Capsulas

Criteria to be considered in the advertising of medical devices

Pending the new Royal Decree on this matter, it is advisable to rely on the criteria set out in the guidelines approved at a regional level

Almost a year has passed since the Ministry of Health launched a public consultation on the draft royal decree on the advertising of medical devices.

Until this new regulation is approved, it is worth paying attention to the criteria applied by the regional authorities in relation to the advertising of medical devices addressed to the public. These include those outlined by the Catalan Department of Health in its latest Guide, approved at the end of last year, which we summarize below.

Prohibited statements and content in advertising materials

The key modifications introduced by the Guide regarding the content of the advertising include:

- The prohibition of the inclusion of terms or labels attributing to a medical device therapeutic property by means of pharmacological, metabolic or immunological actions. This prohibition is a consequence of the fact that only medicinal products can claim therapeutic properties derived from pharmacological, metabolic or immunological actions.

- In case the Instructions for Use of the product include age restrictions, the company shall include information on the minimum permitted age or recommended age range for the use of the product.

- Requirement to include a warning about the need to consult a healthcare professional when indicated in the Instructions for Use.

- Obligation to separate messages regarding the product's environmental sustainability from those related to its health benefits. When submitting materials for approval by the Catalan Authority, the company must include supporting documentation to validate its sustainability claims.

Comparative advertising

The updated Guide notes that it is not necessary to reference the data source when including comparative sales data (e.g., related to volume, revenue or market share) in product advertising. However, information on the period (indicating months and year) and territory (name of the country or countries) to which the data relate should be included.

In addition, the update includes the possibility to compare, in advertising to the public, a medical device with a medicinal product, provided that it is based on a clinical study directly carried out on the two products.

Internet advertising and inclusion of recommendations and/or testimonials

Regarding opinions or mentions of a medical device shared by a well-known person on the internet or social media, the Catalan Authority will classify them as advertising and assume that the company has sponsored or financed them in some way. Even without payment, the Authority may still review the content and context of the publication to assess whether it constitutes a form of advertising for the company, for which the company could be held liable.

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As regards advertising through a website, the Guide introduces the following new requirements:

- Consumer opinions, directly provided by consumers, on the websites of companies advertising medical devices should be clearly separated from the advertising of the medical device. It is sufficient to include a separate section titled "Consumer opinions".

- The person responsible for the website must ensure that they are true, both as regards the person who has provided them and as regards the content.

- These opinions cannot be used as evidence of the product's efficacy.

- The page containing these opinions should include a warning stating: "These opinions have not been evaluated or authorised by the competent health authority".

Authorisation of promotional materials

For companies that do not have a registered office in Spain, the updated Guide clarifies that the competent authority for approving promotional materials aimed at the public will be that of the Autonomous Region where their legal representative is located, or if the dissemination is limited to a single region, the Health Authority of that region.

In addition, the updated Guide states the following with respect to the approval process for advertising materials:

- The rule that an application for authorisation must relate to a single material for a single device has become more flexible. Applications that include several materials for the same medical device or for several medical devices will be accepted, as long as they are all included in the materials submitted.

- In the case of a corporate website or product range that contains links to pages containing advertisements for a different medical device, separate authorisation requests must be submitted: one for the homepage and one for each of the product pages.

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