

GUERNSEY STATUTORY INSTRUMENT

2009 No. 61

**The Medicines (Human) (Labelling and Leaflets) (Bailiwick
of Guernsey) Regulations, 2009**

<i>Made</i>	<i>1st October, 2009</i>
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The Medicines (Human) (Labelling and Leaflets) (Bailiwick of Guernsey) Regulations, 2009

THE HEALTH AND SOCIAL SERVICES DEPARTMENT, in exercise of the powers conferred on it by sections 66, 67, 71(2), 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:-

Application of Directive provisions on labelling and leaflets.

1. (1) The obligations in Title V of the 2001 Directive (labelling and package leaflet) apply in respect of all medicinal products for which a recognised marketing authorisation is in force.

(2) For the avoidance of doubt, the obligations referred to in paragraph (1) apply notwithstanding that the marketing authorisation was automatically recognised as a United Kingdom marketing authorisation by virtue of it being a product licence or a licence of right, in accordance with regulation 12(2) of the Medicines (Human and Veterinary) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009.

(3) The other provisions of these Regulations supplement the requirements of Title V of the 2001 Directive relating to –

- (a) special warnings necessary for particular medicinal products,
- (b) the legal status for supply to the patient,
- (c) identification and authenticity.

^a Order in Council No. V of 2009.

Dispensed medicinal products.

2. (1) Subject to the other provisions of these Regulations, where a medicinal product is a dispensed medicinal product, its container shall be labelled to show the following particulars –

- (a) where it is for use by being administered to a particular person, the name of that person,
- (b) the name and address of the person who sells or supplies it,
- (c) the date on which it is dispensed, and
- (d) such of the following particulars as the appropriate practitioner prescribing it may request –
 - (i) its name or common name,
 - (ii) directions for its use, and
 - (iii) precautions relating to its use,

or where a pharmacist, in the exercise of his professional skill and judgement, is of the opinion that any of such particulars are inappropriate and has taken such steps as in all the circumstances are reasonably practicable to consult with the practitioner but has been unable to do so, particulars of the same kind as those requested by the practitioner as appear to the pharmacist to be appropriate.

(2) Where the container of a dispensed medicinal product is enclosed in a package immediately enclosing that container, the particulars set out

in paragraph (1) may be omitted from that container if that package is labelled to show them.

(3) Where a number of containers or packages of dispensed medicinal products all of the same description are enclosed in a package, paragraph (1)(d) shall be deemed to have been complied with if such of the particulars referred to in that paragraph as would, apart from this paragraph, be required to be shown on each container or package, are shown on one of them.

Delivery and storage.

3. (1) Subject to the other provisions of these Regulations, where for the purposes of transport, delivery or storage a number of packages of medicinal products all of the same description, are enclosed in a package, such package shall be labelled to show the following particulars –

- (a) any special requirements for the storage and handling of the product,
- (b) the expiry date of the product, and
- (c) the manufacturer's batch number.

(2) Paragraph (1) does not apply to any package in the form of a packing case, crate or other covering used solely for the purposes of transport or delivery (but not storage) of containers and packages of medicinal products each of which is labelled in accordance with the provisions of these Regulations.

(3) This regulation does not apply to medicinal products of the type referred to in section 9(a) or (b) of the Law (exemptions for doctors and dentists).

Medicinal products on a general sale list.

4. (1) Subject to the other provisions of these Regulations, where a medicinal product on a general sale list, not being a dispensed medicinal product, is sold by retail, or supplied in circumstances corresponding to retail sale or by means of an automatic machine or is in the possession of any person for the purpose of such sale or supply, every container and every package immediately enclosing a container of such product, if a product described in any of the following subparagraphs, shall be labelled to show the words and particulars set out below –

- (a) if the product contains aloxiprin, aspirin or paracetamol, the words "If symptoms persist consult your doctor" and, except where the product is for external use only, the recommended dosage,
- (b) if the product contains aloxiprin, the words "Contains an aspirin derivative",
- (c) if the product contains aspirin, except where the product is for external use only or where the name of the product contains the word aspirin and appears on the container or package, the words "Contains aspirin",
- (d) if the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the container or package, the words "Contains paracetamol",
- (e) if the product contains paracetamol, the words "Do not exceed the stated dose",
- (f) if the product contains paracetamol, unless it is wholly or mainly intended for children who are 12 years old

or younger, the words "Do not take with any other paracetamol-containing products", and

- (i) if a package leaflet accompanying the product displays the words set out in quotation marks in regulation 8(1), the words "Immediate medical advice should be sought in the event of an overdose, even if you feel well", or
 - (ii) if no package leaflet accompanies the product or the package leaflet does not display the words set out in quotation marks in regulation 8(1), the words "Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage",
- (g) if the product contains paracetamol and is wholly or mainly intended for children who are 12 years old or younger, the words "Do not give with any other paracetamol-containing products", and
- (i) if a package leaflet accompanying the product displays the words set out in quotation marks in regulation 8(2), the words "Immediate medical advice should be sought in the event of an overdose, even if the child seems well", or
 - (ii) if no package leaflet accompanies the product or the package leaflet does not display the words set out in quotation marks in regulation 8(2), the words "Immediate medical advice should be sought in the event of an overdose,

even if the child seems well, because of the risk of delayed, serious liver damage", and

- (h) if the product contains aspirin or aloxiprin, the words "Do not give to children aged under 16 years, unless on the advice of a doctor".

(2) Where a container or package is required by this regulation to show –

- (a) words set out in more than one of sub-paragraphs (b), (c) and (d) of paragraph (1), there may be substituted for those words other words showing that the product contains more than one of the substances aloxiprin, aspirin and paracetamol and naming the substances so contained, except that in the case of aloxiprin the words "aspirin derivative" shall appear and the word "aloxiprin" need not appear,

- (b) words set out in more than one of sub-paragraphs (b), (c), (d), (f) or (g) of paragraph (1), such words shall appear in a prominent position and shall be within a rectangle within which there shall be no other matter of any kind, except that where words set out in more than one of the said sub-paragraphs appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

(3) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall appear adjacent to either the directions for use, where such directions appear on the container or

package, or the recommended dosage, where such recommendation appears on the container or package.

(4) Where a container or package is required to be labelled to show the words "Do not exceed the stated dose", such words shall not be required to be shown if, by virtue of regulation 5, the words set out in paragraph (2)(a) of that regulation are required to be, and are, shown.

(5) Without prejudice to the operation of paragraph (1), where a medicinal product, not being a dispensed medicinal product, is –

- (a) sold by retail,
- (b) supplied in circumstances corresponding to retail sale,
- (c) in the possession of a person for the purpose of such sale or supply, or
- (d) sold by way of wholesale dealing, -

then, if the product is referred to in regulation 8 of the UK Regulations (pack size on retail supply of certain medicinal products on a general sale list) and is not presented for sale in the manner described in relation to that product in that regulation, every container and every package immediately enclosing a container of that medicinal product shall be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

(6) For the purposes of paragraph (5), a reference in regulation 8 of the UK Regulations (pack size on retail supply of certain medicinal products on a general sale list) 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 section 29(b) of the Law.

Medicinal products not on a general sale list.

5. (1) Subject to the other provisions of these Regulations, where any medicinal product other than a medicinal product on a general sale list is sold by retail, or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such a product –

- (a) shall be labelled in accordance with the provisions of regulation 4 as if such provisions applied to such containers and packages as they apply to containers and packages of medicinal products on a general sale list,
- (b) shall, if the product is described in any sub-paragraph of paragraph (2), be labelled to show the words and particulars set out in that sub-paragraph, except that where the words set out in more than one of sub-paragraphs (a), (b) and (c) appear on the container or package then the word "Warning" need not appear more than once, and where the product is a dispensed medicinal product then the words set out in those sub-paragraphs need not be shown, and
- (c) shall, unless any labelling requirement in regulation 6 applies to such container or package or the product is a dispensed medicinal product, be labelled to show the capital letter "P" within a rectangle within which there shall be no other matter of any kind.

(2) The descriptions and words referred to in paragraph (1)(b) are

- (a) if the product would be subject to restrictions imposed under section 35 of the Law (medicinal products on prescription only) if it contained a higher proportion or level of any substance, except where the product is for external use only or contains any of the substances described in sub-paragraph (c), the words "Warning. Do not exceed the stated dose",
- (b) if the product is for the treatment of asthma or other conditions associated with bronchial spasm or contains ephedrine or any of its salts, except where the product is for external use only, the words "Warning: Asthmatics should consult their doctor before using this product",
- (c) if the product contains an antihistamine or any of its salts or molecular compounds, except where the product is for external use only or where the marketing authorisation contains no warning relating to the sedating effect of the product in use, the words "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink",
- (d) if the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, the words "For external use only", and
- (e) if the product contains hexachlorophane, either the words "Not to be used for babies" or a warning that

the product is not to be administered, except on medical advice, to a child under 2 years.

(3) Where any medicinal product other than a medicinal product on a general sale list is sold by way of wholesale dealing, every container and every package immediately enclosing a container of the product shall meet the requirement in paragraph (1)(c).

(4) Where a container or package is required by this regulation to be labelled to show any of the words or particulars specified in sub-paragraphs (a) to (e) of paragraph (2), such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in more than one sub-paragraph of that paragraph appear on the container or package then any of them may be together within a rectangle within which there shall be no other matter of any kind.

Prescription only medicines.

6. Subject to the other provisions of these Regulations, every container and every package immediately enclosing a container of a medicinal product which is subject to restrictions imposed under section 35(4) of the Law (medicinal products on prescription only) shall –

- (a) if the product is described in regulation 5(2)(d) or (e), be labelled to show the words and particulars set out therein, and
- (b) except where the product is sold by retail or supplied in circumstances corresponding to retail sale or is the subject of any exemption, by virtue of the provisions of section 35(6)(a) of the Law, from any of the restrictions imposed by section 35(4) of the Law, be labelled to show the letters "POM" in capital letters

within a rectangle within which there shall be no other matter of any kind.

Exemptions from labelling rules.

7. (1) Nothing in these Regulations requires the labelling of –
- (a) any package in the form of a transparent wrapping or cover to a container and package of a medicinal product, or any package the whole or part of which is transparent or open, if the particulars shown on the labelled container enclosed in that package are clearly visible,
 - (b) any package in the form of a wrapping paper, paper bag or similar covering in which the container and package of a medicinal product labelled in accordance with the provisions of these Regulations is placed when such medicinal product is sold by retail or supplied in circumstances corresponding to retail sale, or
 - (c) any container or package immediately enclosing the container of a medicinal product which is for export, unless it is for export to the United Kingdom,
 - (d) any container which is –
 - (i) an ampoule or other container of not more than 10 millilitres nominal capacity which is immediately enclosed in a package which is labelled in accordance with those provisions of regulations 4 to 6 which apply to such package, or

- (ii) in the form of a wrapper consisting of paper, film, plastic material, metal foil or other sheet or strip material or in the form of a bubble, blister or other sealed unit consisting of such sheet or strip material, enclosing one or more dosage units of a medicinal product and such container is immediately enclosed in a package which is labelled in accordance with those provisions of regulations 4 to 6 which apply to such package.

(2) Where any package immediately enclosing a container as is described in paragraph (1)(d)(ii) is –

- (a) itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph,
- (b) part of a continuous series comprising a sheet or strip of like packages, and
- (c) required to be labelled to show any of the words, particulars or letters referred to in regulations 4 to 6, -

such requirements shall be deemed to have been complied with if the said words, particulars or letters are displayed at frequent intervals on the said sheet or strip of such packages.

Leaflets.

8. (1) Where in accordance with the 2001 Directive a package leaflet is included in the packaging of a medicinal product containing paracetamol, unless the product is wholly or mainly intended for children who are 12 years old or younger, the leaflet shall display the words "Immediate medical advice should be

sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage".

(2) Where in accordance with the 2001 Directive a package leaflet is included in the packaging of a medicinal product containing paracetamol and the product is wholly or mainly intended for children who are 12 years old or younger, the leaflet shall display the words "Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage".

(3) Where in accordance with the 2001 Directive a package leaflet is included in the packaging of a medicinal product containing aloxiprin or aspirin, the leaflet shall display the words "There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor".

Homoeopathic medicinal products.

9. (1) Without prejudice to paragraph (2), all homoeopathic medicinal products shall be labelled in accordance with the provisions of these Regulations and shall be identified by a reference on their labels, in clear and legible form, to their homoeopathic nature.

(2) The labelling and where appropriate the leaflet for any homoeopathic medicinal product, in respect of which a United Kingdom certificate of registration has been recognised, shall bear the information specified in Article 69 of the 2001 Directive and no other information.

Traditional herbal medicinal products.

10. In addition to the other requirements of these Regulations, any labelling and leaflets in respect of a traditional herbal medicinal product in respect of which a United Kingdom traditional herbal registration has been recognised shall contain a statement to the effect that –

- (a) the product is a traditional herbal medicinal product for use in specified indications based exclusively on long-standing use, and
- (b) the user should consult a doctor or other health care professional if symptoms persist during the use of the medicinal product or if side-effects not mentioned in the leaflet occur.

Offences.

11. (1) Any holder of a recognised marketing authorisation who sells or supplies or procures the sale or supply of a medicinal product to which the authorisation, registration or certificate relates –

- (a) the labelling of which, or any package leaflet accompanying which, does not comply with, or
- (b) without a package leaflet required to be provided by virtue of –

any of these Regulations (including, for the avoidance of doubt, the obligations under the 2001 Directive as applied by regulation 1) is guilty of an offence.

(2) Where, in relation to a medicinal product –

- (a) the labelling of the product, or any package leaflet accompanying the product, does not comply with, or
- (b) the product is not accompanied by a package leaflet required to be provided by virtue of –

any of these Regulations (including, for the avoidance of doubt, the obligations

under the 2001 Directive as applied by regulation 1), any person who in the course of a business carried on by him, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe that the labelling does not so comply, or, as the case may be, that the product is not so accompanied, is guilty of an offence.

(3) Any person who contravenes section 66(3) or 67(2) is guilty of an offence.

(4) Any person guilty of an offence under this regulation is liable

(a) on summary conviction to a fine not exceeding level 3 on the uniform scale, and

(b) on conviction on indictment to a fine, or imprisonment for a term not exceeding two years, or to both.

Interpretation.

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

"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;

"common name" in relation to a medicinal product means the international non-proprietary name, or, if one does not exist, the usual name;

"dispensed medicinal product" means a medicinal product prepared or dispensed in accordance with a prescription given by an appropriate

practitioner;

"external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal, when a local action is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;

"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^b;

"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) by the Medicines (Human) (General Sale List) (Bailiwick of Guernsey) Order, 2009;

"name" in relation to a medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product;

"recognised", in relation to a United Kingdom traditional herbal registration or United Kingdom certificate of registration, means recognised in the Bailiwick by the Medicines (Human and Veterinary) (Exemptions and Recognised Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009;

^b Order in Council No. V of 2009.

"**side-effect**" includes adverse reaction within the meaning of the 2001 Directive;

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

"**UK regulations**" means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980^c;

"**United Kingdom certificate of registration**" has the same meaning as in the Medicines (Human and Veterinary) (Exemptions and Recognised Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009;

"**United Kingdom marketing authorisation**" has the same meaning as in the Medicines (Human and Veterinary) (Exemptions and Recognised Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009; and

"**United Kingdom traditional herbal registration**" has the same meaning as in the Medicines (Human and Veterinary) (Exemptions and Recognised Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009.

(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^d applies to the interpretation of these Regulations –

^c United Kingdom S.I. 1980 No. 1923.

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

- (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.

Transitional and saving provisions.

13. (1) If the labelling or leaflets of a medicinal product would breach a provision of these Regulations but –

- (a) a product licence, within the meaning of Part II of the Medicines Act 1968^e was in force in the United Kingdom in respect of that product on the coming into force of the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994^f, and that licence has not been subsequently renewed, and
- (b) the provisions of the Medicines (Labelling) Regulations 1976^g and the Medicines (Leaflets) Regulations 1977^h are satisfied in respect of the labelling and leaflets, -

then that provision of these Regulations shall be deemed not to have been breached.

^e An Act of Parliament, Chapter 67 of 1968..

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

^g United Kingdom S.I. 1976 No. 1726.

^h United Kingdom S.I. 1977 No. 1055.

(2) These Regulations (other than this paragraph) do not apply until the 30th April 2011, to traditional herbal medicinal products which –

- (a) were on the market in the Bailiwick on the 30th April 2004 without a marketing authorisation, and
- (b) are herbal remedies falling within the exemption specified in section 12(2) of the Law.

(3) Where a marketing authorisation or United Kingdom certificate of registration was granted for a medicinal product before the 30th October 2005, these Regulations apply to the labelling of the product as if the 2001 Directive had not been amended by Article 1(40), (41), (42) and (51) of Directive 2004/27/EC (additional information, including product name in Braille, on packaging).

(4) Paragraph (3) expires on the 30th October 2010.

Extent.

14. These Regulations have effect throughout the Bailiwick.

Citation and commencement.

15. These Regulations may be cited as the Medicines (Human) (Labelling and Leaflets) (Bailiwick of Guernsey) Regulations, 2009 and come into force on the 1st October, 2009.

Dated this 1st day of October, 2009



A. H. Adam

Minister of the States Health and Social Services Department
For and on behalf of the Department

EXPLANATORY NOTE

(This note is not part of these Regulations)

These Regulations set out the information which must be included on the labelling, packaging and leaflets of medicinal products. They incorporate the requirements of Title V of the 2001 EU Medicines Directive together with certain supplementary material. They also include requirements for homoeopathic and herbal products.