

GUERNSEY STATUTORY INSTRUMENT

2009 No. 71

**The Medicines (Human) (Sale and Supply) (Bailiwick of  
Guernsey) Regulations, 2009**

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

ARRANGEMENT OF REGULATIONS

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# **The Medicines (Human) (Sale and Supply) (Bailiwick of Guernsey) Regulations, 2009**

**THE HEALTH AND SOCIAL SERVICES DEPARTMENT**, in exercise of the powers conferred on it by sections 30(4), 34, 39, 43(1) and (2), 44(8), and 132 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008<sup>a</sup> and all other powers enabling it in that behalf, hereby makes the following Regulations:-

## **Location of automatic vending machines.**

1. (1) No person shall use an automatic machine for the sale of any medicinal product unless the machine is located in premises which the occupier is able to close so as to exclude the public.

(2) For the purposes of section 30(4) of the Law, a condition of the sale or supply of any medicinal products by means of an automatic machine is that the machine must be located in premises which the occupier is able to close so as to exclude the public.

## **Restrictions on persons to be supplied with certain medicinal products.**

2. (1) Subject to the exceptions specified in paragraph (2), no person

(a) being the holder of a recognised marketing authorisation, or

(b) in the course of a business carried on by him and consisting (wholly or partly) of manufacturing

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<sup>a</sup> Order in Council No. V of 2009.

medicinal products or of selling medicinal products by way of wholesale dealing –

shall sell or supply, by way of wholesale dealing, a prescription only medicine or a pharmacy medicine to any person who does not fall within a class specified in the Schedule.

(2) The restriction imposed by paragraph (1) does not apply to the sale or supply, by way of wholesale dealing, –

- (a) to any person specified in column 1 of Schedule 1 to the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009 (exemptions for certain persons from section 35(4) of the Law), of the prescription only medicines specified in relation to that person in column 2 of that Schedule, but this exception is subject to regulation 3,
- (b) to any person, of the prescription only medicines referred to in section 12 of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009 (exception in relation to medicinal products at high dilutions) that that person may, by virtue of that section, sell by retail or supply in circumstances corresponding to retail sale or administer free from the restrictions imposed by section 35(4) of the Law (restrictions on sale, supply and administration),
- (c) to a registered optometrist, of prescription only medicines which are prescription only medicines by reason only that they contain any one or more of the

substances listed in regulation 5(2)(c) of the UK Regulations,

- (d) to an additional supply optometrist, of prescription only medicines which are prescription only medicines by reason only that they contain the substance Thymoxamine hydrochloride,
- (e) to any person who requires pharmacy medicines for the purpose of administering them to human beings in the course of a business carried on by him, of pharmacy medicines which are for the purpose of being so administered, and
- (f) to any person who, by virtue of an exemption from the restrictions imposed by section 29 of the Law (sale or supply of medicinal products not on general sale list) conferred either by section 33 of the Law (exemption in respect of herbal remedies) or by an order made under section 32(2)(b) of the Law (exemption for doctors and dentists) or section 34(1) of the Law (power to extend or modify exemptions), is enabled to sell by retail or supply in circumstances corresponding to retail sale pharmacy medicines referred to in those exemptions otherwise than by or under the supervision of a pharmacist, of the pharmacy medicines referred to in those exemptions.

**Sale of prescription only medicines in respect of ships.**

3. (1) Where the person specified in column 1 of Schedule 1 to the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009 is

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- (a) the owner of a ship, or the master of a ship which does not carry an appropriate practitioner among the seamen employed in it, or
- (b) the master of a ship which is in a port in the Bailiwick,-

then the exemptions set out in regulation 2(2)(a), in respect of prescription only medicines, apply only if the conditions set out in paragraph (2) are satisfied.

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

- (a) the sale or supply is by a person lawfully conducting a retail pharmacy business,
- (b) a pharmacist has obtained a requisition in writing which -
  - (i) is signed by the person to whom the prescription only medicine is sold or supplied,
  - (ii) states the name, address and profession or occupation of the person to whom the prescription only medicine is sold or supplied, and
  - (iii) specifies the purpose for which the prescription only medicine is required and the total quantity to be supplied,
- (c) a pharmacist is reasonably satisfied that -

- (i) the signature is that of the person purporting to have signed the requisition, and
- (ii) that person is engaged in the profession or occupation specified in the requisition, and
- (d) a pharmacist is reasonably satisfied that the quantity of the prescription only medicine to be supplied is the quantity necessary for the equipment of the ship.

(3) Compliance with any enactment (whether of the Bailiwick, the United Kingdom or elsewhere) in respect of the provision of medical stores on board a ship may be specified for the purposes of paragraph (2)(b)(iii), but this does not limit the kind or nature of purposes that may be specified for the purposes of that paragraph.

(4) In this regulation –

"master" has the meaning given by section 294 of the Merchant Shipping (Bailiwick of Guernsey) Law, 2002<sup>b</sup>; and

"seaman" includes every person (except masters and general pilots) employed or engaged in any capacity on board any ship.

**Pack size on retail sale or supply of certain medicinal products on general sale list.**

4. (1) The conditions specified in regulation 8 of the UK Regulations (pack size on retail sale or supply of certain medicinal products on general sale list) are prescribed for the purposes of section 30(4) of the Law (sale or

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<sup>b</sup> Order in Council No. VIII of 2004; amended by Ordinance XXXIII of 2003; sections 80-83, 85-100, 103-110, 123-129, 270, 289-295 and 297 came into force on the 30<sup>th</sup> May 2007 (Ordinance XV of 2007).

supply of medicinal products on general sale list) as conditions in accordance with which a business, so far as concerns the sale or supply of medicinal products, must be carried on.

(2) For the purposes of this regulation, a reference in regulation 8 of the UK Regulations to a registered pharmacy shall be taken as a reference to –

- (a) a registered pharmacy within the meaning of the Law,  
or
- (b) premises in Sark authorised in writing by the regulatory authority under paragraph (b) of section 29 of the Law, whether or not the business complies with paragraph (c) of that section.

**Exemption for certain collection and delivery arrangements.**

5. (1) None of the restrictions imposed by section 29 (sale or supply of medicinal products not on general sale list) or section 30 (sale or supply of medicinal products on general sale list) of the Law applies to the supply of any medicinal product on premises which are not a registered pharmacy where that supply –

- (a) is in accordance with a prescription given by a doctor or dentist, and
- (b) forms part of a collection and delivery arrangement used by either –
  - (i) a person who lawfully conducts a retail pharmacy business, or
  - (ii) a person who conducts a pharmacy related business in Sark that is

authorised by the regulatory authority  
under section 29(a) of the Law.

(2) In this regulation, "**collection and delivery arrangement**" means any arrangement whereby a person is enabled –

- (a) to take or send a prescription given by a doctor or dentist to premises other than a registered pharmacy, and
- (b) to collect or have collected on his behalf from those premises a medicinal product prepared or dispensed in accordance with the prescription at a registered pharmacy by or under the supervision of a pharmacist

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if the premises at which the medicinal product is supplied are capable of being closed by the occupier so as to exclude the public.

#### Offences.

6. Any person who contravenes regulation 1(1) is guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

#### Interpretation.

7. (1) In these Regulations, unless the context requires otherwise –

"**additional supply optometrist**" has the same meaning as in the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009;

"**appropriate practitioner**", in relation to any medicinal product, means a person specified to be an appropriate practitioner for medicinal

products of that description or falling within that class under section 1 of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009;

**"excepted person"** means –

- (a) a doctor or dentist, or
- (b) a person lawfully conducting a retail pharmacy business;

**"the Law"** means the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008<sup>c</sup>;

**"pharmacy medicine"** means a medicinal product which is not a prescription only medicine and which either –

- (a) is not a medicinal product on the general sale list, or
- (b) is a product referred to in regulation 4 and is not presented for sale in the manner described for that product in that regulation;

**"prescription only medicine"** means a medicinal product of a description or falling within a class specified in section 2 of the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009;

**"registered optometrist"** has the same meaning as in the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009; and

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<sup>c</sup> Order in Council No. V of 2009.

"UK Regulations" means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980<sup>d</sup>.

(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<sup>e</sup> 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 requires otherwise, an expression used in these Regulations has the same meaning as in the Law.

**Extent.**

8. These Regulations have effect throughout the Bailiwick.

**Citation and commencement.**

9. These Regulations may be cited as the Medicines (Human) (Sale and Supply) (Bailiwick of Guernsey) Regulations, 2009 and come into force on the 1<sup>st</sup> October, 2009.

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<sup>d</sup> United Kingdom S.I. No. 1923 of 1980.

<sup>e</sup> Ordres en Conseil Vol. XIII, p. 355.

Dated this 1<sup>st</sup> day of October, 2009

A handwritten signature in black ink, appearing to read 'A. H. Hunter', with a stylized flourish at the end.

A. H. Hunter

Minister of the States Health and Social Services Department

For and on behalf of the Department

## SCHEDULE

### CLASSES OF PERSONS FOR PURPOSES OF REGULATION 2

Regulation 2(1)

- (a) A doctor, dentist, or veterinary surgeon.
  - (b) A person lawfully conducting a retail pharmacy business within the meaning of section 47 of the Law.
  - (c) A person conducting a pharmacy related business in Sark authorised by the regulatory authority under section 29(a) of the Law.
  - (d) An authority or a person carrying on the business of a hospital, infirmary, health centre, dispensary, clinic, family planning clinic, nursing home or other institution at which human ailments are treated.
  - (e) A holder of a wholesale dealer's licence or a person to whom the restrictions imposed by section 8(7) of the Law (provisions as to manufacture and wholesale dealing) do not apply by virtue of an exemption by or under the Law.
  - (f) Any department of the States or any officer thereof.
  - (g) Any person, other than an excepted person, who carries on a business consisting (wholly or partly) of supplying medicinal products in circumstances corresponding to retail sale, or of administering such products, pursuant to an arrangement made with the Department.
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## EXPLANATORY NOTE

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

These Regulations require automatic machines selling medicinal products to be located in an area from which the public can be excluded. They limit the people who can buy pharmacy medicines or prescription only medicines from a wholesale dealer. They provide for a procedure for the purchase of prescription only medicines from a pharmacist by a ship's master. They place limits on the pack sizes of certain general sales list medicines which could prove dangerous if taken in sufficient quantities. These pack size limits follow precisely the pack size limits provided for in the United Kingdom. These Regulations also allow for premises to be used for collection and delivery arrangements for medicinal products.

