Guidelines for the Advertising of Medicinal Products for Human Use

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Post-Licencing Directorate

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1 Introduction and Scope

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

A "medicinal product" is defined as any substance or combination of substances presented as having properties for treating or preventing disease in human beings, as well as any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis (Medicines Act, Chapter 458, Laws of Malta).

The advertising regulations and these guidelines apply to products authorised to be placed on the market in Malta. 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, S.L. 458.32. 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 Malta Medicines Authority, www.medicinesauthority.gov.mt or the ministry of justice website http://www.justiceservices.gov.mt/LOM.aspx?pageid=27&mode=chrono&p=15&lawid=8924 .

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

complete or definitive statement of the law.

Further clarifications on this guideline can be obtained from the Malta Medicines Authority. Requests for clarifications should be made in writing. (Email address: advertising.medicinesauthority@gov.mt)

These guidelines were written (June 2005) and have been updated in April 2013, March 2017 and February 2020. They are applicable accordingly.

2 Background

The legal basis for the control of advertising is specified in the Medicines Act, 2003 (Act No III of 2003) and the Medicinal Products (Advertising) Regulations, S.L. 458.32. 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 Malta Medicines Authority does not evaluate advertisements prior to their publication. Complaints received are investigated by the Malta Medicines Authority.

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

In addition to the legislation under the Medicines Act (the Medicinal Products (Advertising) Regulations, S.L. 458.32). Advertising of medicinal products on the broadcasting media (TV and radio) is regulated by the Broadcasting Act which was amended to reflect the Audio-Visual Media Services Directive which inter-alia regulates

audio-visual commercial communication (advertising) of medicinal products. Of particular relevance is Article 16K(f) of the Broadcasting Act Chapter 350 of the Laws of Malta. In addition Subsidiary Legislation 350.30 (REQUIREMENTS AS TO STANDARDS AND PRACTICE ON PROGRAMMES INVOLVING THE PARTICIPATION OF CERTAIN HEALTH PROFESSIONALS IN THE BROADCASTING MEDIA AND REQUIREMENTS AS TO ADVERTISEMENTS, METHODS OF ADVERTISING AND DIRECTIONS APPLICABLE TO MEDICINAL PRODUCTS) available for download here http://www.ba-malta.org/file.aspx?f=91. This specific legislation is enforced by the Broadcasting Authority.

3 Specific Guidance

3.1 Complaints regarding advertised medicinal products

Complaints on adverts for medicinal products can be made to the Advertising Committee. The complaint form is available on the website of the Malta Medicines Authority (http://www.medicinesauthority.gov.mt/regulationadvertisingofmedicines). The form must be filled in and posted to the Advertising Committee, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann, SĠN 3000, Malta. 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.

3.2 General rules for the advertising of medicinal products

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 authorisation to be placed on the Maltese market may not be advertised. It is therefore in breach of the advertising regulations to issue any advertisements and promotional material until the 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.

3.3 Advertising of Medicinal Products for human use to the General Public

3.3.1 Medicinal products that can be advertised to the public

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

The regulations also prohibit medicinal products being distributed to the general public. [Regulation 5 (3) of the advertising regulations].

3.3.2 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 and/or on the label (outer packaging), 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 authorisation,
- All active ingredients;
- 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/s is/are in line with the SmPC;
- A clear 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.

3.3.3 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, is not be permitted.

3.3.4 Advertorials

Sometimes adverts take the form of an advertorial where the advertisement is similar to a short infomercial presentation of products or services. These can either be in the form of a television commercial or as a segment on a talk show or variety show. Advertorials should be avoided, and Marketing Authorisation Holders and their local representatives are responsible that the provisions of the advertising regulations (SL. 458.32) are complied with.

3.3.5 Children

The advertising of a medicinal product should not be directed or addressed to children (under 16 years).

3.3.6 Recommendations and endorsements

Advertisements should not contain any material which refers to a recommendation by scientists, health professionals or celebrities or well known organisations or persons who because of their profession or celebrity status could encourage the consumption of medicinal products.

3.3.7 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.

3.3.8 Advertising of medicinal treatment services

Although advertising of medicinal treatment services falls outside of the scope of the Medicinal Products (Advertising) Regulations, 2005 (Subsidiary Legislation 458.32), advertisers promoting medical or medical aesthetic services to the general public should do so without promoting specific prescription-only medicines (POMs).

It should be noted that Botox is one of various trade names for medicinal products containing Botulinum toxin. Botox and other injectable medicinal products containing Botulinum toxin are registered as a prescription-only medicine (POM) in Malta, and therefore in line with Regulation 5.(2)(a) of the Medicinal Products (Advertising) Regulations, 2005 may not be advertised to the general public.

Such prohibited advertising includes:

- Printed media (such as magazines, flyers, posters etc...) and digital media (such as websites, social media, online audio-visuals etc...) distributed to and/or made available to general public, which directly or indirectly reference “Botox”, “botulinum toxin” or other trade names for medicinal products containing Botulinum toxin.
- Advertising materials referring to recommendations, endorsements, and testimonials by scientists, health professionals or persons who because of their profession or celebrity status could encourage or promote the use of Botox or other Botulinum toxin containing medicines [Regulation 7.(f)].
- Pictorial representations, including before and after photos illustrating the claimed benefits of Botox or other Botulinum toxin containing medicines [Regulation 7.(k)].

Advertising of treatment of hyperhidrosis of the axillae and facial lines should be done in a non-specific way without a reference to Botox or other Botulinum toxin containing prescription medicines.

3.4 Prescription only medicines

It is unlawful to advertise to the general public medicinal products which -

(a) are available on medical prescription only

(b) contain substances defined as psychotropic or narcotic under the First Schedule to

the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance.

3.4.1 Information to the media

Information on prescription only medicines which is submitted to the lay press, television or radio or through 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 only medicines to the general public.

3.5 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 references to or claims on medicinal products otherwise the 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.

3.6 Advertising on the Internet

The Internet is used widely to provide information to both consumers/patients and healthcare professionals. Website providers should ensure that materials posted on the Internet do not contravene the Advertising Regulations. Material posted on Maltese websites and/or aimed at the Maltese audience is subject to Maltese medicines advertising

legislation. As for other media, the promotion of prescription only medicines to the public on the Internet is prohibited.

Companies may include in a website disease-related information, together with approved package leaflets (PLs), SmPCs and public assessment reports (PARs) for their prescription only medicinal products.

Where companies include links from their Maltese site to their websites serving other countries, it should be clear to Maltese users that they have chosen to access material aimed at users from other countries. Users should not need to access parts of the website not addressed to the Maltese public to obtain basic information about the company's products such as PLs, SmPCs and PARs (these documents should be the ones approved in Malta) and other non-promotional information. It is good practice for each page of the website to include a statement that makes clear the intended audience.

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

3.7.1 Information provided to persons qualified to prescribe or dispense

Any advertising of a medicinal product to persons qualified to prescribe or dispense 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.

3.7.2 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.

3.7.3 Gifts, inducements and other benefits

Regulation 10 of the advertising regulations (SL 458.32) 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 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.

3.7.4 Hospitality and meetings

Regulation 10(2) states that "reasonable" hospitality can be offered to Health Professionals (qualified to prescribe or dispense medicinal products) 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 (qualified to prescribe or dispense medicinal products).

3.7.5 Professional samples

A sample is a small supply of a medicine provided to prescribers so that they may familiarize themselves with it and acquire experience in dealing with it. Sample packs must not be larger than the smallest pack size authorised on the market and must be clearly marked as samples.

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.

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

(a) the number of samples for each medicinal product each year on prescription shall be limited;

(b) any supply of samples shall be in response to a written request, to be signed and dated, from the prescribing agent;

(c) persons supplying samples shall maintain an adequate system of control and accountability;

(d) each sample shall be no larger than the smallest presentation on the market;

(e) each sample shall be marked "free medical sample - not for sale" or shall show some other wording having the same meaning;

(f) each sample shall be accompanied by a copy of the summary of product characteristics;

(g) no samples of medicinal products containing psychotropic or narcotic substances as defined under the First Schedule to the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance, may be supplied.

3.7.6 Medical sales representatives

Medical sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide information which is precise and complete 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.

3.7.7 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 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.

Signatures on file