

When Categories determine Value

*How classification shapes evidence,
price and patient **access***



The problem is not categorisation It is false equivalence

HOW THE CATEGORY SEES THEM



One category

One benchmark, one price logic

WHAT ACTUALLY DIFFERS

Function



Intended use



Outcomes



● A ● B

Illustration only

Categories bring structure. They support consistent decisions, efficient procurement and appropriate substitution. But when technologies are treated as comparable beyond what their functions, intended uses and outcomes justify, meaningful differences risk disappearing from the discussion

MY TAKE

Treating different technologies as the same does not make a system fairer. It makes the difference invisible, and what is invisible cannot be valued



Three mechanisms

Three different questions

1

HEALTH TECHNOLOGY ASSESSMENT

What is the technology's clinical and economic value relative to relevant alternatives?



2

PRICING AND REIMBURSEMENT

Should the technology be funded, under what conditions and at what price?



3

HOMOGENEOUS GROUPS

Which funded medical-device presentations are similar enough to be interchangeable at dispensing?



Related, but not interchangeable. Confusing their purposes risks confusing the evidence needed to assess value with the rules used to organise dispensing and pricing

MY TAKE

Spain's own framework separates these three questions in writing. The risk is practice collapsing them back into one, where a pricing or dispensing rule quietly stands in for a judgement on value

Sources: Royal Decree 415/2026, Arts. 5.2 and 15.1 (assessment informs decisions and is not binding); Royal Decree 90/2026, Art. 18



Comparable for what purpose?

Spain’s Royal Decree 90/2026 groups funded medical-device presentations with the same characteristics, type, size and content, where possible, so they can be exchanged at dispensing

WHAT THE TEST COVERS

Interchangeable at dispensing

A practical test of substitution

WHAT IT DOES NOT COVER

Value across the care pathway

Clinical outcomes, usability, resource use



Interchangeable at the pharmacy counter



A person’s path through diagnosis, care and daily life

MY TAKE

Interchangeable at the pharmacy counter is not the same as equivalent in a person’s life

Source: Royal Decree 90/2026, Article 18(3)



The comparator shapes what the evidence can show



Spain’s HTA framework requires clinical evaluations to define the population, intervention, comparator and health outcomes. The economic assessment also considers relative effectiveness, social value and health-related quality of life



Illustration only

MY TAKE

Choose the wrong comparator and the evidence can be flawless and still answer the wrong question

Source: Royal Decree 415/2026, Articles 8 and 12



Europe is already debating the comparator

Under the EU HTA Regulation, joint clinical assessments start by defining the comparison. A review presented at ISPOR Europe 2026 looked at how far that definition multiplies the evidence required



14 publications · 35 exercises · 20 indications

Mostly oncology and simulations. Medicines, not devices

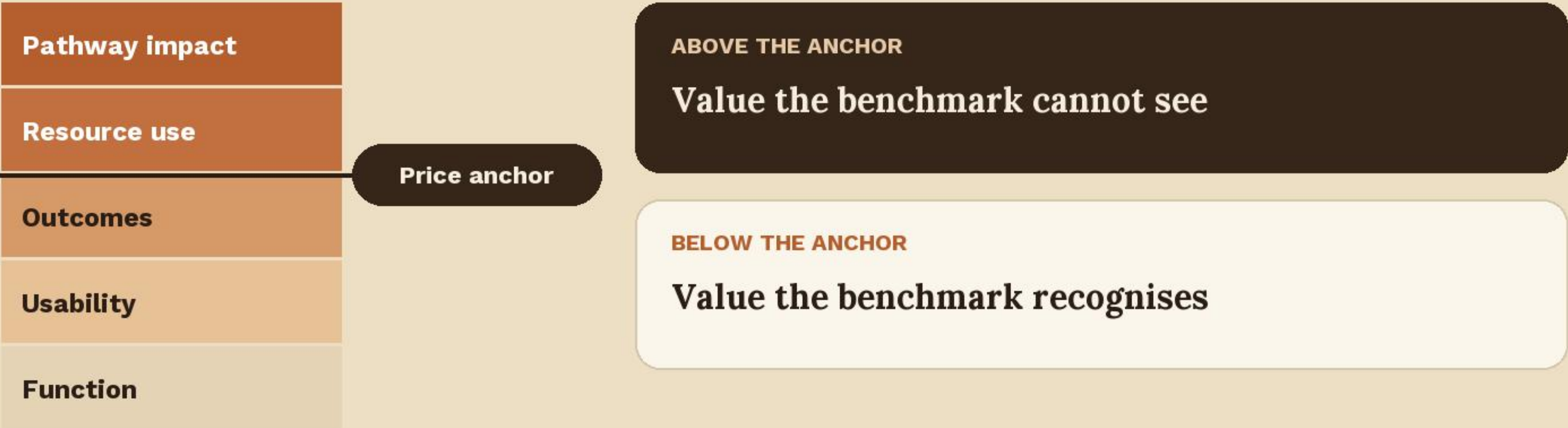
MY TAKE

Europe is learning that defining the comparison is half the evidence. Spain should not learn it later, on the patient's time

Source: Aggarwal, Bela and Topaloglu, ISPOR Europe 2026, poster 'How many PICOs is too many?'. Scoping exercises and simulations, not real assessments



A price benchmark is only as relevant as the comparison behind it



The technology's value
Illustration only

Under Royal Decree 90/2026, the proposed maximum price must be justified, and an upward revision can be requested when economic, technical or health circumstances change. The decision considers changed circumstances, budget impact and whether cheaper alternatives exist

MY TAKE

An anchor set long ago can quietly become the ceiling for what a new technology is allowed to be worth

Source: Royal Decree 90/2026, Articles 6 and 21



What my market-access experience has taught me

5–10%

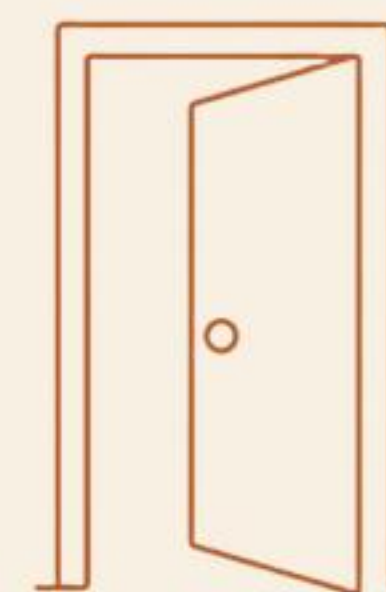
MY EXPERIENCE · NOT A STATUTORY THRESHOLD

In some Spanish pricing discussions, a 5–10% premium was treated as a practical expectation. This reflects my professional experience, not a legal limit or a universal market standard

An incremental pricing mindset can struggle to recognise technologies that change how care is delivered, rather than improve an existing product

When the value proposition changes materially, should the discussion begin and end with a modest premium?





The door is open

Who gets through?

WHAT THE FRAMEWORK OPENS

- Selective financing replaces RD 9/1996
- Applications from 1 July 2026, in windows through 2028
- Priority to unmet medical need and NHS sustainability
- HTA reports mandatory, though not binding

WHAT STILL DEPENDS ON PRACTICE

- Scope set in annexes: new groups need a ministerial order
- One year to launch, or the resolution lapses
- How price anchors and comparators will be applied
- No confirmed product on the market yet in my research

“ 'Es imprescindible que se puedan incluir nuevas categorías y grupos de productos' ”

Fenin, industry federation, February 2026

MY TAKE

An opening in the law is not an opening in the market. In my experience, the real test is always the first product that actually gets through, not the date a decree takes effect

Sources: RD 90/2026 and Ministry of Health FAQ; Cuatrecasas analysis; Fenin via Consalud, 10 Feb 2026; Fenin, Redacción Médica, 27 May 2026



What is at risk is the patient

1 **Innovation** is judged against the wrong comparator

2 **New categories** stay closed behind old ones

3 **Lived outcomes** never enter the file

41.6%



depressive symptoms among people living with an enterostomy (pooled, 9 studies, 823 patients)

67%



of the social return in a Spanish COPD model was intangible (modelled estimate)

MY TAKE

When a category stays closed, the patient is not rejected. They are simply never counted

Sources: Tang et al., *Front Psychiatry* 2022;13:1001232; Merino et al., *Int J COPD* 2022;17:1431-1442 (funded by manufacturers). Association, not causation



Sources and further reading

**Royal Decree 90/2026**

BOE-A-2026-3215, boe.es/buscar/doc.php?id=BOE-A-2026-3215

**Royal Decree 415/2026**

BOE-A-2026-11587, boe.es/diario_boe/txt.php?id=BOE-A-2026-11587

**Ministry of Health, RD 90/2026 FAQ**

sanidad.gob.es, Dirección General de Cartera Común de Servicios

**Fenin**

Consalud, 10 Feb 2026; Redacción Médica (P. Crespo), 27 May 2026

**ISPOR Europe 2026**

Aggarwal, Bela, Topaloglu: 'How many PICO's is too many?'

**Tang et al.**

Front Psychiatry 2022;13:1001232, depression in enterostomy patients

**Merino et al.**

Int J COPD 2022;17:1431-1442, SROI of COPD management in Spain

MY TAKE

Sources inform a judgement, they do not replace it. Reading the evidence is only the first step. Knowing which question it actually answers is the harder, and more valuable, part of the work



Evaluate innovation on the right terms

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

Public resources are finite. The patient is the reason they exist

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'When Reimbursement Systems Fail to Recognize Value'

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