Promotion of approved products in Spain prior to completion of price and reimbursement procedures: a paradigm shift?

The rules on minimum content of advertising materials should not be an obstacle to promote an approved product even if its price and reimbursement decision is pending

On Friday, 21 March, an important judgment was published by the Supreme Court (TS) resolving an appeal against a sanction imposed by the Region of Madrid (CAM) for infringement of Law 1/2015 on Medicines in relation to article 10.2 of Royal Decree 1416/1994. The sanction related to an activity related to product that had received a marketing authorization, but for which no price and reimbursement resolution had yet been issued in Spain. The CAM understood that the activity was promotional and that it could not be carried out if the relevant price and reimbursement ruling had not been issued.

The promotional activity in question and the position of the first instance court

The promotional activity, according to the CAM, consisted of sending several letters to healthcare professionals informing them of the availability of the product despite the price and reimbursement procedure not being finalized. The letters proposed the supply of the product under the conditions set forth in Royal Decree 1015/2009 which governs early access situations, indicating that the product would be supplied free of charge until the ruling on price and reimbursement was adopted.

The CAM considered that the promotion had been conducted at a time when it was not appropriate because the price and reimbursement resolution had not yet been adopted. According to the CAM, the company had infringed the rule contained in Royal Decree 1416/1994 which states that advertising "shall include the retail price, the conditions of the pharmaceutical provision at the National Health System, where applicable; and, where possible, the estimated cost of the treatment."

The first instance court (TSJM), in a ruling of June 17, 2022, upheld the sanction stating, among other things, that:

> *"... given that the information or advertising (...) must necessarily include the information regarding the price of the product and, "if applicable", the "conditions of the pharmaceutical provision of the National Health System" (Article 10.2 of Royal Decree 1416/1994, of 25 June), and (...) we must consider that the plaintiff incurred in the prohibition because, even though the product in question was authorized by the European Medicines Agency, neither its financed price (or notified price if it was not going to be financed by the National Health System) had been determined, and therefore, the product did not meet the requirements to be informed or advertised to the professionals authorized to prescribe or dispense it."*

The TSJM, in short, considered that in order to comply with Article 10.2 of Royal Decree 1416/1994, it was necessary to wait until the financed price (so far confidential in Spain) or the notified price (list price) was determined; and that until this occurred, no promotion could take place.

Promotion of approved products in Spain prior to completion of price and reimbursement procedures: a paradigm shift?

The position of the Supreme Court

In this judgment, the TS confirms the sanction imposed by the CAM, but its interpretation of Article 10.2 of Royal Decree 1416/1994 is very different from the one that inspired the action of the CAM and the interpretation of the TSJM.

A very relevant fact to take into account is that all the parties involved accepted that the promotional material did not include either the price of the product (despite the fact that the letters offered the supply at no cost, at zero price) or the financing conditions. The reading of the TSJM judgment reveals that the company, when appealing the sanction, argued that it did not include these mentions because it thought it was only obliged to do so once a price and reimbursement ruling had been issued.

In its analysis, the TS first considers that any promotional material must include information about the product's price. The Court deems this an essential element that must always be included, regardless of whether the product is financed or not.

Regarding the proviso in Article 10.2 of Royal Decree 1416/1994, which indicates that promotional material must inform about the conditions of financing in the National Health System "where applicable", the TS holds that this information should only be included when it is available, stating that "it is not possible to inform about what does not exist".

In other words, the price must always be included, and the proviso "where applicable" in Article 10.2 applies only to the financing conditions at the National Health System, which is why information on these conditions should only be included when available.

Then, why does the TS confirm the sanction?

As mentioned above, all the parties involved agreed that the company's promotional material did not include the product's price (even though the letters offered the supply at no cost, at zero price). This is why the TS upholds the sanction, as it believes that the letters did not include an imperative element (the price, "whatever it may be" the Court says) as required by Article 10.2 of Royal Decree 1416/1994.

In other words, the TS does not validate the reasoning of the CAM according to which an authorized product cannot be promoted until its price and reimbursement has been decided; rather, it merely confirms the sanction on the grounds that any promotion must include the sale price of the product.

If so, can promotion be made prior to the conclusion of the price and reimbursement procedure? And, if the answer is yes, how should it be done?

The answer to the first question, in view of this judgment, can only be affirmative: once a product has been authorized, the marketing authorization holder or its local representative may submit informative offers aimed at promoting the prescription of the authorized product.

As regards how this should be done, the answer is that the promotion must comply with the legally established requirements and, in particular, it must include the selling price of the product.

At this point, the next question is obvious: what price should be included in promotional materials of a product that has been authorized, but for which a price and reimbursement decision has not yet been issued?

Promotion of approved products in Spain prior to completion of price and reimbursement procedures: a paradigm shift?

According to the TS, what Article 10.2 of Royal Decree 1416/1994 requires is that the price available at that moment be included, "the one that exists."

Going further into this matter, and entering into the field of practice, our impression is that these promotional informative offers will only make sense in relation to medicinal products for hospital use or at least for hospital dispensing; and that the price that should be stated is the price at which the company offers to supply the product until the price and reimbursement resolution is issued. If it is offered free of charge, our recommendation would be to expressly state that the price at which the product is offered is zero.

In light of this judgment, we believe that if, in the future, an authority such as the CAM were to initiate sanctioning proceedings claiming that the promotion prior to the price and reimbursement decision is illegal, the company's chances of successfully defending its position would be high, in the current regulatory environment, as long as the price at which the company offers the supply is clearly and expressly stated.

Does Article 22 of Royal Decree 1015/2009 have an impact?

Let us return to the practical side. A medicinal product that is authorized but for which the price and reimbursement decision is pending, can only be made available to patients under Royal Decree 1015/2009. Specifically, Article 17 states that medicinal products holding a marketing authorization valid in Spain (e.g., all those authorized by the European Commission) but are not commercially available can be supplied "following the procedures" of Chapter IV of Royal Decree 1015/2009.

The offering of these medicinal products, according to what we have explained above, may be preceded by informative materials, which some authorities could consider promotional, provided that the conditions resulting from the applicable rules are complied with. In particular, in line with the judgment we are commenting on, the sale price of the product must be included.

However, Article 22 of Royal Decree 1015/2009 (included in Chapter IV) states that the holder of the marketing authorization in the country of origin must not promote the use of the medicinal product. This leads us to think that someone may argue that this prohibition also applies to products holding a marketing authorization valid in Spain, but for which the price and reimbursement decision is still pending (Article 17). In our opinion, this interpretation would be incorrect for two reasons.

In the first place, because Article 22 refers to medicinal products authorized "in the country of origin", unequivocally implying that such products are not authorized in Spain, which is not applicable to products that hold a marketing authorization valid in Spain, but for which the price and reimbursement decision is pending.

In the second place, because Article 17 of Royal Decree 1015/2009 is a procedural rule that binds the AEMPS, not a substantive rule that binds the companies. When Article 17 says that the AEMPS may authorize access to medicinal products holding a marketing authorization valid in Spain "following the procedures established in this chapter," it does not mean that the holder of the marketing authorization valid in Spain must comply with the same obligations imposed by Chapter IV when the product in question is not authorized in Spain. All it says is that the procedures that the AEMPS must follow to authorize access to these products are those established in Chapter IV. Therefore, in our opinion, the prohibition of promotion in Article 22 only applies to products that do not have a marketing authorization in Spain.

It is possible, in fact, that this rationale explains why the CAM sanctioned the company on the basis of its interpretation of Article 10.2 of Royal Decree 1416/1994 (and not for infringing Article 22 of Royal Decree 1015/2009).

How our interpretation fits in with European law

Article 87 of Directive 2001/83/EC states that "Member States shall prohibit any advertising of a medicinal product for which a marketing authorization has not been granted in accordance with European law". It should be recalled that European case law has stated that "the only requirements to which Member States may subject the advertising of medicinal products are those laid down by Directive 2001/83" and that "a complete harmonization of the rules on advertising contributes to eliminating obstacles to trade in medicinal products between Member States, in accordance with Article 95 EC" (Gintec case; C-374/05).

On this basis, a restriction more burdensome than the one established in Directive 2001/83/EC, such as the requirement that a product, in order to be promoted, must have not only a valid marketing authorization, but also a financing (or exclusion) decision, could only be justified if it were really necessary to safeguard public health (Euroaptieka case; C-530/20). Although the TSJM tried to support this argument by pointing out that the pricing system in Spain is also intended to protect public health, the TS does not accept or support this reasoning.

The ruling we are discussing, by allowing the promotion of an authorized product before a decision is made regarding its reimbursement, as long as the promotional material includes the mandatory information (the price, in the words of the TS, "the price that exists"), settles the issue in terms compatible with Directive 2001/83/EC and European case law.

A final comment

The issue regarding the promotion of an authorized product before a decision is made on its financing and price has been extensively debated in multiple forums. It is a complex matter. The judgment expressly acknowledges it when it says that the description of the prohibited conduct in then law "is clear in the sense that it sanctions the promotion, information or advertising that does not conform to what Law 1/2015 itself or the general legislation on advertising provides"; but the Court then adds that "however, it is a question of knowing what the Law and the legislation establish, and this is not so clear".

The ruling has clarified it: promotional materials do not need to include a reference to the financing conditions if the corresponding administrative procedure has not been completed, as those conditions are not yet known and the phrase "where applicable" applies. However, the price-"whatever it may be"-must be included.

The relevance of the judgment is indisputable, especially if we consider that when the TS agreed to hear this case it stated that the interest of the same "lies in the interpretation to be given to legal and regulatory norms that impose limits on the promotion, information and advertising of medicinal products and sanction their transgression, in a context where this Court has not issued prior rulings and where a real or potential contradiction between different courts is alleged".