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The interest of the administration is not the only public interest that deserves to be protected

Resolution of the Central Administrative Court of Public Procurement Appeals of 27 of March of 2013 in the case of the central purchasing body for medicinal products

At the end of March, the Central Administrative Court of Public Procurement Appeals issued its resolution regarding the Specifications approved by INGESA for the Framework Agreement for the selection of suppliers of medicinal products for various Autonomous Communities and State Organizations, which is known as the central purchasing body for medicinal products. It is a long resolution of 25 pages, which has widely been commented in different media.

Obviously, what has drawn most of the attention has been the operative part of the resolution, which partially upholds the appeal brought by a company as it deemed that the Specifications restricted competition without justification. On our part, in this analysis we will emphasize three aspects.

Modern courts, clear resolutions

First of all, and regardless of whether the final result may be more or less reprehensible, the work of the Central Administrative Court of Public Procurement Appeals and of its counterparts in some Autonomous Communities is promising. Just as it happened with the Competition Court, or with the mercantile courts, they are newly created administrative and judicial entities, staffed by professionals equipped are provided with a high level of training, many of them young people with energy to analyze the issues in detail and with communication skills. This leads to resolutions that are not too complicated to read, which is always to be welcomed when the text in question is of a legal nature. If you compare any resolution recently adopted by these courts with other judgments you will see that my satisfaction to this regard is justified. I say it, furthermore, from a position of profound disagreement with some of the arguments and conclusions of the specific resolution to which I refer.

Protection of competition

Secondly, in the resolution it is emphasized that the Court decides to grant the appeal after weighing up the interests involved. The Specifications, as they had been approved, contained the possibility that the administration may request a discount on the price in case that, during the validity of the framework agreement, a product biosimilar to some of the selected biological products was approved. In case that the company awarded the agreement would not accept the discount, the public procurement agreement could be terminated.

The Court understands that the system designed by INGESA is favorable for the administration, especially with regard to the management of its activity, and it reminds us that the homogenizing and simplifying purpose of the Framework Agreement is legitimate. In fact, it considers that such advantages are reasons of public interest. Despite this, according to the judgment, these reasons cannot prevail over free competition, which would be seriously affected if during the entire validity of the Framework Agreement the pre-

selected winner of the tender is maintained as the only supplier of a very substantial part of the market in spite of the subsequent approval of a biosimilar product.

If we have to choose between the protection of competition and administrative simplification, the Court is clearly in favour of the second option. While repeating that we disagree with various aspects of the resolution, the position maintained by the Court in this point is especially interesting.

Grouping biological medicinal products in the same lot

As regards one of the most relevant aspects of the substance of the matter, the position held by the Court is reprehensible for being excessively formalistic.

In the Specifications of INGESA, the separation in lots was made by active ingredient and not by what the Court calls therapeutic applications or effects. In application of this criterion, darbepoetin was being submitted to tender in lot 1; epoetin alfa in lot 2, epoetin beta metoxi-pg in lot 3; epoetin beta in lot 4; epoetin theta in lot 5; and so on. In view of this separation in lots, the Court had to deal with two appeals based on opposed and mutually incompatible grounds of appeal. In a first appeal, Hospira argued that epoetin alfa and epoetin zeta should not have been separated in lots or that at least lot 2 should have included "epoetin alfa and its equivalents". In a second appeal, Janssen opposed against the inclusion in lot 2 (epoetin alfa) of two non substitutable medicinal products.

In its resolution, the Court rejects the appeal of Hospira deeming that the logic of health regulations endorses the fact that active ingredients should be used as a reference for the preparation of lots instead of therapeutic applications or the effects of each product.

The curious thing about this case is that the Court bases its position on the fact that the only groupings foreseen by Law are the groups of the reference prices system and the homogeneous groupings; but also on the fact that the issue of therapeutic equivalence is subjective, is open to interpretation, and does not imply interchangeability; because between supposedly equivalent products there may be differences as regards side effects, excipients, etc., that according to the Court may and must be taken into account at the moment of purchasing the medicinal product.

It is therefore not clear why the Court likewise rejects the appeal of Janssen, which attacked the inclusion of non substitutable biological medicinal products in the same lot. The differences between two non substitutable biological products should also be taken into account when purchasing the medicinal product.

Finally, it is regrettable that the Court did not dare to question the fact that the tender prices force a discount of more than 75% with respect to the maximum authorized ex-factory price of some products.

With regard to this matter, the resolution recalls that the prohibition of discounts superior to 10% does not apply to agreements that pharmaceutical companies might reach with hospital pharmacy services, and it recognizes that in case of excessive aggressiveness in the request of discounts it is possible that the tenders might be declared deserted. Lastly, the resolution rejects that imposing such low prices is abusive, and accepts the position of INGESA, that defended itself by pointing out that the tender prices are the same as those applied de facto in various Autonomous Communities.