



New rules on health technology assessment

On the entry into force of Royal Decree 415/2026 regulating health technology assessment

Background

The Royal Decree on Health Technology Assessment (Royal Decree on HTA) establishes a stable framework for health technology assessment in Spain. It adapts the Spanish system to Regulation (EU) 2021/2282 on health technology assessment and regulates the national phase following Joint Clinical Assessments (JCAs).

In the field of medicinal products, the Royal Decree on HTA is particularly significant because it fills the regulatory gap created following the annulment by the courts, in 2023, of the Consolidation Plan for the Therapeutic Positioning Reports (TPRs).

Which technologies may be assessed?

The scope of the Royal Decree on HTA is broad. It includes new medicinal products, new indications, class IIb and III medical devices, in vitro diagnostic medical devices and any other health technology, procedure, digital technology or organisational model whose assessment is agreed by the HTA Council. The Royal Decree on HTA also covers reassessments of health technologies previously assessed by the system.

Types of assessment

El RD ETS prevé tres ejercicios que se presentarán de manera separada:

- a clinical assessment;

- a non-clinical assessment (including an analysis of ethical, organisational, social, legal, gender, environmental, , economic aspects and budget impact analysis); and
- a final assessment of the positioning of the technology within the Spanish National Health System (NHS).

The assessments will be carried out by the Health Technology Assessment Offices: one for medicinal products, attached to the Spanish Medicines Agency (AEMPS), and another for non-pharmaceutical technologies, based on the existing Health Technology Assessment Network (RedETS). The final assessment of the positioning of the technology within the NHS will be done by the Adoption Group.

Early dialogue

The new rules allow health technology developers to consult the Offices on their development plans and receive advice (Article 19). The content of these consultations will remain private and will not be made public. Moreover, the advice provided will not be binding. The developer must, however, disclose the existence of the consultation in the documentation subsequently submitted for HTA.

Timelines

Where a European JCA is available, assessments of medicinal products must be completed within a maximum of 85 working days: 15 days for the



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clinical assessment and 70 days for the non-clinical assessment. In the absence of a JCA, the maximum period will be 140 working days (70 + 70).

For medicinal products authorised through the centralised procedure, the period will generally begin on the date on which the marketing authorisation holder notifies its intention to market the medicinal product in Spain following a positive opinion from the CHMP. The Royal Decree also provides that, whenever possible, the clinical and non-clinical assessments may be conducted in parallel, potentially reducing the effective duration of the procedure significantly. No specific deadline applies to the final assessment of the positioning of the technology within NHS.

Effects of the assessments

The Royal Decree on HTA clearly separates assessment from the reimbursement decision and states that assessments “inform the decisions of public authorities, but do not constitute the decision itself, nor is that decision bound by them as regards timing or substance”. It also states that the assessment of the positioning issued by the Adoption Group “shall under no circumstances replace, condition or call into question the powers of the decision-making bodies”.

Against this background, the Royal Decree characterises assessment reports as non-binding and non-mandatory. Their non-binding nature is expressly established in Article 15. Their non-mandatory nature follows from the removal, in the final version, of the references to their mandatory status contained in earlier drafts.

From a practical perspective, we welcome this approach because it helps to keep assessment separate from the reimbursement decision and prevents possible delays in assessments from blocking or unnecessarily delaying pricing and reimbursement

procedures. From a legal perspective, however, some uncertainty remains as to the true extent of their non-binding nature, since Additional Provision Three of Law 10/2013 -a higher-ranking rule than the Royal Decree- continues to expressly attribute binding effect to TPRs.

Duplication

The Royal Decree on HTA provides that health technology assessments must comply with the principle of consistency and avoid duplicating assessments already carried out. This principle should operate both upstream and downstream. On the one hand, national assessments should not reassess aspects already analysed in JCAs, unless exceptional national circumstances arise. On the other hand, further reassessments should not be carried out at regional or even hospital level.

We very much welcome the inclusion of this principle. Nevertheless, we are concerned that the reference to its application “without prejudice to the powers conferred on each public authority” (Article 15) may leave the door open to reassessments at regional level.

A standalone administrative procedure and the right to submit observations

Under the now-annulled Consolidation Plan, the legal nature of TPRs was unclear. The Administration even argued that they did not constitute administrative acts. Their relationship with the pricing and reimbursement procedure was also uncertain: were they an intermediate procedural act within that procedure, or a standalone procedure?

Our position was -and remains- clear: assessment constitutes a standalone procedure because it has its own substance, distinct from the funding decision, and because its reports produce effects that extend beyond the Administration’s internal sphere.



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Among other things, they may influence positioning, the perceived value of the medicinal product and its clinical use.

This issue has important practical consequences, particularly as regards the exercise of technology developers' procedural rights (Article 53 of Law 39/2015), including access to the complete file, access to the allegations made by other interested parties, the right to submit substantive observations and, where appropriate, the right to appeal the reports.

The Royal Decree on HTA does not expressly resolve this issue, but it includes one particularly relevant element: a hearing stage allowing the technology developer to submit allegations "in accordance with Law 39/2015 on the Common Administrative Procedure of Public Administrations". Three aspects are particularly noteworthy in this regard. First, the express reference to Law 39/2015 may be interpreted as implicit recognition that the assessment process is a standalone administrative procedure.

Second, the developer's allegations (Article 14.5) are distinguished from those submitted by patients and other experts (Article 14.4). The current wording appears to allow the developer to submit allegations once the contributions of the other participants have been incorporated, thereby enabling it to comment on a virtually final version of the report. This is highly relevant in practice. In some TPRs, developers submitted allegations on drafts that were subsequently amended substantially following comments made by other participants. The new model appears designed to avoid these situations and promote more effective participation by the developer.

Third, the technology developer's observations are not limited to identifying "purely technical or factual inaccuracies", as is the case for JCAs (Article 11.5 of Regulation (EU) 2021/2282) but may include sub-

stantive observations on the reports. We consider this approach appropriate and essential to ensure adequate protection of developers' rights.

Information on costs and sources of funding

The draft Royal Decree on HTA included a particularly controversial provision requiring developers to provide "reliable production, research and development costs, as well as the sources of funding for those costs, whether public or private" (Article 23.7 of the draft). This information is extremely sensitive and, in many cases, difficult to compile. Moreover, in a context in which the trend is to move away from cost-based pricing models towards value-based systems, we considered that requiring this information made little sense.

We therefore very much welcome the reformulation of this obligation in the final version of the Royal Decree on HTA. The Royal Decree now requires information on "public sources of funding or funding from non-profit entities, where applicable, as well as information on production and development costs necessary to carry out the economic analysis". There is therefore no longer an obligation to disclose information on private sources of funding -unless they are non-profit entities- or on research costs. The latter is particularly relevant because those costs reflect investments in the development pipeline and strategic elements of future competitiveness. In addition, information on production and development costs will only have to be provided where necessary to carry out the economic analysis.

Conflicts of interest

The management of conflicts of interest remains one of the most sensitive issues in HTA systems.

In certain fields, particularly rare diseases or highly specialised areas, it may be difficult to identify



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experts or patient representatives with the necessary knowledge who have no relationship of any kind with the developer. In this context, the addition of a new paragraph to Article 25.4 of the Royal Decree on HTA is welcome: it allows patients and experts with declared conflicts of interest to participate in meetings, with the right to speak but not to vote.

This solution preserves the knowledge and experience of those participants without compromising the impartiality of the assessment process.

This approach is also aligned with recent EU legislation on HTA, which recognises the need to reconcile appropriate management of conflicts of interest with the participation of highly specialised experts where circumstances so require.

Rules, guidelines and deferred application

The Royal Decree on HTA establishes the institutional architecture of the HTA system and regulates its essential elements. It nevertheless leaves several important aspects to subsequent development through “regulatory instructions” and “non-regulatory methodological guidelines” (Article 22).

This regulatory and methodological development will be decisive, as it will provide the operational detail currently lacking in the Royal Decree on HTA on certain matters. Once these documents have been adopted -which must occur during the first year in which the Royal Decree on HTA is in force- the new assessment model will be implemented progressively in accordance with the timetable approved by the Ministry of Health. In the meantime, and until the new system has been fully implemented, the assessment procedures and mechanisms currently in force will continue to apply.

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