



Harmonisation of guidelines for the use of scientific data in advertising to healthcare professionals

New monograph of the Medicines Advertising Bulletin of Catalonia

On 29 April 2024, the Medicines Advertising Bulletin of Catalonia issued a new notice outlining revised guidelines for using scientific publications and data into promotional materials for medicines. The document is based on Royal Decree 1416/1994 which regulates the advertising of medicinal products for human use, the Farmaindustria Code, the resolutions of the Jury of Autocontrol on the matter and ideas that the Department of Health has issued through the Catalan Guide on the Advertising of Medicinal Products for Human Use.

Use of tables, charts or illustrations

The monograph reminds us that when using tables, charts or illustrations in the materials, their reproduction must be “faithful”. The notice lacks clarity on what is meant by faithful reproduction. Previously, graphics were required to be reproduced “literally” (as, in fact, stipulated in earlier versions of the Farmaindustria Code).

At present, the reproduction of these elements is required to be “faithful”. From the analysis of Autocontrol’s rulings, we conclude that a “faithful” reproduction would allow a change of format, or even a simplification of a graphic (provided that the omission of data is not misleading, of course). We understand that Catalonia Government’s position on this point is the same, precisely because it refers, in the notice under analysis, to Autocontrol’s rulings.

Limitations of source scientific studies. Primary and secondary objectives.

The monograph also emphasises that advertising of medicinal products can be supported by scientific studies that have limitations, provided that these limitations are clearly disclosed in the promotional material. For example, it is worth noting that according to Autocontrol referencing results in secondary objectives cannot be prohibited per se if statistical significance was not achieved with respect to the main objective. However, it is necessary to ensure that presenting these results does not infringe the principle of objectivity. For this purpose, it should be clearly stated that the expected statistical significance was not achieved for the primary objective.

Moreover, according to Autocontrol’s doctrine (which the Catalan monograph adopts), it is not possible to rely on secondary results when the study is hierarchical.

Transfer of study results on the active substance
The monograph notes that clinical data and references from studies cannot be applied to the promoted medicinal product when they have been obtained only for the active substance and not for the resulting medicinal product.



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According to the monograph, “if the advertising materials convey that the results have been obtained directly and specifically with the promoted medicinal product and this has not been the case, the principle of objectivity would be infringed”. Therefore, it would be correct to promote the product by referring to studies on an active substance, as long as it is clearly specified that the studies have been carried out on the active substance.

Finally, the monograph points out the most frequent infringements in this area (which can provide insights into both the most common mistakes in preparing promotional materials and the aspects most scrutinised by authorities). Therefore, it is essential to pay particular attention to:

- (i) adaptations or alterations of data, tables and graphs from studies;
- (ii) references to studies that are not carried out accurately; and
- (iii) comparisons of safety, efficacy or other properties across different scientific studies or without specifying their statistical significance.

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