Capsulas

Is it the end of Revalmed?

About the Judgment of the National High Court of 26 June 2023

Plan for the consolidation of TPRs

Following the approval of a new medicine or a new indication for an already approved medicine, a process is initiated to decide whether or not the new medicine should be funded by the National Health System (NHS) and, if funded, its price (the P&R process).

The P&R process is overseen by the Directorate-General of the Basic Portfolio of National Health System and Pharmacy Services ("DGCC" by its Spanish acronym). The DGCC decides on whether or not new medicines/indications should be funded. It also offers technical and administrative support to the Interministerial Committee for the Price of Medicines ("CIPM" by its Spanish acronym). The CIPM sets the maximum price at which medicines are reimbursed by the NHS.

Therapeutic Positioning Reports (TPRs) play an important role in the P&R process. In practice, the DGCC uses TPRs as the basis for preparing the Associated Report that is later submitted to the CIPM. Additionally, TPRs can impact the duration of the P&R process since, in most cases, the DGCC will not submit the new medicine/indication's dossier to the CIPM until the corresponding TPR is available.

TPRs were first introduced in May 2013 within the Permanent Commission of Pharmacy of the Interterritorial Council of the NHS ("CPF" by its Spanish acronym). They were introduced through a collaboration proposal, with the aim of "providing relevant information, based on scientific evidence, on the position of the new medicine in the market when compared to other existing medicines or health interventions, beyond the authorisation of the medicine". In July 2013, Law 10/2013 was enacted, and its Third Additional Provision (DA 3) included the legal basis for TPRs.

In July 2020, the CPF approved the Plan for the Consolidation of Pharmaceutical Therapeutic Positioning Reports within the NHS (the "Consolidation Plan"). The main objective of the plan was to "consolidate TPRs as a primary tool for assessing medicines positioning and economic evaluation of cost-effectiveness within the NHS". To achieve this goal, the plan set out two major lines of action. First, the creation of a new pharmaceutical evaluation network (REVALMED). Second, the modification of the methodology used for the design and approval of TPRs.

The Consolidation Plan also aimed to include an "economic evaluation" section in the TPRs. Some TPRs had mentioned economic aspects between May 2013 and March 2019, but none provided detailed evaluation. The plan aimed to reverse this trend and give greater importance to economic evaluation within TPRs.

Farmaindustria appeal

Farmaindustria (the national trade association of the Spanish based pharmaceutical industry) filed an administrative appeal against the Consolidation Plan. The appeal was based on two grounds.

First, they argued that the Consolidation Plan is a regulation of a general nature and not merely an internal organisational tool, as the MOH had claimed. Farmaindustria therefore sought to nullify the Consolidation Plan on the grounds that it had been adopted by an incompetent body (the CPF), completely disregarding the procedure laid down by law.

Second, they argued that the Consolidation Plan is voidable because it contravenes the principle of regulatory hierarchy. The Consolidation Plan provided that TPRs would be "scientifically and economically based" and they would be approved by the REVALMED Coordination Group. Their provisions were not in line with DA 3. According to DA 3, which is the sole legal basis for the TPRs, TPR's must be "scientifically based" (without mentioning the economic aspects) and approved by the Spanish Agency for Medicines and Medical Devices ("AEMPS").

The position of the Spanish National High Court

The National High Court upheld Farmaindustria appeal in its entirety.

The National High Court considered that the Plan clearly sought to change the current regulatory framework by involving other government bodies besides the AEMPS in the TPRs drafting process; and by establishing a process for the drafting and approval of TPRs, defining their content and the rights and obligations of who might be potentially affected. Therefore, the Court determined that the Plan is regulatory in nature and not merely an "internal organisational tool".

As the Consolidation Plan is regulatory in nature, it should have been approved in accordance with the rules governing the drafting and approval of this type of regulation. Specifically, it should have received approval from the Minister and followed the procedure outlined in the Government Law (including prior consultation, impact assessment, preliminary hearing, etc.). Since the plan was not approved by the Minister, but by the CPF without following the provisions of the Government Law, the Court held that the Plan is null and void because it was issued by a manifestly incompetent body that did not follow the legally mandated procedure.

The Court also upheld the second argument raised by Farmaindustria: the Plan is incompatible with the Third Additional Provision of Law 10/2013, which is the only legal basis for TPRs. Neither the inclusion of the economic evaluation nor the creation of REVALMED are within the legal framework of TPRs established by DA 3. This provision clearly states that TPRs must be "scientifically based" and be approved by the AEMPS.

What's next?

Here are some ideas:

(i) The judgement is not final. It can be appealed to the Supreme Court. Therefore, it has no immediate legal effect for the time being (unless it is provisionally enforced).

(ii) The position and legal reasoning of the judgment are strong and serve as a clear reminder of the importance of respecting the rules on the allocation of competences.

(iii) Notwithstanding the foregoing, it should not be forgotten that this matter is eminently procedural in nature. The National High Court is questioning the way in which the plan was approved, but it is not saying that its content is illegal. Through the proper legal channels, much of what the plan proposes could be accommodated within our legal system.

(iv) The issue of the inclusion of an economic evaluation in the TPRs deserves separate analysis. According to the National High Court, the inclusion of an economic evaluation in TPRs is not aligned with the law. The Third Additional Provision of Law 10/2013 specifies "TPR will be scientifically based, without mentioning the economic aspects". However, it is important to understand that this does not imply a general challenge to the validity or usefulness of economic evaluation in the selection of medicinal products for funding purposes.

If the judgement is upheld, the economic evaluation should "disappear" from TPRs, but not necessarily from the NHS funding process. It is noteworthy that cost-effectiveness and budgetary impact are legally mandated criteria under the Law on Guarantees and Rational Use of Medicines and Medical Devices when deciding whether to fund a new medicine through the NHS. Furthermore, the Court recognises that conducting an economic evaluation is both "necessary and logical from the point of view of public funding" and that the TPRs (presumably the therapeutic evaluation part) "can be used as a technical reference" for this purpose.

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