Capsulas

Nullity of the IPTs Consolidation Plan, risk or opportunity?

Final judgment of the Spanish National High Court of 26 June 2023 declaring the nullity of the Consolidation Plan for TPRs

Background

On June 26, the Spanish National High Court issued a judgement declaring the nullity of the Plan for the Consolidation of Pharmaceutical Therapeutic Positioning Reports (TPRs) within the NHS ("Consolidation Plan") (see Capsulas published on 3 August 2023). This judgment has recently become final because the Ministry of Health did not appeal it. In this Capsulas, we analyse the practical effects of the judgement becoming final from a dual perspective: risks and opportunities.

Risks

¿Is there a risk that the TPRs approved and published based on the Consolidation Plan and/or the pricing decisions based on it will become ineffective as a result of the judgement becoming final?

In our opinion, this risk is very low. The nullity of the Plan does not automatically imply the nullity of the final acts issued under the Consolidation Plan. This is provided for in art. 73 of Law 29/1998. Moreover, two aspects reinforce this conclusion. First, in our experience, it is unlikely that the Administration will question its own acts. This reduces the risk of an ex officio review of the IPTs as a result of the ruling. Second, the Spanish Agency for Medicines and Medical Devices ("AEMPS") has traditionally considered TPRs as a mere "act of judgment or statement of the Administration's criteria" or "technical report", not as an autonomous administrative act.

Opportunities

In terms of opportunities, we believe it is convenient to distinguish the macro scenario (pharmaceutical regulation) from the micro scenario (individual cases of each company). At the macro level, the nullity of the Consolidation Plan means a return to the previous legal framework for TPRs, which was already very limited. This has given impetus to the work for the approval of a Royal Decree on Health Technology Assessment, including a public consultation on this regulation held recently (see Capsules of last October in this regard). The ruling, therefore, has become an opportunity to improve the legal regime for TPRs, and for health technology assessment in general.

At the micro level, the opportunities are more theoretical than practical. For all ongoing TPRs or pricing and reimbursement procedures, companies can require that they comply with the judgement. This is basically that the TPRs are not approved by REVALMED and that they do not contain an economic evaluation (EE). However, the practical usefulness of these requests is not clear. None of them would result in a tangible benefit for the company claiming it; especially the issue of the EE. Even if the EE is not included in the TPRs, this does not mean that it has no legal basis (it does) or that the Ministry of Health - Interministerial Committee for the Price of Medicines (CIPM) cannot take it into account when deciding on the inclusion of a medicinal product in the Pharmaceutical provision of the NHS.