

Subsidiary Legislation made under the Medical and Health Act (1973 No. 5), saved and deemed to have been made under s.66.

## **Medicines (Monitoring of Advertising) Regulations 1996**

**LN.1996/104**

*Commencement*                      **8.11.1996**

**Transposing:**  
Directive 92/28/EEC

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### **ARRANGEMENT OF REGULATIONS**

Regulation

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**1997-25**

**Medical and Health**

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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 Article 12 of Council Directive 92/28/EEC insofar as it refers to the advertising of services, the Governor has made the following Regulations—*

**PART I**

**Title and commencement.**

1. These Regulations may be cited as the Medicines (Monitoring of 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 –

“the Advertising Regulations” means the Medicines (Advertising) Regulations 1996;

“the Complaints Authority” means the Board of the Gibraltar Broadcasting Corporation established under section 3(1) of the Gibraltar Broadcasting Act;

“Court”, means the Supreme Court of Gibraltar;

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

“publication” in relation to an advertisement means the dissemination of that advertisement, whether orally, in writing, by means of television or radio broadcast, or in any other way, and “publish” shall be construed accordingly;

and expressions used in these Regulations which are used in any provision of the Act have, subject to sub-regulations (2) and (3) 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 –

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- (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 the factual, informative statement or announcement which includes no product claim.

(3) In these Regulations “the Minister” means the Minister entrusted under section 48 of the Constitution with health matters.

(4) In these Regulations, unless the context otherwise requires, a reference to a regulation shall be construed as a reference to that regulation contained in these Regulations, and any reference in a regulation to a numbered sub-regulation shall be construed as a reference to the sub-regulation of that regulation bearing that number.

(5) These Regulations apply only to an advertisement for a product, substance or article for human use which is –

- (a) a medicinal product to which the Act applies, or
- (b) a homeopathic medicinal product.

**Proceedings.**

3.(1) Proceedings under these Regulations shall be brought before the Court.

(2) These Regulations are without prejudice to the availability of any criminal proceedings which may be taken under the Act or the Advertising Regulations.

(3) The Minister may, performing functions conferred on him by these Regulations, institute civil proceedings in his own name.

**Complaints about advertisements.**

4.(1) Subject to sub-regulation (2), the Minister shall consider any complaint made to him, other than a complaint to which regulation 5 applies or which it is the duty of the Complaints Authority to consider under regulation 9(1), that an advertisement, whether or not it has yet been published, may be in breach of the Advertising Regulations.

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(2) The Minister shall not proceed with the consideration of any complaint which appears to him to be frivolous or vexatious.

(3) In exercising the powers conferred on him by these Regulations the Minister shall have regard to all the interests involved and in particular the public interest.

**Complaints about certain advertisements.**

5.(1) This regulation applies to any complaint made to the Minister, other than a complaint which it is the duty of the Complaints Authority to consider under regulation 9(1), that an advertisement, whether or not it has yet been published, may be in breach of any provision of regulation 7 of the Advertising Regulations (prohibition of certain material in advertisements to the public) or any regulation in Part III of the Advertising Regulations (advertising to health professionals).

(2) Subject to sub-regulation (4), in relation to a complaint to which this regulation applies, where the Minister and the complainant agree within a reasonable time that the provisions of this sub-regulation should apply, the Minister shall select a body which appears to him to be a self-regulatory body which deals with complaints about advertisements of that type, shall refer the complaint to that body, and that body may consider the complaint.

(3) Subject to sub-regulation (4), the Minister shall consider any complaint to which this regulation applies –

- (a) in the absence of any agreement within a reasonable time in accordance with sub-regulation (2), or
- (b) if, where there is such agreement, the body selected by the Minister in accordance with sub-regulation (2) has not within a reasonable time dealt with the complaint adequately.

(4) Neither the Minister nor the body selected by the Minister in accordance with sub-regulation (2) shall proceed with the consideration of any complaint which appears to him or it to be frivolous or vexatious.

**Applications to the Court by the Minister.**

6. If, having considered in accordance with regulation 4(1) or 5(3) an advertisement about which a complaint has been made, or having considered an advertisement about which no complaint has been made, the Minister considers that that advertisement is in breach of the Advertising Regulations, he may bring proceedings for an injunction (in which proceedings

he may also apply for an interlocutory injunction) against any person appearing to him to be concerned or likely to be concerned with the publication of that advertisement.

**Functions of the Court.**

7.(1) Before granting an injunction the Court shall have regard to all interests involved and in particular the public interest.

(2) An injunction may relate not only to a particular advertisement but to any advertisement in similar terms or likely to convey a similar impression.

(3) An injunction may prohibit the publication or further publication of an advertisement.

(4) In considering an application for an injunction the Court may, either on the application of any party to the proceedings or of its own motion, require any person appearing to the Court to be responsible for the publication of the advertisement to which the application relates to furnish the Court within such time as it allows with evidence as to the accuracy of any factual claim made in the advertisement; and in deciding whether or not to make such a requirement the Court shall have regard to the legitimate interests of any person who would be the subject of or affected by the requirement.

(5) If such evidence is not furnished to it in accordance with sub-regulation (4) or if it considers such evidence inadequate, the Court may consider the factual claim inaccurate.

(6) The Court shall not refuse to grant an injunction for lack of evidence that –

- (a) the publication or anticipated publication of the advertisement in question has given rise to loss or damage to any person, or
- (b) the person responsible for the advertisement intended it to be in breach of the Advertising Regulations, or failed to exercise proper care to prevent its being in breach of those Regulations.

(7) Where the Court grants an injunction following an application under regulation 6, the Court shall give reasons in detail for the granting of the injunction, and the Minister shall communicate those reasons in writing to the person against whom the injunction has been granted, referring to any remedy available in the Court and any time limit which must be met in order for any such remedy to be available.

**Publication of decision and corrective statement.**

8.(1) Where the Court has granted an injunction (other than an interlocutory injunction) following an application under regulation 6, the Minister may require any person against whom the injunction has been granted to publish within a specified time and in such form as the Minister considers adequate –

- (a) the decision, in full or in part, to grant the injunction, and
- (b) a corrective statement in relation to the advertisement in respect of which the injunction was granted.

(2) If any person fails within the time specified in sub-regulation (1) to publish any statement which the Minister may require under the provisions of that sub-regulation, the Minister may certify that failure to the Court.

(3) Where a person's failure is certified in accordance with sub-regulation (2), the Court may enquire into the matter.

(4) Where the Court conducts an enquiry in accordance with sub-regulation (3) and is satisfied that a person has failed within the time specified in sub-regulation (1) to publish any statement which the Minister may require under the provisions of that sub-regulation, it may, after–

- (a) hearing any witness produced against, or on behalf of, the person concerned, and
- (b) considering any statement offered in his defence,

deal with him in any manner that would be available to it had he been in contempt of Court.

#### **Complaints to the Complaints Authority about certain broadcast advertisements.**

9.(1) The Complaints Authority shall consider any complaint made to it that any advertisement included or proposed to be included in any sound or television service may be in breach of any provision of regulation 7 of the Advertising Regulations, unless the complaint appears to it to be frivolous or vexatious.

(2) In exercising the powers conferred on it by these Regulations the Complaints Authority shall have regard to all the interests involved and in particular the public interest.

(3) In this regulation, "sound or television service" means a service which the Gibraltar Broadcasting Corporation is under a duty to maintain pursuant to section 8(1) of the Gibraltar Broadcasting Corporation Act.

**Control by the Complaints Authority of certain broadcast advertisements.**

10.(1) If, having considered a complaint about an advertisement in accordance with regulation 9(1), the Complaints Authority considers that the advertisement in question is in breach of any provision of regulation 7 of the Advertising Regulations, it may give directions for the purpose of preventing the publication or further publication of that advertisement.

(2) Directions referred to in sub-regulation (1) may relate not only to a particular advertisement but to any advertisement in similar terms or likely to convey a similar impression.

(3) The Complaints Authority shall not refuse to exercise its powers under sub-regulation (1) for lack of evidence that –

- (a) the publication or anticipated publication of the advertisement in question has given rise to loss or damage to any person, or
- (b) the person responsible for the advertisement intended it to be in breach of any provision of regulation 7 of the Advertising Regulations, or failed to exercise proper care to prevent its being in breach of any part of that regulation.

(4) The Complaints Authority shall give reasons in detail for its decision under sub-regulation (1), and shall communicate those reasons in writing to the person against whom action has been taken under that sub-regulation, referring to any remedy available in the Court and any time limit which must be met in order for any such remedy to be available.