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# *ANALYSIS*

Pharma & healthcare

## Royal Decree 415/2026: key aspects of the new health technology assessment system

Royal Decree 415/2026 establishes a unified framework for the assessment of health technologies in Spain, distinguishing between the technical assessment and the administrative decision regarding funding, pricing or inclusion in the service catalogue, and incorporating the requirements of Regulation (EU) 2021/2282. The aspect that raises the most legal questions in this new piece of legislation is the connection between the assessment regulated by the Royal Decree and the procedures for funding, pricing, and inclusion in the service catalogue.

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June 2026

## 1. Introduction

Royal Decree 415/2026, of 27 May, regulating the assessment of health technologies (publication in the Official Journal of Spain on 29 May; entry into force on 18 June 2026), establishes a general framework to organise an activity that heretofore was carried out through partially disparate instruments, bodies and procedures. The concept of *health technology* is broadly defined and includes medicines, medical devices, in vitro diagnostic tests, clinical procedures, therapies, digital technologies, organisational models, and measures for prevention, diagnosis or treatment. This breadth is significant because it places technologies subject to different regulatory regimes — and with differing methods of incorporation into the National Health System — under a single methodological framework.

From the perspective of *administrative health law*, this piece of legislation must be situated within a dual context: first, it responds to the European legal framework established by Regulation (EU) 2021/2282, which introduces mechanisms for cooperation and joint clinical assessments of health technologies and requires Member States to take due account of the resulting reports; second, it must be coordinated with the Spanish domestic legal framework on public funding, pricing and inclusion in the service catalogue.

With regard to *medicines and certain medical devices*, the decision on public funding is governed by Article 92 of the recast version of the Medicines and Medical Devices (Guarantees and Rational Use) Act (approved by Royal Legislative Decree 1/2015), which requires an express decision for inclusion in the service catalogue, specifying the conditions for funding and pricing, and by the recent Royal Decree 90/2026, of 11 February, regulating the procedure for the selective funding of medical devices through the National Health System's service catalogue for outpatients and establishes the margins applicable to their distribution and dispensing.

With regard to *techniques, technologies and procedures*, the updating of the National Health System's service catalogue is governed by Act 16/2003 and Royal Decree 1030/2006, which establish the prior assessment of parameters such as safety, efficacy, efficiency, effectiveness, health utility, economic impact, and organisational impact before making new inclusions.

The Royal Decree is therefore part of a broader administrative sequence in which the technical assessment serves as a preparatory or instrumental step for subsequent decisions regarding funding, pricing inclusion in the service catalogue, conditions of use, or potential divestment.

## 2. Purpose, structure and administrative function of the assessment

- Royal Decree 415/2026 is based on a key distinction between *assessment* and *decision-making*. The assessment of health technologies is not a political, budgetary or healthcare management decision, but rather a technical-scientific basis for the administrative decision. As the preamble to the Royal Decree states, the assessment "informs decision-making, but does not constitute the decision-making process itself".

This separation allows for the delineation of the functions of the assessing bodies and the decision-making bodies. The former produce technical and comparative knowledge regarding the assessed technology; the latter retain the authority to decide on funding, pricing, inclusion in the service catalogue, modification of conditions of use, reimbursement or divestment. From an organisational standpoint, this distinction can help preserve the technical autonomy of the assessment process while maintaining the legal liability of the administrative bodies that make the final decision.

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- The system is organised around a Governance Council and two offices: the Office for the Assessment of Medicines, established within the Spanish Medicines and Healthcare Products Regulatory Agency (AEMPS), and the Office for the Assessment of Non-Pharmacological Health Technologies, linked to the Spanish Network of Agencies for the Assessment of Health Technologies and the National Health System's Service catalogue (RedETS). The choice of this dual but coordinated jurisdiction reflects the different regulatory nature of medicines and non-pharmaceutical health technologies. Medicines and medical devices do not follow the same pathways for authorisation, conformity assessment, post-marketing monitoring, or incorporation into clinical practice.

- The Royal Decree expressly incorporates both clinical and non-clinical assessment areas. The clinical assessment focuses on identifying the health problem, the technical characteristics of the technology, relative safety, and relative clinical efficacy. The non-clinical assessment encompasses cost, resource utilization, efficiency, budgetary impact, and ethical, organisational, social, legal, gender, and environmental aspects. This framework brings the Spanish system closer to a broad conception of health technology assessment, in which public decision-making is not based exclusively on clinical outcomes, but also on social value, efficiency, budgetary sustainability and the conditions for implementing the technology within the National Health System.

- The coordination between the provisions of Royal Decree 415/2026 and those of Regulation (EU) 2021/2282 is another central element of this regulation. The Royal Decree provides that national clinical assessments shall not duplicate assessments already conducted within the European framework and that, where a joint clinical assessment exists, the European report shall form the basis

of the national assessment, without prejudice to supplementary analyses justified by the specific characteristics of the National Health System. This provision may reduce burdens on developers, avoid duplication of documentation, and promote greater consistency between the Spanish and European assessments. At the same time, it preserves a national margin to assess elements not covered by the joint clinical assessment, particularly those related to efficiency, budgetary impact, healthcare organisation, legal context and sustainability.

- The Royal Decree also introduces safeguards regarding transparency, participation, and the management of conflicts of interest. These include the publication of reports; a hearing with the developer prior to the completion of the assessment; the participation of patients, consumers, professionals, and experts; the disclosure of the composition of the groups; and the publication of minutes with confidential information redacted. These provisions are relevant in a field where the public authority must weigh very different factors that have a major impact on healthcare innovation, health protection, and financial sustainability, but also on patients' expectations and the economic interests of developers who drive innovation. The traceability of the procedure and the proper management of conflicts of interest (with reservations regarding the excessive scope the new regulation grants them) are essential conditions for assessment reports to serve as a technical basis for subsequent public decisions.

## 3. Coordination with funding, pricing and inclusion in the service catalogue

The aspect that raises the most legal questions in this new regulation is the connection between the *assessment* regulated by the Royal Decree and the procedures for funding, price determination, and inclusion in the service catalogue. The Royal Decree makes an explicit distinction between the assessment and the subsequent administrative *decision*. Article 15 provides that assessments are not binding and do not impose any conditions on the public authority regarding either deadlines or content. In turn, assessment reports shall not contain recommendations regarding adoption, funding, pricing, or inclusion in the service catalogue. That assessment will be carried out at a later stage by the Group for the Adoption of Health Technologies (hereinafter, the "Adoption Group"), "a multi-member body attached to the State Secretariat for Health through the Directorate-General of the Common Service Catalogue of the National Health and Pharmacy System", whose function is to integrate the reports from the offices and issue a final assessment of the technology's relative position to serve as a basis for decision-making bodies. The Royal Decree defers the adoption process to subsequent regulatory implementation.

From a legal-administrative standpoint, this structure preserves the authority of the bodies legally empowered to decide on the funding or new additions to the service catalogue. The technical assessment does not supersede the Interministerial Committee on Drug Prices or the bodies responsible for the common service catalogue, nor does it transform the assessment report into a decision-making act regarding

actual access to public funding. However, the separation between assessment and decision-making requires a precise determination of how the technical outcome is incorporated into the decision-making process. The regulation establishes the existence of coordination mechanisms and the Adoption Group, but it does not fully elaborate on the procedural weight of the assessment report or the standard of justification required when the final decision deviates from its conclusions.

The issue is not merely that the report is non-binding, a common feature of many technical reports in complex administrative proceedings. The main issue is determining *what legal effects* it produces within the subsequent dossier. In particular, it would be advisable to clarify whether a funding decision that deviates from a favourable assessment must specifically justify that divergence; whether a favourable decision may be based on factors unrelated to clinical added value, such as unmet need, equity, social impact, or industrial sustainability; and whether an assessment with high uncertainty may lead to conditional funding arrangements, registries, pilot programmes, or risk-sharing or outcomes-monitoring agreements. The Royal Decree contains provisions regarding uncertainties and the potential generation of additional evidence, but it does not sufficiently specify how these uncertainties are incorporated into the funding decision or the modification of conditions of use.

Current legislation on public funding for medicines is based on general, objective, and published criteria, including therapeutic and social value, incremental clinical benefit, cost-effectiveness, the degree of innovation, and the contribution to the sustainability of the National Health System. Royal Decree 415/2026 provides precisely the technical information that can inform these criteria: clinical added value, economic analysis, budgetary impact, organizational impact, and social, ethical, legal, or environmental considerations. However, it does not specify in detail how the assessment report is incorporated into the funding dossier, what weight it carries relative to other elements of the dossier, what consequences it has for decision-making timelines, or what requirements for justification arise from any discrepancy between the assessment, the Adoption Group's assessment, and the final decision. The provision regarding the developer's obligations clarifies that the submission of the assessment dossier "is understood to be without prejudice to the documentation initiating the application for funding and pricing"; this wording confirms that both procedures retain their documentary and procedural autonomy, but *does not fully resolve their substantive coordination*.

From an administrative perspective, the risk posed by this regulation is that it establishes a comprehensive, transparent, and participatory technical procedure that is, however, insufficiently integrated into the decision that determines actual access to public funding or inclusion in the common services. For patients, autonomous regions, healthcare professionals and developers, the practical value of the assessment will depend on its actual impact on the funding decision, price determination, or adoption of the technology. If that impact is not sufficiently clarified, the system may improve the methodological quality of the assessment without necessarily providing greater legal predictability

regarding the final decision. Predictability does not require that the technical report be binding, but it does require that the legal framework specify its function, its inclusion in the dossier, its relationship to other reports, and the manner in which it must be considered by the decision-making body.

## 4. Procedural issues and administrative safeguards

- Royal Decree 415/2026 defers a substantial part of the applicable regime to future regulatory instructions and methodological guidelines. This *legislative drafting* may be justified by the scientific complexity of the assessment and by the need to update methodologies with greater flexibility than the adoption of a regulatory provision. However, from the perspective of the principle of legal certainty, this reference requires careful delimitation. Anything affecting rights, documentary obligations, time limits, corrections, procedural consequences, or the legal positions of third parties must be approved through appropriate regulatory instruments, with official public disclosure and guarantees of participation. In contrast, non-regulatory methodological guidelines should be limited to technical aspects that do not create direct obligations or adverse consequences for interested parties (and, of course, must also be subject to the participation of any potential interested party). In any case, the line between a methodological guideline and a mandatory instruction may be debatable in practice, especially when non-compliance with certain formats, templates or technical standards could affect the acceptance or assessment of the documentation submitted by the developer.

> *Predictability does not require that the technical report be binding, but it does require that the legal framework specify its function*

- The *position of the Adoption Group* also warrants attention. The regulation states that this body does not replace, condition, or question the powers of the decision-making bodies, yet at the same time it assigns it the role of compiling the assessment reports and issuing the final assessment regarding the relative position of the technology. It is, therefore, an intermediate phase, but one with very significant practical relevance. From a legal standpoint, it would be advisable to specify in greater detail the nature of its decisions, its reasoning framework, access to the dossier for interested parties, the handling of confidentiality, and the possibility of challenging, directly or indirectly, its assessments when they influence the final decision. Regulating this phase is particularly important because it can become the actual link between the technical assessment and the administrative decision regarding funding, pricing or inclusion in the service catalogue.

- Another relevant issue is the *management of uncertainty*. Article 8 of the Royal Decree allows assessments to highlight "the degree of uncertainty regarding the available evidence" and propose ways to reduce it, such as studies, registers, monitoring, or pilot programmes. This provision is appropriate in a context where many innovative technologies enter the market with still-incomplete clinical evidence or limited data on their real-world effectiveness. However, the regulation leaves the implementation of these measures to the decision-making bodies, merely stating that "they must be pragmatic, proportionate and feasible, taking into account the nature of the technology, the disease or the area of care in question, and the nature of the expected benefits". From a legislative drafting perspective, it would be desirable for subsequent implementation to establish clear criteria for determining when conditional funding is appropriate, when additional evidence generation should be required, how real-world data is assessed, and what the consequences are for non-compliance with monitoring obligations.

- *The transparency and confidentiality regime* must also be considered. The Royal Decree provides for the publication of reports with the redaction of confidential information or information subject to the developer's rights. This balance is necessary, but it can create tensions between the protection of trade secrets and the right of access to information relevant to understanding the reasons behind a public funding decision. The greater the budgetary and healthcare impact of a technology, the greater the need for the public authority to sufficiently explain the technical and economic basis of the decision, without prejudice to preserving information that must legally be kept confidential.

## 5. Legal assessment and potential improvements

Overall, Royal Decree 415/2026 constitutes a significant regulatory development for the Spanish health technology assessment system. Its main contribution is to organise the production of technical evidence that can serve as the basis for complex public decisions in which clinical efficacy, safety, added value, efficiency, budgetary impact, healthcare organisation and sustainability must be weighed.

However, from an administrative law perspective, the implementation of the Royal Decree should be supplemented by more precise regulation governing the relationship between assessment and decision-making. In particular, it would be advisable to expressly regulate the inclusion of the assessment report in the funding dossier or service catalogue; establish a strengthened duty to provide justification when the decision-making body deviates from the assessment or the findings of the Adoption Group; clarify the effects, public disclosure, and contestability of intermediate actions with decision-making relevance; and define criteria for the use of conditional funding mechanisms, re-assessment, registers, and pilot programmes when significant uncertainties exist.

It would also be advisable for future legislative instructions to clearly distinguish between procedural obligations required of

developers and non-binding methodological guidelines. This distinction would help avoid disputes regarding the legal nature of development documents and the consequences of non-compliance. Likewise, it would be advisable to establish rules for coordination between the assessment and the funding and pricing procedures, so that the assessment does not unduly delay access, but also does not become a merely parallel phase with no clear impact on the final decision.

The assessment of health technologies should not replace the decision-making authority, nor should it be reduced to a report without defined procedural effects. Its proper function is to provide a verifiable, transparent and comparable technical basis for decisions affecting patients' access to new therapies, the sustainability of the National Health System, regional planning, and the incorporation of health innovation. To fulfil this assessment function, the system must occupy a legally recognisable place within the administrative chain leading to effective access to the assessed technology.

The practical utility of the 2026 Royal Decree will therefore depend on its subsequent implementation and on how administrative bodies integrate the assessment reports into their decisions. If the assessment is effectively incorporated into the process of funding, price determination and inclusion in the service catalogue, the new legal framework can strengthen the consistency, transparency and quality of public decision-making. If, on the other hand, it remains a separate technical phase with poorly defined legal effects, the system will have advanced in methodology but will continue to raise significant uncertainties in terms of legal certainty, administrative justification and predictability for the various operators of the National Health System.