CAPSULAS
Boletín de información jurídica

Number 179 | Faus & Moliner Abogados | February 2017

Purchase of biological medicinal products: reference to the active ingredient is valid for defining batches

Judgment No. 445/2016 of 19 October issued by the Administrative Chamber of the High Court of Justice of the Basque Country

Whilst confusion persists concerning how to reasonably organise the purchase of biological and biosimilar medicinal products in hospitals, this judgment offers a certain amount of clarity and is worth particular note.

The case in hand was initiated following a call for tenders as part of a Framework Agreement (FA) to supply epoetin alfa. Hospira appealed claiming that the definition of the subject of the agreement, which required that in the data sheet epoetin alfa featured as one of the ingredients of the medicinal product offered, represented a barrier to participating in the call for tenders, as it prevented holders of a biosimilar medicinal product (epoetin zeta) from being able to offer their products.

The Administrative Body of Contractual Appeals (OARC) of the Basque Country allowed the appeal as it believed the specifications limited the purpose of the agreement to a product with a specific active ingredient (epoetin alfa) and prevented equivalent products from being submitted, which represented a barrier to participating in the call for tenders. The OARC ordered the production of new specifications that had to included the term "or equivalent" in the definition of the subject of the agreement.

Biosimilars are not equivalents

Osakidetza appealed before the High Court of Justice, claiming that:

i) it is impossible to deduce that two medicinal products are bioequivalent based on the fact that they are biosimilar, they are in the same therapeutic group and they have the same ATC code;

ii) the judgment of the OARC confuses the concepts "bioequivalent medicinal products" and "biosimilar medicinal products", when they are different figures, classifying epoetin alfa and epoetin zeta as equivalent medicinal products, despite this not being the case.

The judgment of the High Court of Justice upheld the appeal of Osakidetza. The judgment is based on the idea that the contracting body is responsible for drafting and approving the specifications and that in doing so they cannot ever breach the principles of free competition and equality required by European Community law. Based on the foregoing, unless the purpose of the call for tender so requires, the technical specifications cannot mention products linked to a specific source or production or specific procedures that favour or rule out competitors.

However, the Court adds that in this case, the purpose of the procedure was to continue with the supply of epoetin alfa for ongoing treatments; therefore, it was justified that the FA was called with reference to the active ingredient and not the therapeutic indication.

The High Court of Justice adds that the use of the active ingredient's DOE (Spanish Official Name) in the specifications ensures the correct identification of the medicinal product sent out to tender, improving the accomplishment of the subject of the agreement without undermining the principles of free competition and equality and non-discrimination; and it concludes that the different epoetins are biosimilar medicinal products, but not equivalent medicinal products.