Regulatory Brief by ECNE Research | 9 October 2026

This Week's Top Global Headlines

Beyond Regulatory Approval

For a patient with severe mitral regurgitation who is not a candidate for surgery or transcatheter edge-to-edge repair, an innovative transcatheter valve may offer another treatment option.

But once a medical device has demonstrated the evidence needed for regulatory certification, another question emerges: How does it compare with the alternatives?

This week, that question became much more tangible for European medtech. On 6 October, the European Commission selected the first two medical devices for Joint Clinical Assessment (JCA) under the EU Health Technology Assessment (HTA) Regulation:

- SAPIEN M3 Transcatheter Mitral Valve Replacement System, manufactured by Edwards Lifesciences; and
- HighLife Trans-septal Mitral Valve Replacement System, manufactured by HighLife.

The SAPIEN M3 assessment will be led by assessors from the Dutch National Health Care Institute and Norwegian Medical Products Agency, while the HighLife assessment will involve France's Haute Autorité de Santé and Poland's Agency for Health Technology Assessment and Tariff System.

Both technologies were selected because they met multiple EU criteria, including unmet medical need, first-in-class status, potential impact on patients and healthcare systems, significant cross-border relevance and potential Union-wide added value.

This is more than an administrative milestone. It is the point at which EU HTA becomes operational for medical devices and introduces a new layer of comparative clinical assessment between regulatory certification and subsequent national access decisions. For manufacturers, the important point is not simply that another assessment now exists. It is that the evidence question changes. **More info here.**

Deep Dive

A CE-marking evidence package and a JCA do not answer the same question. Under the MDR, clinical evidence contributes to demonstrating conformity with applicable safety and performance requirements and supporting the device's benefit-risk profile for its intended use.

Meanwhile, the EU JCA assessment examines the available clinical evidence on the technology's **relative clinical effectiveness and relative safety compared with other health technologies**.

That word '**relative**' matters. A manufacturer may have strong evidence that a device performs as intended and benefits its target population. HTA assessors may still need to understand how

outcomes compare with alternative interventions across the populations and endpoints that matter to European health systems.

For an innovative transcatheter mitral valve system, those questions may extend to survival, morbidity, symptoms, functional status, quality of life, procedural complications and durability, depending on the final assessment scope. And that scope is not determined solely by the manufacturer.

The JCA process defines the **patient population, intervention, comparator or comparators, and health outcomes** to be assessed, reflecting the needs of Member States. Patients, clinicians and other relevant experts can also contribute during scope development.

That creates an important evidence-planning challenge. A clinical investigation designed primarily around regulatory certification may not automatically contain the comparator, follow-up duration or outcomes needed to answer every subsequent HTA question.

And there is limited opportunity to solve that problem once the assessment begins. After the assessment scope is finalized and the Commission issues its first request, the developer has **100 days to submit the JCA dossier**.

That may be enough time to assemble and analyze existing evidence. It is not enough time to **generate comparative evidence that was never planned.**

What comparator or outcome is likely to matter to European HTA bodies?

For manufacturers, the practical implication is that evidence already being generated should be interrogated earlier.

- What comparator is likely to matter to European HTA bodies?
- Which outcomes will demonstrate meaningful clinical benefit rather than technical performance alone?
- Is follow-up long enough to assess durability?
- Are patient-reported outcomes relevant and adequately captured?
- Can differences in operator experience, patient selection or device generation affect interpretation?
- Where direct comparative evidence is impractical, what external evidence, real-world data or appropriately justified analytical approaches could help contextualize the results?

These questions are particularly important for medical devices because the evidence environment often differs from pharmaceuticals. Technologies evolve, operator learning matters, patient populations may be highly selected and conventional randomized comparisons are not always feasible. That makes the comparative evidence question more complex and a defensible strategy for answering it even more important.

JCA Is Not a European Reimbursement Decision

There is also an important boundary to understand. The JCA report provides a shared scientific assessment of the available clinical evidence. It does **not** provide a value judgement or conclude on the overall clinical added value of the technology.

Individual Member States remain responsible for their national HTA conclusions and decisions concerning use, pricing and reimbursement. JCA therefore does not create a single European reimbursement decision. Instead, it creates a common clinical evidence foundation that national decision-makers can use.

That may reduce duplication, but it also means that the strengths and gaps in a manufacturer's comparative evidence may become visible across multiple European markets at the same time.

ECNE Insight

The real HTA risk is having evidence designed for the wrong question. The first medical-device JCAs make that distinction very real. A manufacturer may have invested significantly in clinical evidence capable of supporting regulatory certification, only to discover that subsequent HTA assessment requires different comparators, outcomes, populations, or longer-term effects.

The solution is to consider the future comparative evidence questions while the clinical strategy can still be influenced rather than treat HTA as an additional dossier exercise at the end of development. For medtech developers, that means connecting regulatory strategy, clinical investigation design, PMCF, real-world evidence and HTA planning earlier.

The goal is to make the evidence already being generated work harder across the decisions that follow. One hundred days may be enough to build a JCA dossier. It is not enough to build the evidence that should have been planned years earlier.

On Our Radar

- **EU | 12–15 October 2026 — EMA CHMP meeting:** EMA's Committee for Medicinal Products for Human Use will convene for its October meeting. CHMP is responsible for preparing EMA opinions on questions concerning human medicines, making the meeting worth watching for upcoming regulatory recommendations and decisions. **More info here.**
- **EU | 13–16 October 2026 — EMA Paediatric Committee meeting:** EMA's PDCO will meet to assess paediatric investigation plans, including related waiver and deferral requests relevant to development of medicines for children. **More info here.**
- **USA | 14–15 October 2026 — FDA workshop on inhalation-drug bioequivalence:** FDA and the Center for Research on Complex Generics will examine in-vitro, in-vivo and in-silico approaches to demonstrating bioequivalence for complex inhalation products, including alternatives to comparative clinical endpoint studies. **More info here.**
- **EU | 21 October 2026 — Joint Scientific Consultation request window closes:** The current EU HTA JSC request period, which opened on 23 September, closes on 21 October. The framework provides routes for medicinal products, medical devices and IVDs to seek earlier advice on evidence requirements relevant to future assessment. **More info here.**