Public procurement of biosimilars

Resolutions of the Central Administrative Court of Public Procurement (TACRC) of 27 January 2022 and of 24 February 2022

Introduction

During the first quarter of 2022, the Central Administrative Court of Public Procurement (TACRC) published several resolutions that may be of interest to the biological medicines sector.

Such resolutions address the possibility of favouring biosimilar medicines in tenders (resolution of 27 January) and some issues regarding the INGESA framework agreement (resolutions of 24 February 2022).

Biosimilars may be favoured in tenders

In prior CAPSULAS (23 June 2021) we reported on two cases where tender specifications gave extra points to biosimilars medicines solely because they were biosimilars (20 and 3 extra points respectively). A company participating in the tender appealed against such specifications. While the TACR did not rule on the merits in the first case (because the tender was cancelled by the contracting authority before its resolution), the TACR deemed that the tender specifications of the second case (3 extra points for the biosimilar) were admissible. The TACR considered that granting these extra points was duly justified.

On 27 January 2022, the TACRC issued a decision endorsing again the use of an award criterion that granted 3 extra points to biosimilars.

After this last decision, it can be concluded that, according to a consolidated TACRC doctrine, it is possible to favour biosimilar products (extra points criterion) in public tenders if:

(i) the extra points criterion is proportionate and does not infringe, by excess, the principles of equality and free competition and

(ii) the contracting authority specifies the grounds for including such extra points criterion (the Court will merely confirm that this justification exists, without assessing its content).

Finally, it is worth mentioning that the tender assessed by the resolution of the TACRC dated 27 January contemplated certain terms that ensured that ongoing treatments with reference biological products could continue without interruption. Such terms included the establishment of specific lots in which biosimilars could not participate. It is uncertain whether, in the absence of such specific provisions, the resolution

Resolutions regarding the INGESA framework agreement

INGESA is the Spanish National Institute of Healthcare Management. In December 2021, it launched a nationwide tender to select companies for the supply of biosimilars to some Spanish public hospitals. This tender resulted in the so-called INGESA Framework Agreement. Such Framework Agreement sets forth the main terms under which regional health authorities adhered to it (and therefore their public hospitals) may purchase biosimilar products included in its scope. INGESA sets a "tendering price" for each product. All companies offering a price equal or below such "tendering price" are selected and classified following a priority order based on price and certain technical characteristics of the product.

The terms of this Framework Agreement have been very controversial. One aspect of the Framework Agreement that has been particularly challenged is its "price revision clause". Such clause enables INGESA to reduce the supply price of any contract derived from the Framework Agreement if when presenting a proposal for a derived contract, any bidder would offer such product at a price at least 10% lower than the one foreseen in the Framework Agreement. Many companies appealed against such "price revision clause". According to INGESA this clause was acceptable because it relates to an "unforeseeable situation".

The appellants first argued that the "price revision clause" would only be admissible in the context of a centralised public procurement of goods; and that the purchase of products through the Framework Agreement is not a centralized public procurement of goods, but a public nationwide tender to determine supply conditions that requires the ulterior formalization of the purchases at a regional (not centralized) level. The TACRC rejects the appellants' position, and concludes that a framework agreement is a form of centralised procurement and, therefore, the "price revision clause" is admissible.

The appellants also argued that the "price revision clause" violates the general prohibition to modify awarded supply prices (art. 204 of the Public Sector Contracts Law, "LCSP"). The TACRC rejects this claim. According to the TACRC, art. 222(1) LCSP (specifically related to framework agreements) allows the modification of awarded unit prices under certain conditions. According to the TACRC, art. 222(1) LCSP prevails over art. 204 when it comes to framework agreements.

Finally, the appellants argued that the execution of the "price revision clause" may alter the awardees' priority order. On this subject, the TACRC highlights that this kind of modification of the contract does not necessarily alter the order of priority, as such order is not only based on price, but also on the technical characteristics of the supplies. The TACRC further highlights the importance of communicating the price change to the remaining awardees to enable them to review their offered price downwards. According to the TACRC, it is crucial to give publicity to this change in conditions "so as to encourage competition".