



Advertising of authorised medicinal products

Judgement of the High Court of Justice of the Basque Country of 30 June 2021

Background

This judgement is well-known. Farmaindustria filed an appeal against an Order governing medical visits in the Basque Country. The appeal was filed because, inter alia, Farmaindustria considered that the Order did not allow the advertising of authorized medicinal products for which a national price and reimbursement decision was pending. The Judgement concludes that neither the Order nor any other applicable law ban the advertising of authorized medicinal products, including those that are pending to receive a price and reimbursement ruling. The Judgement is relevant because it reaches this conclusion not only on the basis of the wording of the law but also on the basis of its spirit and general purpose.

The letter of the law and the legal interest protected

The Judgement makes it very clear that Royal Decree 1416/1994, which implements European directives into Spanish law, prohibits the advertising of unauthorized medicinal products but does not ban the advertising of authorized medicinal products for which a national price and reimbursement decision is pending.

On another note, EU case law has indicated that the main purpose of EU law in the field of advertising of medicines is the protection of patients, and that Directive 2001/83/EC has brought about complete harmonization in such field. Because of this, Member States cannot adopt provisions departing from the rules laid down in Directive 2001/83/EC. In view of the

foregoing, any authorized medicinal product may be promoted.

Grey zones

Spanish law has some grey zones. The law states that “the marketing of a medicinal product requires the prior completion of the corresponding price and reimbursement proceeding”. Royal Decree 1015/2009 provides that the Spanish Medicines Agency may authorize access to products which are authorized in Spain but are not commercialized (e.g. authorized products with a pending price and reimbursement decision); and prohibits the advertising of products in such conditions. This prohibition, which is included in a regulation with insufficient legal rank, may be questioned from both a Spanish and EU perspective. This Judgement sheds light on the matter; however, whether we like it or not, we must recognize that there are still grey zones.

Meanwhile...

Three recommendations for marketing authorization holders of products with a pending price and reimbursement ruling: (i) continue to opt for information activities; (ii) ensure that any activity that may be reputed to have a promotional nature has as main purpose the provision of technical/scientific information to healthcare professionals to enable them to form his or her own opinion of the therapeutic value of the medicinal product concerned; and (iii) include a reference regarding the price and reimbursement situation of the product in all printed materials.