

Subsidiary Legislation made under the Medical and Health Act (1973-05), saved and deemed to have been made under s.66.

Medicines (Advertising) Regulations 1996

LN.1996/103

Commencement **8.11.1996**

Transposing:

Directive 92/28/EEC

Directive 92/73/EEC

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In exercise of the powers conferred on him by section 47(g) and (m) of the Medical and Health Ordinance, and of all other enabling powers, and for the purpose of transposing into the national law of Gibraltar Council Directives 92/28/EEC and 92/73/EEC in so far as they refer to the advertising of services, the Governor has made the following Regulations—

PART I.

GENERAL.

Title and commencement.

1. These Regulations may be cited as the Medicines (Advertising) Regulations 1996 and shall come into effect on the 8th day of November, 1996.

Interpretation.

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

“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 the relevant medicinal products;

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

“essential information” has the meaning it bears in Council Directive 92/28/EEC;

“homeopathic medicinal product” means any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in EEA States;

“medicinal product for supply by prescription only” means a medicinal product supplied in accordance with a prescription given by a medical or other practitioner under regulations made under Article 47 of the Act;

“medicinal product on a general sale” means a medicinal product on a general sales list in regulations made under section 44 of the Act;

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“name” in relation to a relevant 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 trademark or the name of the person responsible for marketing the products;

“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;

“pharmacy medicinal product” means a medicinal product which is neither a medicinal product for supply by prescription only nor a medicinal product on a general sale list;

“promotional aid” means a non-monetary gift for a promotional purpose by a commercially interested party;

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

“reference material” includes entries which are in the form of, and limited to, a brief description of a medicinal product, its uses and any relevant contra-indications and warnings, appearing without charge in a publication consisting wholly or mainly of such entries where the publication is sent or delivered to persons qualified to prescribe or supply relevant medicinal products by a person who is not a commercially interested party;

“relevant medicinal product” means a medicinal product for human use to which the Act applies;

“summary of product characteristics” means –

- (a) name of the product;
- (b) qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product; the international non-names recommended by the World Health Organisation shall be used, where such names exist, or failing this, the usual common name or chemical description;
- (c) pharmaceutical form;
- (d) pharmacological properties and, in so far as this information is useful for therapeutic purposes, pharmacokinetic particulars;

(e) clinical particulars:

- therapeutic indications,
- contra-indications,
- undesirable effects (frequency and seriousness),
- special precautions for use,
- use during pregnancy and lactation,
- interaction with other medicaments and other forms of interaction,
- posology and method of administration for adults and, where necessary, for children,
- overdose (symptoms, emergency procedures, antidotes),
- special warnings,
- effects on ability to drive and to use machines;

(f) pharmaceutical particulars:

- incompatibilities (major),
- shelf life, when necessary after reconstitution of the product or when the container is opened for the first time,
- special precautions for storage,
- nature and contents of container,
- special precautions for disposal of unused products or waste materials derived from such products, if appropriate.

and expressions used in these Regulations which are used in any provision of the Act have, subject to sub-regulation (2) and unless the context otherwise requires, the meaning which they bear in the Act.

(2) For the purposes of these Regulations, “advertisement” has the meaning assigned to it by section 41(1) of the Act, except that, in relation to a relevant medicinal product—

- (a) provided that it makes no product claim, 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,

and for the purposes of this sub-regulation, “representation” has the meaning assigned to it by section 41(1) of the Act, except that it does not include the making of a factual, informative statement or announcement which includes no product claim.

(3) In these Regulations, unless the context otherwise requires, a reference to a regulation, Part or Schedule is to that regulation in, Part of or Schedule to, these Regulations and any reference in a regulation or Schedule to a numbered sub-regulation is to the sub-regulation of that regulation bearing that number.

PART II.
ADVERTISING TO THE PUBLIC.

Scope of Part II.

3. This Part, with the exception of regulation 10 (prohibition of supply of medicinal products to the public), applies only to advertisements wholly or mainly directed at members of the public, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.

Prohibition of advertisements relating to specified diseases.

4.(1) Subject to sub-regulation (2) and to regulation 9 (exception for approved vaccination campaigns), no person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product for the purpose of the treatment, prevention or diagnosis of any disease specified in, or any disease falling within a class of disease specified in, Schedule 1.

(2) Sub-regulation (1) shall not be taken to prohibit a person from issuing an advertisement which is likely to lead to the use of the relevant medicinal product for the purpose of the prevention of neural tube defects.

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

Prohibition of advertisements for medicinal products on prescription only.

5. Subject to regulation 9, no person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product which is a medicinal product for supply by prescription only and which is subject to any of the restrictions imposed by regulations made under section 47(e) of the Act.

Prohibition of advertisements relating to certain medicinal products.

6. Subject to regulation 9, no person shall issue an advertisement relating to any relevant 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 of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures to control in accordance with paragraphs 2 and 3 of article 3 of that Convention).

Prohibition of certain material in advertisements.

7.(1) Subject to regulation 9, no person shall issue an advertisement relating to any relevant 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 by suggesting treatment by post, FAX or telephone,
- (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 exclusively or principally at children,
- (f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products,
- (g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product,
- (h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural,
- (i) might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis,
- (j) refers, in improper, alarming or misleading terms, to claims of recovery, or

- (k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

(2) In this regulation, “FAX” means the making of a facsimile copy of a document by the transmission of electronic signals.

Form and content of advertisements.

8.(1) Subject to sub-regulation (2), no person shall issue an advertisement relating to a relevant medicinal product unless that advertisement –

- (a) is set out in such a way that it is clear that the message is an advertisement and so that the product is clearly identified as a medicinal product, and
- (b) subject to regulation 20(2), includes the following –
- (i) the name of the medicinal product,
 - (ii) if it contains only one active ingredient, the common name of the medicinal product,
 - (iii) the information necessary for correct use of the medicinal product, and
 - (iv) the 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.

(2) This regulation shall not apply to an advertisement relating to a relevant medicinal product which is on a promotional aid if-

- (a) the advertisement consists solely of the name of the product, and
- (b) the advertisement is intended solely as a reminder.

Exception for approved vaccination campaigns.

9. The provisions of Regulations 4(1), 5, 6 and 7(1)(d) shall not apply to any advertisement as part of a vaccination campaign relating to a relevant medicinal product which is a vaccine or serum, provided that such campaign has been approved by the Minister charged by the Governor under section 48 of the Constitution with responsibility for public health.

Prohibition of supply of medicinal products to the public.

10. No person in the course of a business carried on by him and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing, shall sell or supply for a promotional purpose any unsolicited relevant medicinal product to any member of the public.

PART III.**ADVERTISING ETC. TO HEALTH PROFESSIONALS.****Scope of Part III.**

11.(1) Subject to sub-regulation (2), this Part, with the exception of Regulations 17, 18, and 19, applies only to advertisements wholly or mainly directed at persons qualified to prescribe or supply relevant medicinal products, and accordingly references in this Part to advertisements are to advertisements to which this Part applies.

(2) Nothing in this Part has any effect in relation to veterinary surgeons or veterinary practitioners.

Advertisements to health professionals.

12.(1) Subject to sub-regulation (2) and to regulations 15 and 20(2), no person shall issue an advertisement relating to a relevant medicinal product unless such advertisement –

- (a) contains essential information compatible with the summary of product characteristics,
- (b) contains the particulars set out in paragraphs 1 to 6 of Schedule 2, and
- (c) is in accordance with paragraph 7 of Schedule 2.

(2) This regulation shall not apply to an advertisement to which regulation 13 or 14 applies.

Audio-visual advertisements.

13.(1) Subject to regulations 15 and 20(2), no person shall issue when broadcasting or in a video recording any advertisement relating to a relevant medicinal product which includes or shows any words, unless that advertisement –

- (a) contains essential information compatible with the summary of product characteristics, and

(b) refers to the particulars contained in paragraphs 1 to 5 of Schedule 2.

(2) For the purposes of this regulation the particulars contained in Schedule 2 may (where appropriate) be supplied by way of written material made available to all persons to whom the advertisement is shown or sent as an alternative to being referred to in the advertisement.

(3) In this regulation, “broadcasting” has the meaning assigned to it in section 2 of the Gibraltar Broadcasting Corporation Act.

Abbreviated advertisements.

14. Subject to Regulations 15 and 20(2), no person shall issue an abbreviated advertisement relating to a relevant medicinal product unless such advertisement –

- (a) contains essential information compatible with the summary of product characteristics;
- (b) contains the particulars set out in Schedule 3,

and any warning which the Governor has required in exercise of powers under section 47(g) of the Act to be included in any advertisement relating to that medicinal product has been included.

Exception for promotional aids.

15. The prohibitions and requirements imposed by regulations 12, 13 and 14 shall not apply to an advertisement relating to a relevant medicinal product which is on a promotional aid if–

- (a) the advertisement consists solely of the name of the product; and
- (b) the advertisement is intended solely as a reminder.

Written material accompanying promotions.

16.(1) No person shall send or deliver to persons qualified to prescribe or supply relevant medicinal products as part of the promotion of a relevant medicinal product any written material relating to that product unless it –

- (a) includes essential information compatible with the summary of product characteristics,

- (b) contains the particulars specified in paragraph 2 of Schedule 2, and
- (c) states the date on which it was drawn up or last revised.

(2) No person shall include any information in written material to which sub-regulation (1) applies which is not accurate, up-to-date, verifiable or sufficiently complete to enable the recipient to form his own opinion of the therapeutic value of the product to which the documentation relates.

(3) No person shall include in written material to which sub-regulation (1) 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.

17.(1) This regulation applies only to the supply of a free sample of a relevant medicinal product to a person who receives it for the purpose of acquiring experience in dealing with such a product.

- (2) A person may supply a sample to which this regulation applies only –
 - (a) to a person qualified to prescribe relevant medicinal products,
 - (b) if the sample is of a medicinal product which does 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), or
 - (ii) a substance which is listed in any of Schedules I to IV of 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), and
 - (c) in accordance with Schedule 4.

Medical sales representatives.

18.(1) This regulation applies only to the activities of medical sales representatives who promote relevant medicinal products to persons qualified to prescribe such products.

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(2) In relation to any relevant medicinal product which they promote, all medical sales representatives shall, during each visit, give to all persons whom they visit or have available for them a copy of the summary of product characteristics for each such product.

(3) In relation to the use of any relevant medicinal product which they promote, all medical sales representatives shall forthwith report all information which they receive from persons whom they visit, including reports of any adverse reactions, to the Specialist in Community Medicine in the Gibraltar Health Authority.

Inducements and hospitality.

19.(1) Subject to sub-regulation (2), where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) The provisions of sub-regulation (1) shall 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 relevant medicinal products, provided that-

- (a) such hospitality is reasonable in level,
- (b) it is subordinate to the main scientific objective of the meeting, and
- (c) it is offered only to health professionals.

(3) No person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless –

- (a) such hospitality is reasonable in level,
- (b) it is subordinate to the main purpose of the meeting or event, and
- (c) the person to whom it is offered is a health professional.

(4) No person qualified to prescribe or supply relevant medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

PART IV.

HOMEOPATHIC MEDICINAL PRODUCTS.

Advertisements for homeopathic medicinal products.

20.(1) No person shall issue an advertisement relating to a homeopathic medicinal product which –

- (a) contains any details which are not specified in Schedule 5; or
- (b) mentions any specific therapeutic indications.

(2) Nothing in Regulations 8(1)(b), 12(1), 13(1) or 14 shall be construed as requiring in an advertisement relating to a homeopathic medicinal product the inclusion of any detail which is not specified in Schedule 5.

**PART V.
OFFENCES.**

Offences.

21. Any person who contravenes Regulations 4(1) or (3), 5, 6, 8(1), 12(1), 13(1), 14, 16(1), (2) or (3), 17, 18(2) or (3), 19(1) or (3) or (4) or 20(1) shall be guilty of an offence.

**PART VI.
TRANSITIONAL PROVISION.**

Transitional provision.

22. The provisions of Parts II and III shall not have effect in relation to any advertisement relating to a relevant medicinal product in respect of which advertisement a contract has been made before the coming into force of these Regulations under the terms of which that advertisement may not be cancelled or altered without a financial penalty being payable.

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SCHEDULE 1.

Regulation 4

**DISEASES IN RESPECT OF WHICH ADVERTISEMENTS TO THE PUBLIC ARE
PROHIBITED**

Bone diseases
Cardiovascular diseases
Chronic insomnia
Diabetes and other metabolic diseases
Diseases of the liver, biliary system and pancreas
Endocrine diseases
Genetic disorders
Malignant diseases
Psychiatric diseases
Serious disorders of the eye and ear
Serious gastrointestinal diseases
Serious infectious diseases including HIV-related diseases and tuberculosis
Serious neurological and muscular diseases
Serious renal diseases
Serious respiratory diseases
Serious skin disorders
Sexually transmitted diseases.

SCHEDULE 2.

Regulations 12 and 13

PARTICULARS TO BE CONTAINED IN ADVERTISEMENTS TO HEALTH
PROFESSIONALS

1. The name and address of the person or business responsible for the sale or supply of the medicinal product in Gibraltar.
2. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.
3. The name of the 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. A succinct statement (where relevant) of the entries in the summary of product characteristics relating to side-effects, precautions and other relevant contra-indications.
5. A succinct statement 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.
6. The cost of either a specified package of the medicinal product to which the advertisement relates, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except that such cost may be omitted in the case of an advertisement inserted in a publication which is printed in Gibraltar but with a circulation outside Gibraltar of more than 15% of its total circulation.
7. The particulars contained in paragraphs 4 and 5 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 readily be appreciated by the reader.

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SCHEDULE 3.

Regulation 14

PARTICULARS TO BE CONTAINED IN ABBREVIATED ADVERTISEMENTS

1. The name and address of the business responsible for the sale or supply of the medicinal products.
2. The supply classification of the medicinal product, specifying whether the product is a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.
3. The name of the 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. A form of words which clearly indicates that further information is available in the summary of product characteristics relating to the product.

SCHEDULE 4.

Regulation 17

CONDITIONS FOR THE SUPPLY OF FREE SAMPLES

1. Samples shall be supplied on an exceptional basis only.
2. A limited number only of samples of each product may be supplied in any one year and to any one recipient.
3. Samples shall be supplied only in response to a written request, signed and dated, from the recipient.
4. Suppliers of samples shall maintain an adequate system of control and accountability.
5. Every sample shall be no larger than the smallest presentation available for sale in Gibraltar.
6. Every sample shall be marked “fresh medical sample - not for resale” or shall bear a similar description.
7. Every sample shall be accompanied by a copy of the summary of product characteristics for each such product.

SCHEDULE 5.

Regulation 20

**PARTICULARS WHICH MAY BE CONTAINED IN ADVERTISEMENTS FOR
HOMEOPATHIC MEDICINAL PRODUCTS**

1. The scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in relation to the homeopathic manufacturing procedure described therein for that stock or stocks.
2. 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 words "homeopathic medicinal product without approved therapeutic indications".
11. A warning advising the user to consult a doctor if the symptoms persist during the use of the product.