

MEDICINES AUTHORITY



**Guidelines for the Advertising of Medicinal
Products for human use**

Guidelines for the advertising of medicinal products for human use

Introduction

These guidelines are applicable for the advertising of medicinal products for human use.

A “medicinal product” is defined as any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

The guidelines explain the provisions and requirements for the advertising of medicinal products to the general public and to healthcare professionals, as laid down in the advertising regulations and provide additional clarification, where necessary, on the interpretation of the regulations and their application.

Therefore, these guidance notes should be read and construed alongside the Medicines Act, 2003 (Act No III of 2003) and the Medicinal Products (Advertising) Regulations, 2005, L.N. 380. The regulations transpose Directive 2001/83/EC, Title VIII. A copy of the Medicines Act and the Regulations can be obtained from the website of the Medicines Authority, <http://www.medicinesauthority.gov.mt/legislation.htm> .

The guidelines do not replace, or constitute, formal decisions of the Medicines Authority and the Licensing Authority. Also, the guidelines should not be taken as a complete or definitive statement of the law.

Further advice can be obtained from the Advertising Committee within the Medicines Authority. Requests for advice should be made in writing. (Email address: advertising.mru@gov.mt)

These guidelines are applicable from 1 May 2008.

Background

The legal basis for the control of advertising is contained in the Medicines Act, 2003 (Act No III of 2003) and the Medicinal Products (Advertising) Regulations, 2005. The regulations explain the different requirements for advertising to the general public and healthcare professionals.

The control of medicines advertising in Malta, from 1 May 2004, is based on the system of self-regulation. The Advertising Committee within the Medicines Authority does not evaluate advertisements prior to their publication. The Committee investigates complaints received, routinely monitors advertisements and provides advice to industry, health professionals and other regulatory bodies.

Guidelines for the advertising of medicinal products for human use

It is an offence for any person to breach the regulations. Should there be a breach in the advertising regulations immediate warnings, sanctions and penalties will be issued. Reference is made to the offences and penalties under Article 99 (1) (e) and Article 100 of the Medicines Act.

Complaints regarding advertised medicinal products

Complaints on advertised medicinal products can be made to the Advertising Committee. The complaint form is available on the website of the Medicines Authority (<http://www.medicinesauthority.gov.mt/advertising.htm>). The form must be filled in and posted to the Advertising Committee, Medicines Authority, 198, Rue D'Argens, Gzira GZR 1368. All relevant fields must be completed so that the complaint can be processed and investigated. Anonymous complaints and complaint forms that have not been signed will not be accepted.

General rules for the advertising of medicinal products

The continuous monitoring and control of advertising of medicinal products is essential at all times for the protection of public health.

The following general rules apply when medicinal products are advertised.

1. By regulation 5 (1) of the Medicinal Products (Advertising) Regulations, medicinal products which do not have a valid marketing authorization (that is an authorization to place a medicinal product on the market) may not be advertised. It is therefore in breach of the advertising regulations to issue any advertisements and promotional material until the marketing authorization for a medicinal product has been granted.
2. Advertising of a medicinal product must encourage rational use, that is, the correct and proper use of the product by presenting it objectively and without exaggeration as to its safety, quality and efficacy [Regulation 4(a)].
3. Also, by regulation 4(b) of the Regulations, an advertisement must comply with the particulars listed in the Summary of Product Characteristics (SmPC). Therefore, all parts of an advertisement must be consistent with the approved SmPC. The SmPC is a summary of the characteristics of the product and it forms an intrinsic and integral part of the marketing authorization.

Guidelines for the advertising of medicinal products for human use

Advertising of Medicinal Products for human use to the General Public

Medicinal products that can be advertised to the public

Advertising to the public is allowed for medicinal products that are legally classified as over the counter (OTC) products. The regulations prohibit the advertising of prescription only medicines (POM) to the general public [Regulation 5(2)(a)(b)].

The regulations also prohibit advertising to the general public of medicinal products for the treatment, prevention or diagnosis of certain diseases or conditions which are specified in Regulation 5 (3) of the advertising regulations.

The information necessary for the correct use of the medicinal product

Advertising to the general public should contain a clear and legible invitation to read carefully the instructions on the package leaflet or on the label, as the case may be. A reference can be made to the label alone if there is no package leaflet or where the label gives specific instructions to refer to the package leaflet.

When the safe and correct use of some medicinal products depends on compliance with certain conditions for use, this should be stated in the promotional material. For example when treatment should be continuous in order to be successful.

Overall, there are four compulsory items of information which must be present in all advertising aimed at the public. These include:

Name of the medicinal product. This must be as stated in the marketing authorization;

The active ingredient, if the product contains only one active ingredient;

The information necessary for the correct use of the medicinal product. This is usually fulfilled by stating the licensed indication. However, for products used for a prolonged or specified period, more information may be necessary. Companies must ensure that the indication is line with the SPC;

An express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be. The advertisement must contain an instruction to “always read the leaflet”. For products without an in-pack leaflet, all the necessary information would be on the outer packaging and therefore “always read the label” would suffice.

Guidelines for the advertising of medicinal products for human use

Prohibition of certain promotion material

Advertising to the general public should not suggest that the effects of taking the medicine are guaranteed or that one product is better than or equivalent to another treatment or medicinal product.

Also, advertising must be true and must not mislead or contain any exaggerated claims. Therefore, advertising material, which refers in improper, alarming or misleading terms to claims of recovery, shall not be permitted.

Children

The advertising of a medicinal product should not be directed exclusively or principally at children (under 16).

Recommendations and endorsements

Advertisements should not contain any material which refers to a recommendation by scientists, health professionals or celebrities or well known organisations who because of their celebrity could encourage the consumption of medicinal products. An advertisement should not mention either directly or indirectly that a medicinal product is licensed and should not imply or state that a product has been approved.

Distribution of samples

The regulations on advertising prohibit the sale or supply of samples of medicinal products for promotional purposes to any member of the public.

Supply of samples through published media or by post for example with magazines is also unacceptable.

Prescription only medicines: information to the media

Information on prescription medicines which is submitted to the lay press, television or radio or by press releases must be factual, non-promotional and should not encourage the general public to ask their GP to prescribe such products. Special attention should be given when providing information in response to direct approaches from the media where a company has little control over the final outcome, for example, television programmes which could result in the advertising of prescription medicines to the general public.

Disease awareness and health education campaigns

Campaigns directed at the general public in order to provide information, promote awareness or educate the public on a disease or condition are encouraged. However, the information provided must not contain claims on medicinal products otherwise the

Guidelines for the advertising of medicinal products for human use

material would be considered promotional material and would fall under the advertising regulations. The use of brand names, restricting the range of treatments described in the campaign or drawing attention by advertising which can lead to the use of a specific medicinal product on prescription can result in a potential breach of the advertising regulations.

Advertising of Medicinal Products for human use to Health Professionals (Persons qualified to prescribe or supply medicinal products)

Information provided to persons qualified to prescribe or supply

Any advertising of a medicinal product to persons qualified to prescribe or supply must include essential information compatible with the Summary of Product Characteristics (SmPC). Regulation 8 of the advertising regulations lists the essential information which must be included.

This essential information should be presented clearly, legibly and be planned out in such a way that it is easy for the reader to refer to.

A copy of the approved SmPC must accompany each sample of the medicinal product supplied to prescribers and be available from medical sales representatives during visits when a medicinal product is being promoted.

Promotional aids

Advertisements of medicinal products which are on a promotional aid (e.g. a pen, notepad, mug) and intended as reminders, may include only the name of the product and are exempt from the need to include other essential information. These promotional aids must be relevant to the practice of medicine or pharmacy.

Gifts, inducements and other benefits

Regulation 10 of the advertising regulations states that where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

Any promotional activity which is aimed at encouraging the purchase or sale of medicinal products by persons qualified to prescribe or supply is covered by regulation 10. Such promotional activities include for example advertising, bonus schemes and public relations exercises.

The item or benefit offered must be both inexpensive and relevant to the practice of pharmacy or medicine for it to fall outside the prohibition in regulation 10 of the Advertising Regulations. Both conditions must be fulfilled. Inexpensive items are those

Guidelines for the advertising of medicinal products for human use

which do not cost the company more than Euro 30.

Relevant items or benefits to the practice of pharmacy or medicine are those which have a general business use such as for example pens, notepads, calculators, mugs, inexpensive computer accessories and diaries.

An equivalent approach applies to membership schemes and cumulative points schemes which have the effect of conferring personal benefits in the form of free or reduced price goods or services.

The prizes in competitions which are applicable to persons qualified to prescribe or supply and which are associated with the promotion of a medicinal product must also be both inexpensive and relevant to the practice of pharmacy or medicine. The maximum prize figure considered appropriate for a competition is Euro 232. The number of prizes should be restricted to a few only.

Hospitality and meetings

Regulation 10(2) states that “reasonable” hospitality can be offered to health professionals at meetings or events held to promote medicines, provided it is subordinate to the main purpose of the meeting or event.

Also, hospitality should not be offered to persons who are not health professionals.

Professional samples

A sample is a small supply of a medicine provided to health professionals so that they may familiarize themselves with it and acquire experience in dealing with it.

Starter packs are small packs for which a marketing authorization has been granted. They are designed to provide sufficient medicine for a prescriber to initiate treatment in such circumstances where there might be undesirable or unavoidable delay in having a prescription dispensed, where immediate commencement of treatment is necessary, or where the prescriber feels that the use of such presentation is indicated in the interests of the patient.

Therefore, starter packs are not considered to be samples for promotional or advertising purposes and are not covered by the Advertising Regulations.

Regulation 11 refers to the supply of free samples of medicinal products to persons qualified to prescribe them. Samples may only be supplied to a person qualified to prescribe medicinal products and on the following conditions:

1. They shall be supplied on an exceptional basis only;
2. Twelve samples of each product may be supplied in any one year to any one recipient;

Guidelines for the advertising of medicinal products for human use

3. They should be supplied only in response to a written request, signed and dated from the prescribing agent;
4. Suppliers of samples shall maintain an adequate system of control and accountability;
5. They shall be no larger than the smallest presentation on the market;
6. Each sample must be appropriately labelled and marked “free medical sample-not for sale”, or similar wording having the same meaning;
7. Each sample shall be accompanied by a copy of the approved SmPC.

Samples of medicinal products containing psychotropic or narcotic substances, as defined under the First schedule of the Dangerous Drugs Ordinance and the Third Schedule of the Medical and Kindred Professions Ordinance, cannot be supplied.

Medical sales representatives

Medical sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and complete as possible about the medicinal products they are promoting.

During each visit, medical sales representatives should give the persons visited, or have available for them, SmPCs of each medicinal product they promote at the visit together with details of the price. They must also report all information relating to the safety of a product which they receive from health professionals directly to scientific services set up by the marketing authorisation holder.

Provision of medical or pharmaceutical education, goods and services

Schemes which are launched by the pharmaceutical industry offering sponsorship of research posts, study visits etc. may well be acceptable provided that there is no element of promotion of individual products associated with them. The provision of goods or services to hospitals and health care units for the benefit of patients should not be dependent upon, or subject to, the prescription or supply of medicinal products and should not refer to them by name.