



The rights of patients justify a final "No" to the ATE's even under the new Spanish Law on Public Tenders

Decision No 31/2018, of 28 of February, of the Public Tender Court of Catalonia

Background

The Catalan Institute of Health and the Consortium for Health and Social Care of Catalonia called a tender for the award of a medicines supply framework agreement for the lipid lowering treatment with inhibitors of PCSK9. The tender was initially set as a single lot which would be awarded to a single supplier. After the initiation of the tender, in light of the complaints filed, the contracting authority modified the specifications so that the agreement could be executed with several suppliers.

Farmaindustria and Sanofi-Aventis challenged the decision before the Public Tender Court of Catalonia, requesting that the tender was divided into lots according to their active substance. Their position was that the medicinal products that formed the single lot of the tender could not be considered therapeutically equivalent, as they were not interchangeable biologic medicinal products that featured significant differences in spite of sharing a therapeutic indication.

Moreover, Sanofi-Aventis argued that combining in one lot two medicinal products that were not equivalent infringed the criterion of functional unit set forth by Spanish law.

Subsequently, the appellant brought before the Public Tender Court of Catalonia the judgement of the Spanish Supreme Court of 29 of January, that ruled against the equivalent therapeutic alternatives (knowns as ATEs for its Spanish acronym) provided for in the Framework Agreement of the Andalusian Health Service of 2013.

The functional unit and the fulfilment of needs

The Public Tender Court of Catalonia dismissed the appeals and considered the abovementioned judgment of the Supreme Court was inapplicable to this case because, among other reasons, the new Spanish Law on Public Tenders establishes that the division of the contractual purpose into lots has now become the general rule and the functional unit is no longer a criterion to be considered when setting the lots.

In our opinion, even under the provisions of the new Law on Public Tenders, the tender procedures should not define the lots according to the therapeutic indications of the medicinal products if this implies the inclusion in the same lot of medicinal products that have not been declared equivalent, interchangeable or replaceable by a competent healthcare authority.

Any public contract must adequately define its subject matter according to the needs that it must fulfil. This need, when it comes to acquiring medicinal products, is to guarantee the right of patients to a pharmaceutical provision under the legally and regulatory terms, and the right of healthcare professionals to prescribe the product that they consider more adequate for each patient, even when there are alternative solutions in the market. Therefore, it is necessary that products which are not interchangeable are not included in the same lot.