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The Administration cannot rely only on the ATC Classification to create the groups of the reference price system

Judgements of the Supreme Court 1217/2017, 1208/2017, and 1284/2017 of 11 of July, 10 of July and 18 of July of 2017

Background

These judgements are related to Order SSI/1225/2014, through which the Spanish Ministry of Health, Social Services and Equality (MOH) updated the reference prices for various medicinal products for 2015. Through this Order, the medicinal products Myfortic®, Reandron® and Kogenate® were included in groups C164 (mycophenolate), C410 (testosterone), and H84 (factor VIII of coagulation), respectively.

Novartis and Bayer, under the legal direction of our firm, appealed the order, on the understanding that the active ingredient of their products was different from the one of the other products that formed part of such groups. Upholding the appeals, the Supreme Court has issued these very important judgements, which are followed at present by a fourth one, issued pursuant to another appeal filed by Zambon. These judgements will represent, without any doubt, a complete paradigm shift regarding the criteria used over the last years by the MOH for the creation of the groups of the reference price systems.

Conclusions of the Court

The rationale of the Supreme Court departs from the fact that, when forming the groups, the MOH included in the same group medicinal products that had the same level 5 code of the ATC Classification of the World Health Organization (WHO), without taking into account the allegations of the companies which claimed that, within the same ATC5 level, there are products with different active ingredients.

The Court considers that this action of the MOH is not acceptable for several reasons.

In the first place, because there is no regulation in Spain contemplating the use of the ATC classification as a criterion to establish the identity of the active ingredient of the medicinal product of each reference price group.

The Court, moreover, recalls that the collaborating centre of the WHO responsible for creating, developing and updating the ATC Classification has warned that such classification is neither a suitable nor adequate instrument in order to adopt decisions in terms of price and reimbursement of medicinal products.

The judgement points out that when in the marketing authorisation of two medicinal products their active ingredients are identified with different names, the administration cannot include them in the same reference price group just because they have the same ATC5 Code. In these cases, the administration must prove that the substances identified under different names in the marketing authorisation are in fact the same active ingredient. In the absence of this proof, and considering that both Novartis as well as Bayer provided expert reports proving the differences of their products with respect to others included in the same groups, the court revokes the creation of such groups.