Advertising of Medical Devices in Italy

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Legal Framework

UE Regulation

- Regulation (EU) 2017/745 (MDR)

National Legislation

- Law Decree 137/2022 (Artt.26 e 27)
- Ministry of Health Decree 23.02.2006 «*Advertising of Medical Devices*»
- Law Decree219/2006 (Art.118)
- Ministerial Giudelines

MDR 745/2017, Art.7

Art 7 of the MDR prohibits the use of text, names, trademarks, pictures, figurative or other signs that may **mislead the user or patient with regard to the device's intended purpose, safety and performance** by:

a) ascribing functions and properties to the device that it does not have;

b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

d) suggesting uses for the device other than those that form part of the intended purpose for

e) which the conformity assessment was carried out.

Law Decree 137/2022, Art. 26

Prohibits the advertising of:

(See also M.D. Feb. 23, 2006):

- custom-made devices referred to in Article 2, number 3 of the Regulations;
- devices requiring the mandatory assistance of a physician or other health professional pursuant to the Regulations;
- devices requiring the mandatory assistance of a physician or other health professional pursuant to the manufacturer's instructions;
- medical devices that can only be purchased with a doctor's prescription.

Any device not falling within the above categories (or any exceptions identified from time to time) must be **prior authorized by the Ministry of Health** according to the issuance procedures set forth in Article 118, paragraphs 8, 9, 10, 11, 12, 13, of Leg. Decree 219/2006.

Institutional advertising - i.e., forms of communication that are aimed at promoting a company's name, brand or image rather than a product or service - **is not subject to the authorization regime. However, the message must not boast specific properties of the medical device referred to.**

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Law Decree 219/2006, Art.118

Authorization

The manufacturer, or company responsible for placing a product on the market can apply for permission to carry out health advertising by submitting a specific application.

A specific application must be made to the Ministry of Health ("**MOH**") for each single advertisement, even if the same advertisement is released through several different media.

If the MOH fails to provide authorization within 45 days from the submission of the application, the request will be deemed granted, however, in this case, the advertising message must include the details of the application for authorization.

The MOH's response will notify the applicant that the request for authorization:

- is granted subject to the changes specified in the ministerial notice; or
- cannot be granted

Validity. Advertising authorizations for medicinal products are valid for **twenty-four months** provided the MOH can, with justification, to reduce the period of validity. The period of validity runs from the date indicated by the applicant for the commencement of the advertising campaign (which however must not be more than 6 months after the date of the application). If no date is indicated, the start date will be

D.Lgs. 219/2006, Art.118, e D.Lgs.137/2022, Art. 27

Penalties

Ministry of Health Orders

If advertising to the public is carried out in violation of the law, the **MOH** can order:

- the immediate cessation of the advertisement;
- the transgressor to publish (at the transgressor's expense) a statement of correction and clarification, as determined by the MOH.

Fines

The manufacturer (or person responsible for placing the product on the market) that violates the provisions of art 26 of D.Lgs.137/2022 is liable to pay a fine ranging from €2,600 to €15,600. **Supreme Court Ruling No. 10892/2018 further extends this liability to the owner of the communication tool** used to disseminate the advertising message to the public.

Minesterial Guidelines 2010-2013

- **Guidelines of 17 February 2010**, on the use of new means of dissemination (web, sms, mms, e-mail) still apply but only for self-medication and veterinary medicines.

- **Guidelines of 28 marzo 2013**, on advertising of medical devices, in vitro diagnostic medical devices, and medical-surgical devices.

The guidelines clarify which messages require authorization and which don't:

Messages that require prior authorization:

- Those addressed to the public concerning the health characteristics of the medical device;

Communications that don't require authorization:

- Information of a promotional nature addressed to health professionals;
- Institutional advertising;
- Promotion of commercial operations;
- Information of a technical nature in the post-sale phase;
- Communication of an informative nature.

Ministerial Guidelines 20 December 2017 and 24 October 2019

- **Guidelines – 20 December 2017**, on advertising of medical devices, in vitro diagnostic medical devices, and medical-surgical devices

The novelty, and goal, of the new guidelines is the attempt to specifically regulate the use of social networks in the context of authorized advertising of medical devices.

The guidelines apply to the advertising of medical devices through:

a) corporate websites promoting institutional advertising;
b) corporate-owned websites;
c) non-corporate-owned websites;
d) advertisements containing actionable links;
e) social networks;
f) email, SMS and MMS messages; and
g) toll-free numbers

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Ministerial Guidelines December 20, 2017 and October 24, 2019

Institutional Advertising Via Corporate Websites or Under Direct Control of the Company

Institutional advertising, aims to promote a company's name or field of activity, image or logo. This form of advertising may contain the so-called *umbrella brand* (a single name, logo, and overall brand identity to connect a range of related products, for different needs) provided it promotes the image of an enterprise or its activities and not a product.

This form of advertising does not require authorization if it does not boast specific properties of the product. The advertising message can state that a company markets a type of medical device (and show images of the packaging with the brand name, trade name, and type of product) as long as it doesn't promote the health properties of the product; if it does, the message would require authorization.

Advertising aimed at professionals does not require authorization and is, therefore, "unrestricted».
When such information - intended exclusively for professionals- is disseminated on the internet, companies must warn the user, with an appropriate "disclaimer" that the information contained on such website or section is intended exclusively for professionals.

Ministerial Guidelines 20 December 2017 and 24 October 2019

Advertisements containing activated links

- Links from websites, banners and other frames containing promotional material (authorized by the MOH and aimed at the general public) are permitted provided that the company responsible for the material on the network warns the user with the following wording:

  "*you are leaving the website of Company XXXXXX... containing promotional material authorized under current legislation on health advertising*".

- Links from sites, banners and other frames containing authorized promotional material to other sites, banners or frames containing promotional material that do not require authorization (e.g. containing health education information, self-medication, etc.), are acceptable provided the Company responsible for the material on the network warns the user with the wording referred to in the previous point.

- Links from sites, banners and other frames containing authorized promotional material to other Italian or foreign sites, banners or frames containing unauthorized promotional material in the Italian language are not acceptable.

Ministerial Guidelines 20 December 2017 and 24 October 2019

Social Network

The dissemination of advertising messages via social networks is only permitted in limited circumstances with ministerial authorisation:

- Facebook
- YouTube
- Instagram

Advertising messages must be "static", that is, they cannot be changed either by the company or by third parties:

- Users must not be able to comment or react to the messages; and
- Related functions must be disabled.

Ministerial Guidelines 20 December 2017 and 24 October 2019

1) Facebook (Ministerial Guidelines)

Wall advertising (including app/mobile) is allowed subject to the following limitations:

- The "**comment**" feature and reactions (i.e. likes, emoticons) **MUST BE DISABLED**

- There must be a **DISCAIMER** . Given the impossibility of restricting the sharing of posts (including any comments), the following disclaimer should be included: "*The Ministry of Health only authorizes the content of the advertising message. Any comments are the sole responsibility of the user, the company disassociates itself from user comments.*"

- **ONLY INSTITUTIONAL-TYPE ADVERTISING** is allowed on the company Facebook page.

Subject to authorization from the MOH, it is possible to insert a link from the advertisement to an external website.

The dissemination of advertising messages (image, script, video, audio) in the right column of the "wall" is allowed; this type of advertisement, visible and available only in desktop mode, allows the affixing of an image and a short text. The user, upon clicking on the advertisement, will be directed to a site outside of Facebook; in such a case, the company must indicate the target websites and whether they contain any advertising messages that have already been authorized.

Ministerial Guidelines 20 December 2017 and 24 October 2019

2) Youtube

The Youtube platform can be used to advertise messages (image, script, video, audio) subject to prior uthorisation from the MOH, and provided **the following options ARE DISABLED**:

- **"allow comments"** - preventing third-party user comments (for each uploaded video) within the "watch page";
- **"users see the votes of this video“** - preventing users from viewing the tally of "likes" and "dislikes“; individual users can still "like" or "dislike" the video in question, but the corresponding numerical count will not be displayed;
- **"allow embedding"**- preventing the user from making the content of the video accessible outside (but permitting it to be shared and viewed within) the "watch page".

The static image of the videos (Thumbnail) must contain the graphic representation of the product.

Permitted videos in Pre-Roll mode (broadcast before videos are searched by the user) are allowed.

Ministerial Guidelines 20 December 2017 and 24 October 2019

3) Instagram

Advertising messages are not allowed, except for images or short video advertisements authorized in the "Stories" section.

Users, however, must not be able to comment, express reactions or publicly share stories.

In viewing the video, by clicking on "*find out more,*" the user will be taken directly back to the external product site, previously authorized by the MOH.

Ministerial Guidelines 20 Dec. 2017 Legislative Decree 219/2006, Art. 117

Use of Testimonials

Advertising of a medicinal product to the public must not contain any element that includes a recommendation from a scientist, health professionals, or popular public figure ("*testimonials*" Art. 117(f), Legislative Decree 219/2006). The rational is that an advertising message, especially involving a popular public figure, could incite reckless (instead rational and informed) consumption of the product.

Case law has however identified exceptions to the aforementioned prohibition in cases **where the testimonial is limited to *supporting*** the advertising communication **without *actively endorsing* (or *expressing a preference* for) the product/medical device.** (TAR Lazio, ruling No. 8943/2014 and TAR Lazio, ruling No. 5859/2016).

Ministerial Guidelines 20 Dec. 2017 Legislative Decree 219/2006, Art. 117

To curb the more permissive interpretations of case law on testimonials, the December 20th, 2017 Ministerial Guidelines on the "*Use of Testimonials in Advertising of Medical Devices*" specify that the **PRESENCE OF TESTIMONIALs in an advertising message MUST BE AUTHORIZED BUT will not be permitted if the testimonial:**

- actively endorses the product, invites people to buy it, and or expresses (even implicitly) a preference for the product;

- portrays symptoms of the condition for which the product is indicated or if the message suggests that the testimonial has used, is using, or will use the product.

The MOH reserves the right to refuse authorization, if the **mere presence of the testimonial could result** in the **inappropriate use of the product to the detriment of a consumer's health.**

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