L.N. 60 of 2008

MEDICINES ACT
(CAP. 458)

Medicines Products (Injunction to Advertising) Regulations, 2008

IN exercise of the powers conferred by articles 31 and 106 of the Medicines Act, the Minister of Health, the Elderly and Community Care, has made the following regulations:-

Citation and commencement.

1. (1) The title of these regulations is Medicines Products (Injunction to Advertising) Regulations, 2008

(2) These regulations shall come into force on last of February, 2008.

Interpretation.

2. In these regulations, unless the context otherwise requires:

"the Act" means the Medicines Act;

"the Authority" means the Medicines Authority established under article 4 of the Act;

"the Commission" means the Commission of the European Community;

"Court of Appeal" means the Court of Appeal sitting in its inferior jurisdiction as constituted in terms of sub-article (6) of article 41 of the Code of Organization and Civil Procedure; Cap. 12.

"the Directive" means the provisions of Directive 98/27/EC of the European Parliament and of the Council of 19th May, 1998 on injunctions for the protection of consumersí interests;

"EEA State" means any State which is a contracting party to the agreement on the European Economic Area signed at Oporto on the 2nd May, 1992 as amended by the Protocol signed at Brussels on 17th March, 1993 and as amended from time to time;

"European Community" means the organisation established by the Treaty of Rome in 1957 and amended institutionally and

otherwise in 1986 by the Single European Act, in 1993 by the Treaty on European Union, in 1997 by the Treaty of Amsterdam and in 2001 by the Treaty of Nice and as amended by accession agreements and as may be further amended from time to time;

"list of qualified entities" means the list compiled and updated by the Commission and published in the Official Journal of the European Communities listing the qualified entities in Member States and EEA States in accordance with Article 4 of the Directive;

"medicinal products" means medicinals for human use;

"Member State" means a member of the European Community;

"the Minister" means the minister responsible for health;

"qualified entity" means any body or organization which, being properly constituted according to the law of a Member State, has a legitimate interest in ensuring that the provisions referred to in article 3 of this Order are complied with and, without prejudice to the generality of the foregoing, includes:-

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(a) a registered consumer association within the meaning of Part IV of the Consumer Affairs Act;

(b) one or more independent public bodies, having a legitimate interest in ensuring the protection of the collective interests of consumers of medicinal products advertising in other Member States or EEA States in which such bodies exist;

(c) voluntary organisations in other Member States or EEA States whose purpose is to protect the interests referred to in paragraph (a) of this definition in accordance with the criteria laid down by their national law;

(d) organisations recognised by the Authority as collectively representing medicinal products manufacturers, suppliers and distributors; or

(e) any qualified entity from a Member State or EEA State included in the list of qualified entities;

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"the 2005 Regulations" means the "Medicinal Products (Advertising) Regulations, 2005.

(2) Words and expressions used in these regulations which are also used in the Act or in the 2005 Regulations shall have the same meanings as in the Act or in the said regulations.

Object.

3. The object of these regulations is to implement the provisions of the Directive, as applicable to the advertising of medicinal products contained in Directive 92/28/EEC as transposed by the 2005 Regulations, and shall be interpreted and applied accordingly.

Scope.

4. These regulations apply to any advertising of medicinal products in or from Malta as regulated by Directive 92/28/EEC.

Application for compliance orders by qualified entities

5. (1) Where a qualified entity wishes to seek a compliance order, it shall submit its written application to the Authority. In its application, it shall satisfy the Authority that it has tried to achieve the cessation of the infringement in consultation with either the defendant or both the defendant and another qualified entity of the Member State or EEA State in which the injunction is sought. The Authority shall only entertain a written application if the qualified entity shows to its satisfaction that the cessation of the infringement was not achieved within two weeks after the request for consultation was received.

(2) Where the qualified entity is from another Member State or EEA State, the Authority shall treat the list of qualified entities published by the Commission as conclusive proof of the legal capacity of the legal entity to present such written application in Malta.

(3) The Authority shall, at the request of a qualified entity from Malta, communicate to the Commission the name and objects of such entities and that such qualified entity should be added to the list of qualified entities so as to facilitate the redress of inter-community infringements.

(4) Before proceeding for the issue of a compliance order under article 6, the Authority shall, if it considers it to be possible and reasonable to do so, seek first to achieve voluntary compliance by a person licensed under the Act and other persons involved, in accordance with these regulations, the Act or any other law dealing with consumer rights and protection.

(5) For the purposes of these regulations, an infringement occurs when any act is committed contrary to Directive 92ċ28ċEEC as transposed by the 2005 Regulations.

Issue of compliance orders.

6. (1) Where the Authority feels it reasonably appropriate or necessary for the protection of consumers, it may, on a written

application to it by a qualified entity, issue a compliance order against any person licensed under the Act for one or more of the following purposes:-

(a) ordering any such person to cease any advertisement of a medicinal product which the Authority considers to be in breach of the provisions of the 2005 Regulations;

(b) requiring such person to take any measures specified in such order, within the time specified in the compliance order to ensure that such order is complied with;

(c) requiring such person to cease or desist from committing a breach of these regulations or of the provisions of the Act regulating advertisements or of the 2005 Regulations.

(2) The Authority shall, when issuing a compliance order under these regulations -

(a) serve a copy of the compliance order on each person against whom the order is made;

(b) include with the compliance order, information about the right to institute an action before the Court of Appeal, in accordance with regulation 9; and

(c) briefly state the reasons for issuing the compliance order, which reasons shall be notified to each person against whom the compliance order is issued and, if any, to the qualifying body on whose application the compliance order is issued.

(3) No precautionary warrant or other order under any other law shall be issued by any court or tribunal restraining or restricting the Authority from issuing a compliance order under such order.

Discretion of the Authority to issue a compliance order.

7. (1) It shall be at the discretion of the Authority whether or not to issue a compliance order after a written request by a qualified entity has been made to it in terms of sub- regulation (1) of regulation 6.

(2) If the Authority decides not to issue a compliance order after an application has been made to it by a qualified entity, it shall, within seven days from the date of its decision, notify in writing the qualified entity and the persons against whom the compliance order is requested with its decision stating the reasons therefore.

(3) A qualified entity may within fifteen days from the date of notification upon it of the decision of the Authority not to issue a compliance order, institute an action before the Court of Appeal for the issue of an order requiring the Authority to issue a compliance order under regulation 6. The persons against whom the compliance order is requested to be made shall be parties to the suit, and it shall be the duty of the qualified entity to notify such persons accordingly.

(4) In the exercise of its functions and powers under this Order, the Court of Appeal shall in all cases act as expeditiously as possible.

Compliance order to take immediate effect.

8. A compliance order issued by the Authority shall come into force with immediate effect.

Appeal from a compliance order.

9. (1) A person against whom a compliance order has been made, may, within fifteen days from receipt of notification of the compliance order, appeal in writing to the Court of Appeal for the revocation or amendment of the compliance order, giving detailed grounds for the request. Such appeal may be made only on the following grounds:-

(a) the Authority has, in its decision wrongly applied any of the provisions of these regulations; or

(b) the decision of the Authority constitutes an abuse of discretion or is manifestly unfair.

(2) The Court of Appeal may confirm, change or cancel the compliance order on any terms or conditions it considers appropriate.

(3) Where an appeal is instituted under sub- regulation (1), the compliance order shall remain in force unless the Court of Appeal specifically orders that the compliance order shall be stayed pending the outcome of the appeal, subject to such conditions and amendments as it may determine. In any such instance, the Authority may request the Court of Appeal to make an interim compliance order, ordering that the compliance order shall, subject to such modifications as the Authority may suggest, continue in force pending the final determination of the case instituted in accordance with sub-regulation (1). An interim compliance order shall expire upon the final determination of the case.

(4) Subject to these regulations, the provisions of the Code of Organization and Civil Procedure shall, *mutatis mutandis*, govern appeals to the Court of Appeal. Cap.12.

No need to prove actual loss, etc.

10. The Authority, when issuing a compliance order under regulation 6, shall not be required to prove:-

(a) actual loss or damage or

(b) actual recklessness, negligence or fault on the part of the person against whom the order is made.

The Authority may require publication.

11. (1) The Authority may, for the better information of the public:-

(a) publish a copy of the compliance order made under regulation 6 against any such person, in full or in part; or

(b) order any person licensed under the provisions of the Act to publish a corrective statement in relation to any contravention of these regulations; or

(c) take both measures mentioned in paragraph (a) and (b) above.

(2) Publication in terms of sub-regulation (1) shall be made at the expense of the against whom the order was issued, in at least two daily newspapers within seven days from receipt of the notice and shall be at the expense of the person served with such notice. Where such publication is not effected as aforesaid, the Authority may proceed to effect publication itself, in which case it shall have the right to recover from the person on whom the notice is served, any expenses incurred, as a civil debt, constituting an executive title for the purposes of Title VII of Part I of Book Second of the Code of Organization and Civil Procedure as if payment of the amount of the civil debt has been ordered by a judgment of a court of civil jurisdiction.

Delegation of powers of the Authority.

12. The Authority may in writing authorize any of its employees, a public or other officer or any other person to perform any of its functions in relation to the enforcement of these regulations or exercise any power granted to it under these provisions. Any such authorized person shall, when required, produce the written authorisation signed by the Authority.

Obtaining information.

13. (1) The Authority may, for the purpose of discharging its functions under these regulations, require any person to provide any information in any manner, including by:-

(a) answering any questions, orally or in writing; or

(b) producing any item or data as aforesaid as the Authority may consider to be necessary; or

(c) producing any books, documents or other records as the Authority may consider to be necessary.

(2) Any such person shall promptly comply with any such request.

Failure to comply with these regulations.

14. (1) A person licensed under the provisions of the Act, shall be liable to an administrative penalty in terms of regulation 15 if such personĠñ

(a) fails to observe any other provision in these regulations;

(b) fails to comply with a compliance order issued under these regulations; or

(c) refuses or fails to furnish information as required under these regulations or else provides false or misleading information.

(2) A person licensed under the provisions of the Act, shall be liable to an administrative penalty if such person:-

(a) wilfully obstructs, assaults, threatens, resists or interferes with the Authority or any person delegated by it in terms of regulation 12 or any public officer in the exercise of his duties under these regulations or attempts so to do; or

(b) uses threatening, abusive or insulting language to the Authority or any person delegated by it in terms of regulation 12 or any public officer in the course of duties.

Administrative penalties.

15. (1) In the event of liability arising in terms of article 14 the Chief Executive of the Authority may by notice in writing request the Authority to impose on the person licensed under the provisions of the Act an administrative penalty in terms of article 100 of the Act and the procedure laid down in that article shall mutatis mutandis apply.

Other administrative sanctions.

16. (1) Nothing in these regulations shall prejudice or limit the exercise of the powers of the Authority to take administrative measures or impose penalties under the Act, against a person licensed under the provisions of the Act who has contravened any provisions of these regulations or has failed to satisfy or comply with any obligation or condition to which he may be subject under the Act or the 2005 Regulations.

(2) Nothing in these regulations shall be deemed to restrict or detract from the powers of the Authority under any other law, or from the powers of the Police under the Criminal Code or any other law.

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Services of orders or notices.

17. (1) Where an order or notice is required or authorised to be served under these regulations it shall be served in any of the following manners:-

(a) by delivering it, or by sending it by registered mail to the person on whom it is to be served at such personís place of residence, office or place of work; or

(b) in the case of a body corporate or other body of persons, by delivering it to an officer or servant thereof at the registered office or any other place of business, or sending it in a registered letter addressed to any such office.

(2) In any case where it is not reasonably possible to effect service in any manner stated in sub- regulation (1), service may be affected by publishing a summary of such notice in the Gazette.

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