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Advertising of medical devices (ES requirements)

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What is advertising?

Any form of communication:

- Carried out by a natural or legal person, public or private, in the exercise of a commercial, industrial, artisanal, or professional activity.
- With the purpose of directly or indirectly promoting the acquisition of movable or immovable property, services, rights, or obligations.

For which medical devices can publicity be carried out?

All medical devices can be publicly advertised, except in the following cases:

- Medical devices financed by the National Health System.
- Active implantable medical devices.
- Advertising to the general public medical devices intended for the exclusive use of healthcare professionals. If possible, for the healthcare professionals themselves.
- Self-diagnostic medical devices, except those intended for pregnancy diagnosis, fertility diagnosis, and HIV detection.
- Medical devices for genetic diagnosis.

General Advertising Requirements

According to the General Advertising Law, advertising is illegal:

- ✖ If violates human dignity, that presents women in a humiliating or discriminatory manner.
- ✖ If violates the values and rights recognized in the Constitution.
- ✖ If it is directed at minors and encourages them to purchase a good or service by taking advantage of their inexperience or credulity, or that presents minors persuading parents or guardians to purchase the product, or that shows minors in dangerous situations.
- ✖ If is deceptive, disloyal, aggressive, or subliminal.

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Prohibitions on advertising medical devices

Advertising may not contain statements or labels that:

- Are misleading.
- Attribute properties to the product that it does not have.
- Provide expectations of guaranteed success.
- Claim that no harmful effects will appear after prolonged use.
- Make medical or surgical intervention superfluous, and in the case of in vitro diagnostic medical devices, undermine the usefulness of other diagnostic methods that require professional intervention.

Refer to:

- A health authority.
- Recommendations made by scientists, health professionals (individually or as a group, such as an association, foundation, or scientific society), or other persons who, due to their notoriety, may encourage their use.
- Violate human dignity.
- Violate the values and rights recognized in the Constitution.

What should be included in the advertising of medical devices?

- The product's compliance with current legislation: "Complies with medical device regulations".
- Contraindications and possible side effects that may arise from its use. According to the information on the product label or leaflet.
- "Sold exclusively in pharmacies" for pregnancy and fertility tests and HIV detection tests.
- The CPSP code (Health authority authorization code) assigned at the time of authorization.

What must be done to advertise medical devices to the public?

When advertising is aimed at the general public, it requires **prior health authorization** from the autonomous community (CPSP code is obtained). For healthcare personnel, this does not require authorization.

Advertising messages for medical devices and in vitro diagnostic medical devices directed at the public that **are subject to evaluation and authorization are exclusively those with a health-related purpose and content**.

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All advertising messages directed at the public in the following media:

- Audiovisual (television, radio, point-of-sale video, etc.)
- Digital (blogs, websites, social media, advertising strips, SMS, tweets, etc.)
- Print (magazines, newspapers, informational brochures, leaflets, patient letters, posters, displays, linear displays, billboards, banners, totems, etc.)

They are subject to prior health authorization from the health authority of the autonomous community where the company's registered office is located, when the scope of dissemination is the entire Spanish state. If the scope is limited to a single autonomous community, authorization will be granted by the health authority of that community.

When the company is not domiciled in Spain, the autonomous community where the media through which the advertising message will be disseminated is located must act.

The advertising message and material about the medical device that may be disseminated is exclusively that **whose content has been expressly authorized** and is attached to the authorization resolution.

Material Not Considered as Advertising and Material Not Requiring Authorization

- Instructions for use are not considered advertising. Therefore, **material that includes only these instructions**, verbatim and in full, **does not require prior authorization** for its dissemination.

- A **fictitious medical device packaging is considered advertising**, but **does not require prior authorization** for its dissemination if it is a scaled, exact, and complete reproduction of the packaging in which it is being marketed. However, it must be accompanied by an **accompanying document containing the mandatory information** that must be included in medical device advertising directed at the public.

- If the advertising material **only contains the name** of the medical device, accompanied or not by an image of the product or the packaging in which it is marketed, without any advertising message, **it is considered advertising**, but **does not require prior authorization** for its dissemination. However, the **mandatory information that must be included** in advertising directed at the public for such products must be included, unless the advertising material in which it is included is so small that it is impossible to include it in a font size that can be adequately read (for example, a ballpoint pen).

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Regulatory Framework in Spain

Law 14/1986, of April 25, on General Health, as amended by the ninth and tenth additional provisions of Law 3/2014 (March 28, 2014).

Royal Legislative Decree 1/2015, of July 24, approving the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices.

Law 34/1988, of November 11, on General Advertising.

Law 3/1991, of January 10, on Unfair Competition.

Law 34/2002, of July 11, on information society services and electronic commerce

Law 7/2010, of March 31, on general audiovisual communication

Royal Decree 1591/2009, of October 16, regulating medical devices

Royal Decree 1662/2000, of September 29, on in vitro diagnostic medical devices

Royal Decree 1616/2009, of October 26, regulating active implantable medical devices. Requirements and conditions for advertising medical devices to the public

Royal Decree 1083/2017, of December 29, amending Royal Decree 1662/2000, of September 29, on medical devices for in vitro diagnosis, in order to regulate the sale to the public and advertising of self-testing products for HIV detection.

***Note**: A new Royal Decree is currently being drafted in Spain to regulate the advertising of medical devices, adapting it to the requirements set by European regulations.*

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