

When Reimbursement Systems Fail to Recognize Value

When Spain approved Royal Decree 415/2026 on health technology assessment in May 2026, the government presented it as a step toward more transparent, coordinated and evidence-based decisions about health technologies.

At the press conference on 26 May, government spokesperson Elma Saiz highlighted the ambition to strengthen the evidence underpinning decisions about medicines, medical devices and other technologies used within Spain's National Health System. The decree itself recognizes that health technology assessment should inform decisions on adoption, funding, pricing and reimbursement — while making clear that assessment is not the same as decision-making. Read the government's announcement.

That distinction matters. Because one of the most important questions in healthcare is not simply how we assess innovation, but whether the systems responsible for funding it are equipped to recognize its value.

I spent four years working on a strategic market-access effort to help open Spain's reimbursement system to new categories of medical technology. It involved consulting firms, stakeholder engagement, advisory boards, knowledge-sharing meetings, manifestos and industry alliances. The work gave me a close view of how difficult it can be to introduce new approaches into systems built around established categories, assumptions and pricing structures.

The challenge was never just to demonstrate that a technology could work. It was to make sure the system had a meaningful way to evaluate what it did, whom it served and whether its outcomes justified a different approach to reimbursement.

That experience left me with a broader concern: a healthcare system can be open to innovation in principle while remaining difficult to access in practice. The barrier does not always take the form of an explicit rejection. It can be embedded in the rules used to compare technologies, define their value and determine what the system is prepared to pay.

Spain's own experience illustrates why the relationship between evidence and decisions deserves scrutiny. A study published in *The European Journal of Health Economics* in 2025 examined reimbursement decisions for medicines and new indications in Spain between May 2019 and December 2022. Of 477 therapeutic indications identified, 253 could be matched to a corresponding health technology assessment report. Among those 253, 142 — approximately 56% — were not recommended for reimbursement. More strikingly, just 24 decision reports, or 9.49%, mentioned the corresponding assessment report in their conclusions. The researchers also found that only 21.74% of the assessment reports included keywords aligned with the specific criteria used to justify reimbursement decisions.

These findings concern medicines, not medical devices or every category of health technology. Nor do they establish that the assessment process alone determined the decisions. But they raise a fundamental policy question: if the evidence produced through assessment

does not clearly connect to the criteria used in the final decision, how transparent and predictable can the pathway to patient access really be?

Read the full study on Spain's health technology assessment and reimbursement system.

The same challenge appears when we consider how technologies are grouped and compared. Reimbursement categories can serve a legitimate purpose: they help systems manage budgets, apply consistent rules and compare options that are genuinely comparable. But consistency becomes a problem when it is achieved by treating different things as if they were the same.

Technologies may differ in their intended use, functionality, clinical outcomes, patient populations or the resources they require. If they are placed in the same reimbursement category without adequately accounting for those differences, the established, lower-cost option can become the reference point for alternatives that do not serve the same purpose. The price benchmark may then reflect the history of the category more than the value of the technology being assessed.

This is not an argument for automatically paying more for innovation. Nor should every new technology be entitled to a separate category. It is an argument for making comparability an evidence-based decision rather than an administrative assumption.

When meaningful differences are overlooked, a system risks rewarding what is already familiar and inexpensive while making it harder for alternatives to demonstrate their value on appropriate terms. In that situation, a reimbursement framework can unintentionally preserve the status quo, even when policy explicitly supports innovation.

The question of value is equally important. Healthcare decisions must consider clinical effectiveness, safety, affordability and opportunity cost. Public budgets are finite, and resources spent on one intervention cannot be spent on another. But a narrow focus on immediate expenditure can also obscure relevant consequences beyond the budget in which the decision is made.

For some technologies, the impact may extend to a patient's ability to manage daily life independently, participate in work and social activities, or reduce reliance on informal care. For others, value may be reflected in earlier diagnosis, fewer complications, reduced treatment burden, improved adherence or changes in how care is delivered. The relevant outcomes depend on the technology and the population; they should be demonstrated, not assumed.

This is why I have long believed that market-access discussions need to look beyond a single clinical endpoint or an immediate budget impact. Social return on investment can help broaden the questions being asked by bringing potential effects on patients, caregivers and wider society into view. It should complement rigorous clinical and economic evidence, not substitute for it. Wider benefits also need credible measurement, and decision-makers must be careful not to count the same benefit twice or attribute outcomes to a technology without sufficient evidence.

The wider debate is not about whether healthcare systems should consider every possible benefit. It is about whether they have a transparent and consistent way to decide which dimensions of value are relevant, how they should be measured and how they should influence decisions.

Research into value assessment frameworks highlights the challenge. A systematic review of 55 frameworks found that 42 — 76% — included societal impact among their value categories. Yet only 11 frameworks involved patients or the public in their development. This does not prove that societal value is ignored in every reimbursement decision. It does, however, illustrate the gap that can exist between recognizing a dimension of value in theory and ensuring that the people affected have a meaningful role in defining and evaluating it.

Read the systematic review of value assessment frameworks.

Spain's Royal Decree 415/2026 provides an opportunity to address some of these questions. Its assessment framework covers clinical and non-clinical dimensions, including economic, ethical, organizational, social and legal considerations, as well as environmental aspects. It also seeks to establish common methods and improve coordination between the assessment process and the decisions made by the competent authorities. [Read the Royal Decree in the Official State Gazette.](#)

At the European level, the EU Health Technology Assessment Regulation has applied since January 2025. It introduces joint clinical assessments for specified categories of health technology, beginning with certain new cancer medicines and advanced therapy medicinal products, with further categories phased in over time. The aim is to strengthen cooperation and reduce duplicated assessment work. But European clinical assessment does not replace national decisions on pricing, reimbursement or the organization of healthcare. Those decisions remain critical to whether patients ultimately gain access.

Read the European Commission's overview of the EU HTA Regulation.

The policy direction is therefore important, but frameworks alone cannot guarantee better outcomes. The real test is whether assessment methods, decision criteria and reimbursement mechanisms work together. Do they make clear what evidence is required? Do they distinguish technologies that are genuinely different? Do they explain how clinical benefit, economic impact and wider societal considerations are weighed? And can innovators and patients understand how the evidence translates into a decision?

These are not questions that can be answered by adding more criteria to an assessment template. They require governance, methodological consistency and a transparent connection between what is assessed and what is ultimately decided.

My four years working on market access in Spain taught me that changing the conversation is only part of the work. Meaningful progress requires the system itself to be capable of translating evidence into decisions that reflect the needs of patients, the constraints of public budgets and the differences between available technologies.

Innovation should not be funded simply because it is new. But neither should it be disadvantaged because existing categories, comparators or pricing structures fail to capture what makes it different.

The measure of a health technology assessment system is not only the quality of its evaluations. It is whether those evaluations lead to transparent, consistent and evidence-based decisions — and whether the reimbursement system can recognize meaningful value when it sees it.

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