), substitute ", or". Immediately after paragraph (b), insert the following paragraphs – "(c) a European Union marketing authorisation, or (d) a Member State marketing authorisation."
Paragraph	For this subparagraph, substitute the following subparagraph –

3(a) of the Schedule	"(a) keep the regulatory authority updated in relation to information concerning the product or any connected matter as required by the 2001 Directive, the 2004 Regulation or any applicable enactment,".
Paragraph 3(b) and (c) of the Schedule	Immediately after "the 2001 Directive," in both subparagraphs, insert "or any applicable enactment".
Paragraph 3(d) and (e) of the Schedule	For these subparagraphs, substitute the following subparagraph – "(d) provide information to the regulatory authority 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, the 2004 regulation or any applicable enactment, or".
Paragraph 3(f) of the Schedule	For this subparagraph, substitute the following subparagraph – "(f) submit any application to the regulatory authority to make any changes or variation as required by the 2004 Regulation, Article 23 or any other provision of the 2001 Directive, or any applicable enactment –".
Paragraph 4 of the Schedule	Delete "or (as the case may be) the MHRA" Immediately after "the 2001 Directive", insert "or any applicable enactment".

EXPLANATORY NOTE

(*This note is not part of the Regulations*)

These Regulations are made in consequence of the withdrawal of the United Kingdom from the European Union.

Regulations 2 to 6 amend the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 ("**the principal Law**").

Regulations 2 and 3 amend sections 7(6) and 8(2) and (7) of the principal Law to refer to the United Kingdom alongside references to Member States of the European

Union.

Regulations 4 and 5 amend the principal Law in order to provide for the sale or supply of prescription only medicines by retail pharmacy businesses under a serious shortage protocol issued and published by one of three office-holders (the Chief Pharmacist, Director of Public Health, or Medical Director). An office-holder will be authorised to issue such a protocol where, in his or her opinion, the United Kingdom, the Bailiwick of Guernsey or any part of the United Kingdom or Bailiwick of Guernsey is experiencing or may experience a serious shortage of particular prescription only medicines.

A serious shortage protocol, if issued, will allow for substitution, in restricted circumstances, of a different quantity of a prescription only medicine, or a different prescription only medicine, to that ordered by the prescriber. A protocol would expire unless endorsed by the Committee *for* Health and Social Care within 28 days of being issued.

Regulation 6 inserts a new subsection (1A) in section 136 of the principal Law. This new subsection provides that references in Community provisions (or documents made or issued under these) to the European Community, the European Union or Member States include a reference to the United Kingdom and the Bailiwick of Guernsey; references to placing things on the market are to be regarded to include a reference to placing things on the market in the United Kingdom or the Bailiwick of Guernsey; and references to competent authorities or regulatory authorities are to be regarded to include a reference to the MHRA or the Committee for Health & Social Care.

Regulation 7 and the Schedule to these Regulations amend various provisions in the Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009 ("**the 2009 Regulations**"). These amendments provide for automatic recognition, under the principal Law, of

marketing authorisations issued by the competent authority of any Member State of the European Union, and for consequential amendments in the 2009 Regulations.

Regulations 8, 9 and 10 are the extent, citation and commencement provisions respectively.

These Regulations will come into force on 'exit day', that is when the United Kingdom leaves the European Union, which is either 11pm on 29th March, 2019 or another day and time appointed by regulations made by the Policy & Resources Committee under the European Union (Brexit) (Bailiwick of Guernsey) Law, 2018.