

GUERNSEY STATUTORY INSTRUMENT

2009 No. 70

**The Medicines (Human) (Advertising) (Bailiwick of
Guernsey) Regulations, 2009**

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The Medicines (Human) (Advertising) (Bailiwick of Guernsey) Regulations, 2009

THE HEALTH AND SOCIAL SERVICES DEPARTMENT, in exercise of the powers conferred on it by sections 75 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:-

PART I

PROVISIONS APPLYING TO ALL ADVERTISEMENTS

Prohibition of advertisements for unauthorised medicinal products.

1. No person shall issue an advertisement in respect of a medicinal product unless there is a recognised marketing authorisation in force in respect of the product.

Advertisements to comply with summary of product characteristics.

2. No person shall issue an advertisement in respect of a medicinal product unless all parts of that advertisement comply with the particulars listed in the summary of product characteristics.

Advertisements to promote rational use of medicinal products.

3. No person shall issue an advertisement in respect of a medicinal product unless that advertisement encourages the rational use of that product by presenting it objectively and without exaggerating its properties.

^a

Order in Council No. V of 2009.

PART II
ADVERTISEMENTS TO THE PUBLIC

Application of this Part.

4. In this Part references to advertisements mean advertisements wholly or mainly directed at members of the general public.

Prohibition of advertisements relating to abortifacients.

5. No person shall issue an advertisement which is likely to lead to the use of a medicinal product or any other substance or article for the purpose of inducing an abortion in women.

Prohibition of advertisements for prescription only medicines.

6. Subject to regulation 11, no person shall issue an advertisement which is likely to lead to the use of a medicinal product which is a prescription only medicine.

Prohibition of advertisements for narcotic or psychotropic substances.

7. Subject to regulation 11, no person shall issue an advertisement in respect of any medicinal product which –

- (a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention), or
- (b) contains a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in

accordance with paragraphs 2 and 3 of Article 3 of that Convention).

Prohibition of certain material in advertisements.

8. Subject to regulation 11, no person shall issue an advertisement in respect of any medicinal product which contains any material which –

- (a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or suggesting treatment by post, by email, by telephone, over the internet or by other means,
- (b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by side-effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product,
- (c) suggests that health can be enhanced by taking the medicinal product,
- (d) suggests that health could be affected by not taking the medicinal product,
- (e) is directed wholly or mainly at children,
- (f) refers to a recommendation by scientists, health professionals or those purporting to be scientists or health professionals,

- (g) refers to a recommendation by persons who, because of their celebrity, could encourage the consumption of medicinal products,
- (h) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product,
- (i) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural,
- (j) might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis,
- (k) refers, in improper, alarming or misleading terms, to claims of recovery, or
- (l) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or the action of a medicinal product on the human body or parts of it.

Form and content of advertisements.

9. Subject to regulation 10, no person shall issue an advertisement in respect of a medicinal product unless the advertisement –

- (a) makes it clear that it is an advertisement,
- (b) makes it clear that the product is a medicinal product,
- (c) includes the name of the medicinal product and, where

it contains only one active ingredient, its common name,

- (d) includes the information necessary for correct use of the medicinal product, and
- (e) includes an express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be.

Exception for promotional aids.

10. Regulation 9 does not apply to an advertisement in respect of a medicinal product which is on a promotional aid if –

- (a) the advertisement consists solely of the name of the product or its international non-proprietary name, where this exists, or the trademark, and
- (b) the advertisement is intended solely as a reminder.

Exception for approved vaccination campaigns.

11. Regulations 6, 7 and 8(d) do not apply to any advertisement as part of a vaccination campaign relating to a medicinal product which is a vaccine or serum, if the campaign has been approved by the Department.

Prohibition of supply of medicinal products to public for promotional purposes.

12. No commercially interested party shall, for a promotional purpose, whether of his own or of a third party, sell or supply any medicinal product to any member of the public.

PART III
ADVERTISEMENTS TO HEALTH PROFESSIONALS

Application of this Part.

13. In this Part references to advertisements mean advertisements wholly or mainly directed at persons qualified to prescribe or supply medicinal products.

Form and content of advertisements.

14. (1) Subject to paragraph (2), no person shall issue an advertisement in respect of a medicinal product unless the advertisement –

- (a) contains essential information compatible with the summary of product characteristics,
- (b) contains the particulars set out in paragraphs 1 to 9 of Schedule 1, and
- (c) complies with paragraph 10 of Schedule 1.

(2) This regulation does not apply to an advertisement to which regulation 15, 16 or 17 applies.

Audio-visual advertisements.

15. (1) This regulation applies to any advertisement in respect of a medicinal product issued in a broadcast, sound recording or film.

(2) Subject to regulation 17(2), no person shall issue an advertisement to which this regulation applies unless the advertisement –

- (a) contains essential information compatible with the summary of product characteristics, and
- (b) refers to the particulars set out in paragraphs 1 to 8 of Schedule 1.

(3) For the purposes of this regulation, an advertisement shall be taken to meet the requirements of paragraph (2)(b) if the particulars referred to in that paragraph are supplied by way of written material –

- (a) made available to all persons to whom the advertisement is shown, or
- (b) sent as an alternative to being referred to in the advertisement.

Abbreviated advertisements.

16. (1) This regulation applies to any abbreviated advertisement in respect of a medicinal product.

(2) Subject to regulation 17(2), no person shall issue an advertisement to which this regulation applies unless the advertisement contains –

- (a) essential information compatible with the summary of product characteristics, and
- (b) the particulars set out in Schedule 2.

Exception for promotional aids.

17. (1) This regulation applies to any advertisement in respect of a

medicinal product which is on a promotional aid, where –

- (a) the advertisement consists solely of the name of the product or its international non-proprietary name, where this exists, or the trademark, and
- (b) the advertisement is intended solely as a reminder.

(2) Nothing in regulation 15 or 16 applies to an advertisement to which this regulation applies.

Written material accompanying promotions.

18. (1) This regulation applies to any written material, in respect of a medicinal product, sent or delivered –

- (a) to persons qualified to prescribe or supply medicinal products, and
- (b) as part of the promotion of the medicinal product.

(2) No person shall send or deliver to a person referred to in paragraph (1)(a) any written material to which this regulation applies, unless the material –

- (a) includes essential information compatible with the summary of product characteristics,
- (b) states the supply classification of the medicinal product, specifying whether the product is prescription only medicine, a medicinal product on a general sale

list, or a pharmacy medicinal product, and

(c) states the date on which it was drawn up or revised.

(3) No person shall include in written material to which this regulation applies any information unless the information is accurate, up to date, verifiable, and sufficiently complete to enable the recipient to form his own opinion of the therapeutic value of the product to which the written material relates.

(4) No person shall include in written material to which this regulation applies any quotation, table or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information indicated.

Free samples.

19. (1) No person shall supply a free sample of a medicinal product to a person qualified to prescribe it, except in accordance with paragraphs (2) and (3).

(2) No sample may be supplied except –

(a) for the purpose of the recipient acquiring knowledge in dealing with the product, and

(b) in response to a signed and dated written request by the recipient.

(3) The sample supplied –

(a) must not be larger than the smallest presentation

available for sale in the Bailiwick,

- (b) shall be marked "free medical sample – not for resale",
 - (c) shall be accompanied by a copy of the summary of product characteristics,
 - (d) must not contain –
 - (i) a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention),
 - (ii) a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of Article 3 of that Convention), or
 - (iii) any product, substance or article which has as its purpose the inducing of an abortion in women.
- (4) The person supplying the sample shall –
- (a) maintain an adequate system of control and

accountability, and

- (b) ensure that, in any one year, no more than 6 free samples of each medicinal product is supplied to any one recipient.

Medical sales representatives.

20. (1) This regulation and regulation 21 apply only to the activities of medical sales representatives who promote medicinal products to persons qualified to prescribe or supply such products.

(2) A medical sales representative visiting a person referred to in paragraph (1) shall give to, or have available for, that person, a copy of the summary of product characteristics for each medicinal product promoted by the representative.

(3) The medical sales representative shall promptly report all information in respect of the use of any medicinal product promoted by the representative which he receives from the person visited (including reports of any side-effects), to a scientific service established to compile and collate all information relating to that product by the holder of the recognised marketing authorisation.

Training of medical sales representatives.

21. Each person who holds a recognised marketing authorisation in respect of a medicinal product shall ensure that medical sales representatives who promote the product are given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about that product.

Inducements and hospitality.

22. (1) Subject to paragraphs (2), (3) and (5), where medicinal products are being promoted to persons qualified to prescribe or supply them, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is –

(a) inexpensive, and

(b) relevant to the practice of medicine or pharmacy.

(2) Paragraph (1) does not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply medicinal products, if –

(a) such hospitality is strictly limited to the main professional or scientific objective of the event, and

(b) it is offered only to health professionals.

(3) Paragraph (1) does not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events held for the promotion of medicinal products if –

(a) such hospitality is strictly limited to the main purpose of the event, and

(b) it is offered only to health professionals.

(4) No person qualified to prescribe or supply medicinal products

shall solicit or accept any gift, pecuniary advantage, or benefit in kind prohibited by this regulation.

(5) Nothing in this regulation affects measures or trade practices relating to prices, margins or discounts which were in existence on the 1st January, 2008.

PART IV

TRADITIONAL HERBAL AND HOMOEOPATHIC MEDICINAL PRODUCTS

Advertisements for traditional herbal medicinal products.

23. (1) Where a United Kingdom traditional herbal registration is recognised in respect of a traditional herbal medicinal product, no person shall issue an advertisement relating to the product unless it contains a statement in the form specified in paragraph (2).

(2) The form referred to in paragraph (1) is the words "Traditional herbal medicinal product for use in", followed by –

- (a) a statement of one or more therapeutic indications for the product consistent with the terms and conditions of the United Kingdom traditional herbal registration for that product, and
- (b) the words "exclusively based on long standing use".

Advertisements for homoeopathic medicinal products.

24. (1) Where a United Kingdom certificate of registration is recognised in respect of a homoeopathic medicinal product, no person shall issue an advertisement relating to the product which –

- (a) contains any details other than those set out in Schedule 3, or
- (b) mentions any specific therapeutic indications.

(2) Nothing in regulation 9, 14, 15, 16, or any other regulation shall be construed as requiring the inclusion of any details other than those described in Schedule 3 in an advertisement relating to the product.

PART V MONITORING OF ADVERTISEMENTS

Monitoring of advertisements.

25. (1) The regulatory authority may consider whether an advertisement for a medicinal product has breached, or if issued would breach, these Regulations or Part VI of the Law.

- (2) The regulatory authority may consider an advertisement –
 - (a) before it is issued, or
 - (b) after it is issued.
- (3) The regulatory authority may consider an advertisement –
 - (a) following a complaint made to it, or
 - (b) of its own motion.

Provision of advertisement information to regulatory authority.

26. (1) This regulation applies to each person who –

- (a) is a commercially interested party in respect of a medicinal product, or
- (b) is concerned with the issue of an advertisement of a medicinal product.

(2) Subject to paragraphs (3) and (4), the person shall at all times–

- (a) retain advertisement information in respect of each advertisement or proposed advertisement,
- (b) make the advertisement information available for inspection by the regulatory authority, and
- (c) provide advertisement information to the regulatory authority within any period specified in a notice served on him by the regulatory authority.

(3) Paragraph (2) ceases to apply in respect of a proposed advertisement, where it is no longer proposed to issue the advertisement.

(4) Unless there are safety concerns over the medicinal product, paragraph (2) ceases to apply in respect of an advertisement that has been issued, as of the latest of these –

- (a) the date 3 years after the advertisement was last issued,

- (b) where an advertisement is likely to be in use more than 3 years after it is issued, the date 3 years after the date the advertisement is likely to cease to be in use, or
- (c) where there has been a complaint, regulatory or self-regulatory action about an advertisement, the date 3 years after the complaint was resolved or the action concluded.

(5) In this regulation, "**advertisement information**" means a sample of the advertisement or proposed advertisement (including a data sheet) together with a statement indicating –

- (a) the person to whom the advertisement is addressed or proposed to be addressed,
- (b) the method or proposed method of dissemination, and
- (c) the date or proposed date of first dissemination.

Provision of information and assistance to regulatory authority.

27. (1) The regulatory authority may serve a notice on any person who holds a recognised marketing authorisation in respect of a medicinal product, requiring that person to provide the regulatory authority with information or assistance specified in that notice in order to carry out its functions under this Part or Part VI of the Law.

- (2) The person on whom the notice is served shall provide that

information or assistance to the regulatory authority within the period specified in that notice.

Pre-vetting notice.

28. (1) The regulatory authority may serve a notice on any person appearing to it to be concerned with the proposed issue of an advertisement in respect of a medicinal product or class of medicinal products stating –

- (a) that it intends to make a determination that the advertisement, if published, would breach a provision of these Regulations or of Part VI of the Law,
- (b) the reasons why it intends to make the determination,
- (c) that if the determination is made, that person may be required to refrain from publishing that advertisement, and
- (d) that the person on whom the pre-vetting notice is served has 21 days from the date of the notice in which to make written representations that the determination should not be made.

(2) If the regulatory authority thinks fit, the notice may require the person to refrain from issuing the advertisement until the sooner of –

- (a) the regulatory authority making its determination, or
- (b) the date 6 months after the date of the notice.

(3) Any person on whom a notice is served containing a requirement made under paragraph (2) shall comply with the requirement.

Post-vetting notice.

29. (1) The regulatory authority may serve a notice on any person appearing to it to be concerned with the issue of an advertisement in respect of a medicinal product or class of medicinal products stating –

- (a) that it intends to make a determination that the advertisement is in breach of a provision of these Regulations or of Part VI of the Law,
- (b) the reasons why it intends to make that determination,
- (c) that if the determination is made, that person may be required to cease issuing and refrain from any further issuing of that advertisement, and
- (d) that the person on whom the post-vetting notice is served has 21 days from the date of the notice in which to make written representations that the determination should not be made.

(2) If the regulatory authority thinks fit, the notice may require the person to cease issuing and withdraw the advertisement, and refrain from any further issuing of the advertisement until the sooner of –

- (a) the regulatory authority making its determination, or
- (b) the date 6 months after the date of the notice.

(3) Any person on whom a notice is served containing a requirement made under paragraph (2) shall comply with the requirement.

Determination of whether or not advertisement in breach.

30. (1) Where the regulatory authority has served a pre-vetting notice or post-vetting notice, the authority shall determine whether or not the advertisement is in breach of any provision of these Regulations or of Part VI of the Law upon further consideration of the matter, including consideration of –

- (a) any representations made in accordance with regulation 28(1)(d) or 29(1)(d), and
- (b) any other representations made by a person appearing to it to be concerned with the issue of the advertisement.

(2) The regulatory authority shall serve a notice of its determination on any person appearing to it to be concerned or likely to be concerned with the issue of the advertisement or proposed advertisement.

Determination that advertisement in breach.

31. (1) Where the regulatory authority determines that the advertisement is in breach of a provision of these Regulations or of Part VI of the Law, the notice under regulation 30(2) –

- (a) shall state the reasons for the determination, and
- (b) may require the recipient of the notice to refrain from issuing the advertisement, or to cease issuing and

withdraw the advertisement, and refrain from any further issuing of the advertisement.

(2) If a requirement is made under paragraph (1)(b), the recipient of the notice shall comply with it.

Publication of determination and corrective statement.

32. (1) Where the regulatory authority determines that the advertisement is in breach of a provision of these Regulations or of Part VI of the Law and that advertisement has already been issued, it may require the recipient of the notice under regulation 30(2) to publish, within a specified time, in a form the regulatory authority considers appropriate –

- (a) the reasons for the determination, as notified to the recipient by the regulatory authority under regulation 31(a), in full or in part as the regulatory authority requires, and
- (b) a corrective statement in respect of the advertisement in respect of which the determination was made.

(2) If a requirement is made under paragraph (1), the recipient of the notice shall comply with it.

Appeals to the Royal Court.

33. (1) Any person who is aggrieved by a decision of the regulatory authority in respect of any of the following matters may appeal to the Royal Court -

- (a) a requirement under regulation 28(2) to refrain from issuing an advertisement,

- (b) a requirement under regulation 29(2) to cease issuing, withdraw, or refrain from any further issuing of an advertisement,
- (c) a determination under regulation 30 that the advertisement is in breach of a provision of these Regulations or of Part VI of the Law,
- (d) a requirement under regulation 31 to cease issuing and withdraw the advertisement, or refrain from any further issuing of the advertisement, or
- (e) a requirement under regulation 32 to publish the reasons for the determination and a corrective statement.

(2) An appeal may be made on one or more of the following grounds –

- (a) the decision was *ultra vires* or there was some other error of law,
- (b) the decision was unreasonable,
- (c) the decision was not proportional,
- (d) the decision was made in bad faith, or

(e) there was a material error as to the facts or the procedure.

(3) An appeal must be made -

(a) within a period of 28 days immediately following the date of the notice setting out the requirement or (as the case may be) the determination, or a longer period allowed by leave of the Court, and

(b) by summons served on the regulatory authority stating the grounds and material facts on which the appellant relies.

(4) At the appellant's request, the Court may suspend or modify, on such terms and conditions as the Court thinks just, the operation of the regulatory authority's decision (against which the appeal was made) pending the determination of the appeal.

(5) The regulatory authority may apply to the Court, by summons served on the appellant, for an order that the appeal be dismissed for want of prosecution; and on hearing the application the Court may -

(a) dismiss the appeal or the application (in either case on such terms and conditions as the Court may direct), or

(b) make such other order as the Court considers just.

(6) On determining an appeal, the Court may -

(a) set the decision of the regulatory authority aside and, if the Court considers it appropriate to do so, remit the matter to the regulatory authority with such directions as the Court thinks fit, or

(b) confirm the decision, in whole or in part.

(7) An appeal from a decision of the Court under this regulation lies to the Court of Appeal on a question of law.

(8) Paragraph (5) is without prejudice to the inherent powers of the Court or to rule 52 of the Royal Court Civil Rules, 2007^b.

Matters to consider in exercising powers.

34. (1) In exercising its powers under this Part the regulatory authority shall have particular regard to the public interest.

(2) In considering any appeal under this Part the Royal Court shall have particular regard to the public interest.

(3) In issuing a pre-vetting notice, post-vetting notice or making a determination that an advertisement is in breach of a provision of these Regulations or of Part VI of the Law, the regulatory authority can proceed without proof of –

(a) actual loss or damage to any person caused by the issue or proposed issue of the advertisement, or

(b) an intention to breach or a failure to exercise proper

^b

Order No. IV of 2007.

care to prevent a breach.

(4) In considering any appeal under this Part, the Royal Court can proceed without proof of –

- (a) actual loss or damage to any person caused by the issue or proposed issue of the advertisement, or
- (b) an intention to breach or a failure to exercise proper care to prevent a breach.

PART VI GENERAL PROVISIONS

Offences.

35. (1) Any person who contravenes regulation 1, 2, 3, 5, 6, 7, 8, 9, 12, 14(1), 15(2), 16(2), 18(2), 18(3), 18(4), 20(2), 20(3), 21, 22(1), 23(1), 24(1), 26(2), 27(2), 28(3), 29(3), 31(2), or 32(2), is guilty of an offence and 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 to imprisonment for a term not exceeding two years, or to both.

(2) Any person who contravenes regulation 19 or 22(4) is guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

Interpretation.

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

"**abbreviated advertisement**" means an advertisement, other than a loose insert, which does not exceed in size an area of 420 square centimetres, in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply medicinal products;

"**advertisement**" has the meaning given by paragraph (2);

"**broadcast**" has the same meaning as in Part I of the Copyright (Bailiwick of Guernsey) Ordinance, 2005^c;

"**commercially interested party**" has the meaning given by section 72(4) of the Law;

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

"**cosmetic**" includes any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration;

^c

Ordinance XIX of 2005.

"**film**" has the same meaning as in Part I of the Copyright (Bailiwick of Guernsey) Ordinance, 2005^d;

"**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^e;

"**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;

"**the Narcotic Drugs Convention**" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30th March 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972;

"**persons qualified to prescribe**", in relation to medicinal products, includes persons, and employees of such persons, who in the course of their

^d Ordinance XIX of 2005.

^e Order in Council No. V of 2009.

profession or in the course of a business may lawfully prescribe medicinal products;

"persons qualified to supply", in relation to medicinal products, includes persons, and employees of such persons, who in the course of their profession or in the course of a business may lawfully sell by retail, or supply in circumstances corresponding to retail sale, medicinal products;

"pharmacy medicinal product" means a medicinal product which is neither prescription only medicine nor a medicinal product on a general sale list;

"post-vetting notice" mean a notice served under regulation 29;

"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;

"pre-vetting notice" mean a notice served under regulation 28;

"promotional aid" means a non-monetary gift made for a promotional purpose by a commercially interested party;

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971;

"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;

"Royal Court" or **"Court"** means the Royal Court sitting as an Ordinary Court, constituted by the Bailiff sitting unaccompanied by the Jurats; and for the purposes of an appeal under these Regulations the Court may appoint one or more assessors to assist it in the determination of any matter before it;

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

"sound recording" has the same meaning as in Part I of the Copyright (Bailiwick of Guernsey) Ordinance, 2005^f;

"summary of product characteristics" means the information listed in Article 11 of the 2001 Directive which is required under that Directive to accompany any application for a marketing authorisation or traditional herbal registration, and where there is no such information, it means the data sheet;

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

"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; and

^f Ordinance XIX of 2005.

"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) In its application to these Regulations "advertisement" has the meaning given by section 72 of the Law, except that –

(a) if it makes no product claim, an item of reference material, a factual, informative statement or announcement, a trade catalogue or a price list, shall not be taken to be an advertisement, and

(b) an advertisement includes a representation.

(3) For the purposes of paragraph (2) "representation" has the meaning given by section 72 of the Law, except that it does not include the making of a factual, informative statement or announcement which includes no product claim.

(4) 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.

(5) The Interpretation (Guernsey) Law, 1948^g applies to the interpretation of these Regulations –

(a) throughout the Bailiwick, and

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

(b) for the avoidance of doubt, as it applies to the interpretation of an enactment.

(6) 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 provisions.

37. (1) This regulation applies where, before the coming into force of these Regulations, -

(a) a contract has been made to issue an advertisement for a medicinal product, and

(b) under the terms of the contract, the advertisement may not be cancelled or altered without a financial penalty being payable.

(2) Where this regulation applies, the provisions of Parts II and III have no effect in relation to an advertisement referred to in paragraph (1)(b).

Extent.

38. These Regulations have effect throughout the Bailiwick.

Citation and commencement.

39. These Regulations may be cited as the Medicines (Human) (Advertising) (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. Adam', with a horizontal line extending to the right.

A. H. Adam

Minister of the States Health and Social Services Department

For and on behalf of the Department

SCHEDULE 1
PARTICULARS TO BE CONTAINED IN ADVERTISEMENTS TO HEALTH
PROFESSIONALS

Regulation 14(1)

1. The marketing authorisation, United Kingdom traditional herbal registration or United Kingdom certificate of registration number of the medicinal product.

2. The name and address of the holder of the marketing authorisation, United Kingdom traditional herbal registration or United Kingdom certificate of registration or the business name and address of the part of his business that is responsible for its sale or supply.

3. The supply classification of the medicinal product, specifying whether the product is prescription only medicine, a medicinal product on a general sale list, or a pharmacy medicinal product.

4. The name of the medicinal product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display name of the product.

5. In the case of all medicinal products other than homoeopathic medicinal products in respect of which a United Kingdom certificate of registration has been recognised, one or more indications for the medicinal product consistent with the terms of the marketing authorisation or United Kingdom traditional herbal registration.

6. A succinct statement (where relevant) of the entries in the summary

of product characteristics relating to side-effects, precautions and relevant contra-indications.

7. A succinct statement (where relevant) of the entries in the summary of product characteristics relating to dosage and method of use relevant to the indications shown. The method of administration should also be shown where this is not obvious.

8. Any warning issued by the regulatory authority which is required to be included in advertisements.

9. The cost of either a specified package of the medicinal product, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product.

10. The particulars contained in paragraphs 6, 7 and 8 shall be printed in a clear and legible manner and be placed in such a position in the advertisement that their relationship to the claims and indications for the product can be readily appreciated by the reader.

SCHEDULE 2

PARTICULARS TO BE CONTAINED IN ABBREVIATED ADVERTISEMENTS

Regulation 16(2)

1. The name and address of the holder of the marketing authorisation, United Kingdom traditional herbal registration or United Kingdom certificate of registration which relates to the medicinal product, or the business name and address of the part of his business that is responsible for its sale or supply.

2. The supply classification of the medicinal product, specifying whether the product is prescription only medicine, a medicinal product on a general sale list, or a pharmacy medicinal product.

3. The name of the medicinal product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.

4. Any warning issued by the regulatory authority which is required to be included in advertisements.

5. A form of words which clearly indicates that further information is available on request to the holder of the marketing authorisation, United Kingdom traditional herbal registration or United Kingdom certificate of registration or in the summary of product characteristics.

SCHEDULE 3
PARTICULARS WHICH MAY BE CONTAINED IN ADVERTISEMENTS FOR
HOMOEOPATHIC MEDICINAL PRODUCTS

Regulation 24

1. The scientific name of the stock or stocks, and, where the homoeopathic medicinal product is composed of two or more stocks, an invented name, followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homoeopathic manufacturing procedure described therein for that stock or stocks.

2. The name and address of the holder of the recognised United Kingdom certificate of registration and, where different, the name and address of the manufacturer.

3. The method of administration and, if necessary, route.

4. The expiry date of the product in clear terms (stating the month and year).

5. The pharmaceutical form.

6. The contents of the sales presentation.

7. Any special storage precautions.

8. Any special warning necessary for the product concerned.

9. The manufacturer's batch number.

10. The registration number allocated by the MHRA preceded by the letters "HR" in capital letters.

11. The words "homoeopathic medicinal product without approved therapeutic indications".

12. A warning advising the user to consult a doctor if the symptoms persist.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for the regulation of the advertising of medicinal products both to the general public and to health professionals. They implement Titles VIII and VIIIa of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.