

Island of



Guernsey

Ordinance of the States

XXIV
2009

Made29th September, 2009

Coming into Operation1st October, 2009

The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 (Commencement and Amendment) Ordinance, 2009

**The Medicines (Human and Veterinary)
(Bailiwick of Guernsey) Law, 2008
(Commencement and Amendment) Ordinance, 2009**

ARRANGEMENT OF SECTIONS

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SCHEDULE: Amendments to the Law

**The Medicines (Human and Veterinary)
(Bailiwick of Guernsey) Law, 2008
(Commencement and Amendment) Ordinance, 2009**

THE STATES, in exercise of the powers conferred on them by sections 131, 132 and 137(2) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008^a and all other powers enabling them in that behalf, hereby order:-

Commencement of Law.

1. (1) Subject to subsections (2) and (3), and sections 2 to 4, the Law comes into force on the 1st October, 2009.

(2) Part IV of the Law does not come into force until a date appointed by further Ordinance.

(3) Part VII of the Law does not come into force until a date appointed by further Ordinance, except to the extent necessary to give effect to section 3 of this Ordinance.

Limited commencement of section 4.

2. Section 4 of the Law comes into force on the 1st October 2009 only to the extent necessary to establish and provide for the sub-committee for human medicines referred to in subsection (1)(a) of that section, but not the sub-committee for animal medicines referred to in subsection (1)(b) of that section.

^a Order in Council No. V of 2009.

Commencement of section 82.

3. Section 82 of the Law comes into force on the 1st October 2009.

Limited commencement of section 135.

4. Section 135 of the Law comes into force on the 1st October 2009 only to the extent necessary to repeal the provisions set out below –

<i>Ordinance</i>	<i>Extent of repeal</i>
The Pharmacists, Poisons and Pharmacy Ordinance, 1970 ^b	Parts I, III, IV and V of the Ordinance.
The Penicillin and Allied Substances Ordinance, 1950 ^c	The whole Ordinance.

Amendments to the Law.

5. The Law is amended as set out in the Schedule.

Transitional provision relating to pharmacies.

6. Until Part IV of the Law comes into force, the definition of "**registered pharmacy**" in section 136(1) shall be read as if that definition were substituted by the following definition –

" **registered pharmacy**" means premises where –

- (a) a retail pharmacy business is carried on, and
- (b) medicinal products, other than medicinal products on a general sale list, are sold by retail under the personal

^b Recueil d'Ordonnances Tome XVI, p. 236.

^c Recueil d'Ordonnances Tome X, p. 64.

control, management, or supervision of a pharmacist who is resident in the Bailiwick –

and for the purposes of this definition "**medicinal product on a general sale list**" means a medicinal product specified for the purposes of section 28(1) of the Law (general sale lists);".

Interpretation.

7. (1) In this Ordinance, unless the context otherwise requires, "**the Law**" means the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008^d.

(2) A reference in this Ordinance 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 this Ordinance throughout the Bailiwick.

(4) For the avoidance of doubt, unless the context otherwise requires, an expression used in this Ordinance has the same meaning as in the Law.

Extent.

8. This Ordinance has effect throughout the Bailiwick of Guernsey.

Citation and commencement.

9. This Ordinance may be cited as the Medicines (Human and

^d Order in Council No. V of 2009.

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

Veterinary) (Bailiwick of Guernsey) Law, 2008 (Commencement and Amendment) Ordinance, 2009, and comes into force on the 1st October, 2009.

K.H. TOUGH,
Her Majesty's Greffier.

SCHEDULE

AMENDMENTS TO THE LAW

Provision	Amendment
Section 7(2)	In the proviso after paragraph (d), for the words "or recognised" substitute the words "or a licence, by or under regulations made under subsection (3),".
Section 7(3)	For the words "is recognised", substitute the words "is or may be recognised".
Section 7	<p>Immediately after subsection (3), insert the following subsection –</p> <p style="padding-left: 40px;">"(3A) Any regulations made under subsection (3) may –</p> <p style="padding-left: 80px;">(a) impose duties and obligations on persons who do not require a licence, or on persons who hold a licence or marketing authorisation recognised by or under those regulations,</p> <p style="padding-left: 80px;">(b) create indictable offences, summary offences, or offences triable either way, in respect of those duties and obligations, and</p> <p style="padding-left: 80px;">(c) specify penalties for each offence, not exceeding–</p> <p style="padding-left: 120px;">(i) on summary conviction, a fine of level 3</p>

Provision	Amendment
	<p>on the uniform scale, and</p> <p>(ii) on conviction on indictment, a fine, or imprisonment for a term of 2 years, or both."</p>
Section 7(4)	For the word "accordance", substitute the word "compliance".
Section 7(5)	Insert the word "or" at the end of paragraph (a), and omit paragraph (b).
Section 8	<p>Immediately after subsection (6), insert the following subsection –</p> <p>"(6A) The Department may by regulations –</p> <p>(a) impose duties and obligations in respect of the sale or supply by any person of starting materials used or intended to be used in the manufacture of medicinal products,</p> <p>(b) create indictable offences, summary offences, or offences triable either way, in respect of those duties and obligations, and</p> <p>(c) specify penalties for each offence, not exceeding-</p> <p>(i) on summary conviction, a fine of level 5 on the uniform scale, or imprisonment for a term of 3 months, or both, and</p>

Provision	Amendment
	(ii) on conviction on indictment, a fine, or imprisonment for a term of 2 years, or both."
Section 11(e)	For the word "Department", substitute the word "States".
Section 12	Omit subsection (2).
Section 12(3)	Omit the words "which are sold, supplied, prepared or assembled".
Section 12(4)	For the word "Ordinance", substitute the word "order".
Section 15(3)	For the word "Ordinance", substitute the word "order".
Section 16(2)	<p>For paragraph (a) and the words preceding it, substitute the following words and paragraphs –</p> <p>"Section 7(2)(a), (b), and (d) shall not have effect in relation to a person in respect of his selling, supplying, procuring the sale or supply, or placing on the market in the Bailiwick, of a medicinal product if –</p> <p>(aa) it is not, and does not involve, an exportation of the product other than an exportation exempt under subsection (2B) from the prohibitions in section 7(2)(a) and (b), and (4),</p> <p>(ab) the condition in either paragraph (a) or paragraph (b) of subsection (2A) is satisfied,</p> <p>(a) in the course of a business carried on by him,</p>

Provision	Amendment
	<p>medicinal products of the same description as that medicinal product were sold, supplied, or procured to be sold or supplied, at any time before the first appointed day, and".</p>
Section 16	<p>Immediately after subsection (2), insert the following subsections –</p> <p>"(2A) The conditions referred to in subsections (2)(ab), (2B)(a), and (5)(b) are –</p> <ul style="list-style-type: none"> (a) that product was imported into the Bailiwick before the first appointed day, or the importation of that product is exempt under subsection (3) from the prohibitions in sections 7(4) and 8(2), or (b) that product was manufactured or assembled in the Bailiwick before the first appointed day, or its manufacture or assembly in the Bailiwick is exempt under subsection (4) from the prohibitions in sections 7(2)(c) and 8(2). <p>(2B) Neither section 7(2)(a) and (b), nor section 7(4) shall have effect in relation to a person in respect of his exporting, or procuring the exportation of, a medicinal product if –</p> <ul style="list-style-type: none"> (a) the condition in either paragraph (a) or paragraph (b) of subsection (2A) is satisfied,

Provision	Amendment
	<p style="text-align: center;">and</p> <p style="text-align: center;">(b) in the course of a business carried on by him, medicinal products of the same description as that medicinal product were exported within the period of 12 months ending with the first appointed day. "</p>
Section 16(3)	For the words "Section 7(4) shall not", substitute the words "Neither section 7(4) nor section 8(2) shall".
Section 16(4)	For the words "Section 8(2), shall not", substitute the words "Neither section 7(2)(c) nor section 8(2) shall".
Section 16	<p>For subsection (5), substitute the following subsections –</p> <p style="text-align: center;">"(5) Section 8(7)(a) shall not have effect in relation to a person in respect of his selling or offering for sale any medicinal product by way of wholesale dealing in the course of a business carried on by him if –</p> <p style="text-align: center;">(a) it is not, and does not involve, an exportation of the product, other than an exportation exempt under subsection (2B) from the prohibitions in section 7(2)(a) and (b), and (4),</p> <p style="text-align: center;">(b) the condition in either paragraph (a) or paragraph (b) of subsection (2A) is satisfied, and</p> <p style="text-align: center;">(c) in the course of that business, medicinal</p>

Provision	Amendment
	<p>products of the same description as that product were sold or offered for sale by way of wholesale dealing within the period of 12 months ending with the first appointed day.</p> <p>(6) For the avoidance of doubt, nothing in this section affects or limits any prohibition or restriction that relates to sale, supply, placing on the market, importation, exportation, manufacturing, assembly, wholesale dealing, or any other dealings with medicinal products that are imposed by or under any enactment other than this Law."</p>
Section 18	Immediately after the word "effect", insert the words "subject to any regulations to the contrary made under this Law".
Section 35(6)	For the words "made by the Department for the purposes of", substitute the word "under".
Section 36(1)	<p>For the words before paragraph (a), substitute the following words –</p> <p>"Subject to subsection (4), in advising the States in relation to their exercise of powers under section 35(1) (Medicinal products on prescription only), the Department shall make best efforts to ensure that every product".</p>
Section 37(1)(b)	For the word "order", substitute the word "Ordinance".
Section 37(2)(a)	For the expression "35(2)," substitute the expression "35(4)".
Section 37(2)(b)	For the expression "35(4)(a)," substitute the expression "35(6)(a)".

Provision	Amendment
Section 41	<p>For subsection (1), substitute the following subsection –</p> <p style="padding-left: 40px;">"(1) No person shall, to the prejudice of the purchaser, –</p> <p style="padding-left: 80px;">(a) sell any medicinal product knowing that it is not of the nature or quality demanded by the purchaser, or</p> <p style="padding-left: 80px;">(b) recklessly sell any medicinal product that is not of the nature or quality demanded by the purchaser. "</p>
Section 73	<p>Immediately after subsection (10), insert the following subsection –</p> <p style="padding-left: 40px;">"(11) Notwithstanding any of the preceding provisions, subsections (2) and (4) have effect subject to any exception or exemption prescribed by regulations made by the Department."</p>
Section 75(3)	<p>For paragraph (a), substitute the following paragraph –</p> <p style="padding-left: 40px;">" (a) the particulars or material which advertisements relating to medicinal products must contain, or must not contain,".</p>
Section 75	<p>Immediately after subsection (5), insert the following subsections –</p> <p style="padding-left: 40px;">" (5A) Without prejudice to the preceding provisions,</p>

Provision	Amendment
	<p>the Department may by regulations regulate the promotion of medicinal products by any means whatsoever (whether or not involving advertisements or representations), and such regulations may impose duties and obligations on any or all of the following –</p> <ul style="list-style-type: none"> (a) any person who holds a recognised marketing authorisation in respect of the products, (b) any person who is a commercially interested party in respect of the products, (c) any person concerned in any way with the promotion of the products, and (d) any person to whom the products are promoted. <p>(5B) Regulations made under this section may confer on the regulatory authority or any other person any powers and functions that appear necessary or expedient to the Department to enforce the regulations."</p>
Section 78	<p>For the words "a veterinary medicinal product that is", substitute the words ""veterinary medicinal product" means-".</p> <p>For the comma at the end of paragraph (b), substitute a full stop.</p>

Provision	Amendment
	Omit the words after paragraph (b).
Section 80(2)	For the word "specify", substitute the words "advise the States to specify".
Section 80(5)	For the word "Department", substitute the word "States".
Section 97(2)(a)	For the expression "7(3)", substitute the expression "7(4)".
Section 107(2)	For the word "Ordinance" substitute the word "Order".
Section 112(2)(b)	Omit the words "or any regulations made under".
Section 113	<p>Add the following subsection –</p> <p>" (7) The Chief Inspector shall be regarded as having all the powers, rights, and privileges of an inspector duly appointed under subsection (3), as well as any related duties; the exercise or performance by the Chief Inspector of such a power, right, privilege, or duty shall be treated as if it were an exercise or performance of the power, right, privilege, or duty concerned by an inspector so appointed."</p>
Section 132	<p>Add the following subsection –</p> <p>" (3) Anything which, under this Law, may be prescribed, specified, or otherwise provided for by an order made by a Department, may be prescribed, specified, or otherwise provided for by regulations made by the Department; any such regulations have effect for all purposes as if they were provisions of an order made by the Department."</p>

Provision	Amendment
Section 136(1)	<p>For the definition of "enactment", substitute the following definition –</p> <p style="padding-left: 40px;">" "enactment" includes</p> <p style="padding-left: 40px;">(a) any subordinate legislation,</p> <p style="padding-left: 40px;">(b) any enactment of the United Kingdom, and</p> <p style="padding-left: 40px;">(c) any Directive or Regulation of any institution of the European Union, ".</p>
Section 136(1)	<p>Insert the following definitions in the correct alphabetical order–</p> <p style="padding-left: 40px;">" "this Law" includes any Ordinance, regulation, or order made under this Law;</p> <p style="padding-left: 40px;">"pharmacist" means a person registered as a recognised pharmacist under the Doctors, Dentists and Pharmacists Ordinance, 1987^f;</p> <p style="padding-left: 40px;">"subordinate legislation" means any regulation, rule, order, rule of court, resolution, scheme, byelaw or other instrument made under any enactment and having legislative effect; ".</p>

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Recueil d'Ordonnances Tome XXIV, pp. 79, 238 and 262.

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