Conformity with the SmPC is a "per se" rule in advertising of medicinal products

Decisions of the Jury of Advertising of Autocontrol of 29 February 2024 and 12 April 2024 in the Fasenra® case

Background

These decisions stem from a complaint by GSK against AstraZeneca for promotional materials related to the medicinal product Fasenra® that had been presented at several satellite symposia during national scientific congresses.

AstraZeneca markets Fasenra® (benralizumab) which is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma ("AGE" by its Spanish acronym). According to GSK, AstraZeneca had conveyed the message at the satellite symposia that Fasenra® was effective for the treatment of chronic rhinosinusitis with nasal polyposis ("RSCcPN" by its Spanish acronym) when presented with AGE.

Compatibility with the SmPC and misleading information

One of the basic principles governing the advertising of medicinal products is that it must comply with the summary of product characteristics (SmPC), according to article 1.2 of Royal Decree 1416/1994 on the advertising of medicinal products. This is usually known as the principle of compatibility with the SmPC.

In this case, the Jury analyses whether the Fasenra® messages concerning the treatment of RSCcPN are compatible with the SmPC of the product. AstraZeneca denied infringement of the principle of compatibility with the SmPC on the grounds that it was not possible for the recipients of the messages to perceive an efficacy message for Fasenra® for RSCcPN, noting that the materials included a warning that the product was not indicated for the treatment of RSCcPN.

The Jury determines that it is incompatible with the SmPC of Fasenra® to disseminate messages about its efficacy for a disease other than the approved therapeutic indication of the medicinal product (i.e. AGE). In this regard, the decision points out that the legislation and the Farmaindustria Code prohibit the dissemination of messages incompatible with SmPC, regardless of whether they are misleading to the recipients. Therefore, whether the recipient of the information is misled as to the scope of the authorised indication of the medicinal product is irrelevant when assessing compliance with the principle of compatibility with SmPC.

Advertising will be incompatible with the SmPC of the promoted medicinal product if, according to Autocontrol's established doctrine, it includes claims/statements (i) objectively incompatible with those included in the SmPC or (ii) assessed at the time by the health authorities for their potential inclusion in the SmPC and expressly or implicitly rejected.

Unauthorised indications and international congresses

Without prejudice to Autocontrol's ruling, it should be recalled that there is an exception to this principle of compatibility of SmPC and it is

contained in Article 7.4 of the Farmaindustria Code, in the Circular No 1/2000 of the Autonomous Community of Madrid and in the Catalan Guide to the advertising of medicinal products.

This exception allows the promotion of unauthorised products or indications at international congresses organised by third parties and attended by numerous professionals from other countries, provided that the materials comply with two requirements: (i) be written in English or in the language of a country where the product or indication in question is authorised; and (ii) include a warning (at least in Spanish) in prominent, clearly visible, continuous, durable and legible letters of the following type: "this medicinal product is not authorised in Spain for the following indication…" or similar.

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