



Capsulas

Advertising of healthcare services or advertising of products?

Appeal against the judgment of the Provincial Court of Barcelona of 24 July 2024

The Supreme Court will soon have the opportunity to rule on an issue of great practical importance in the field of the promotion of medical devices and medicinal products: when should a communication addressed to the public be regarded as advertising for a healthcare centre or service, and when should it instead be classified as advertising for a regulated product?

The case of clear aligners

The dispute arises from several advertising campaigns by the company Impress. In these campaigns, invisible orthodontic treatments were promoted with the support of well-known public figures. The Official College of Dentists and Stomatologists of Catalonia argued that the advertising referred to a medical treatment linked to the use of medical devices -clear aligners- and should therefore be subject to the rules applicable to the advertising of medical devices.

The Barcelona Court of Appeal, however, held that the advertising at issue did not concern a specific medical device, but rather the dental clinics of the advertising company and the orthodontic services provided there. In the Court of Appeal's view, the references to 'invisible orthodontics' and 'clear aligners' were generic and served to explain the type of service offered by the clinic, rather than to promote a specific medical device.

This debate is particularly relevant because many healthcare centres and services refer in their advertising to the products or technologies they use. Although these products or technologies are

not promoted in isolation, they are often integrated in the promotion of the healthcare service. The question is whether this form of communication allows such advertising to fall outside the restrictions applicable to the advertising of medical devices or whether, on the contrary, it must be assessed whether there is indirect promotion of the product used.

In the case now to be decided by the Supreme Court, the Barcelona Court of Appeal itself acknowledged that the classification may change when, in the context of advertising a healthcare centre or service, elements are introduced that may be perceived as advertising specific medical devices. For these purposes, it will be relevant to assess whether the product or technology used is a necessary condition for the provision of the promoted service and, in addition, whether it can be identified by the recipient of the communication.

The fine line between products and treatments

The issue may also extend to the field of advanced therapy medicinal products and, in particular, in relation to gene therapies developed under Royal Decree 477/2014 of 13 June, which regulates the authorisation of non-industrially manufactured advanced therapy medicinal products.

This royal decree, which governs what is known as the hospital exemption, allows certain advanced therapy medicinal products to be prepared and used in a hospital institution, under medical



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responsibility, to meet an individual medical prescription. In such cases, the hospital may hold the authorisation for use -but not a marketing authorisation- and may communicate, in institutional, scientific or healthcare-related terms, that it has developed a particular therapy, that it has a leading unit or that it offers an innovative treatment.

This is where a grey area emerges, similar to the case to be decided by the Supreme Court. If a pharmaceutical company cannot promote to the public an industrially manufactured gene therapy medicinal product, can a hospital communicate to the public that it has developed and offer its own gene therapy? Formally, the communication may be presented as information about the hospital's healthcare activities, its research capabilities or a highly specialised healthcare service. In practice, however, such communication may have a promotional effect very similar to that of advertising a medicinal product authorised or marketed by a pharmaceutical company.

This situation creates tension because public communication about therapies developed by hospitals may have a significant competitive impact, especially where authorised or developing industrial alternatives exist. Once again, the question is whether we are dealing with the promotion of a healthcare service or with the indirect promotion of the product or therapy that makes that service possible.

A future judgment with far-reaching implications

The judgment to be handed down by the Supreme Court in the clear aligners case will be relevant beyond the dental sector and the promotion of medical devices.

In sectors where healthcare provision relies on highly regulated products -medical devices, medicinal products (including advanced therapies), digital health tools or procedures based on specific technologies- it will be essential to determine whether the message genuinely promotes the healthcare service or whether, under that appearance, it is promoting the product or technology that makes the service possible.

The admission of the appeal in cassation therefore gives the Supreme Court the opportunity to provide useful guidance on an increasingly relevant boundary in an environment where healthcare innovation is communicated to the public not as a 'product', but as a 'service', 'treatment', 'programme' or 'therapy' offered by a healthcare centre.

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