

Integration of JCA within existing HTA bodies: What we know so far

In January 2025, the European Union Health Technology (euHTA) Regulation (EU) 2021/2282 has been implemented across EU Member States, launching the start of joint clinical assessments (JCAs) of medicinal products and medical devices. Since then, 10 oncology drugs have begun the JCA process, with 1 withdrawal. As the number of new oncology medicines in the JCA increases, national HTA bodies are progressively considering JCA integration into their processes.



Germany

The Federal Joint Committee (G-BA) has begun considering how to integrate the EU HTA within national early benefit assessment of new medicines. The major changes noted include:

- > Equal consideration of all submissions undergoing the national HTA and EMA, with existing dossier structures and templates still in effect as they undergo refinement

- > Facilitation of the integration of JCA findings into the national benefit assessment, with Germany's Federal Ministry of Health, in March 2025, clarifying submission timelines and how data submitted at the EU level can be incorporated into national assessments
- > Revision by the G-BA of current procedures to facilitate the process for pharmaceutical companies, who can now avoid work duplication by referencing clinical data and documents already submitted through the EU HTA process
- > Inclusion of the JCA findings into the Institute for Quality and Efficiency in Health Care (IQWiG)'s evaluation

These process adaptations lead to 3 scenarios:

- > If the JCA is available at the time of submission, the G-BA will consider the JCA report throughout the AMNOG process, including the initial assessment
- > If the JCA is available at a later stage during the process, it can be incorporated as long as it's during the hearing phase
- > If the JCA is not available, the G-BA proceeds with the national assessment

Germany's IQWiG is also an assessor and co-assessor for several ongoing JCAs, with completion of the first process expected in Q2 2026. It would be interesting to see if Germany will revisit the JCA integration, after going through the process as an assessor.

Italy

Similarly to Germany, Italy's AIFA (Italian Medicines Agency) is seeking to adapt existing processes to facilitate implementation of the JCA. According to news from September 2025, AIFA is planning to create a new Office for European HTA Procedures.

The new office will be part of AIFA's Access to Medicines and HTA Division and will support a variety of tasks, including, but not limited to:

- > Participation in the JCA and JSC
- > Building of European dossiers

- > Ensuring EU-level evaluations are integrated into national P&R processes
- > Coordination with the HTA Coordination Group and Subgroups
- > Support development of methodological and procedural guidelines to advance the EU HTA framework
- > Support the Technical-Scientific Directorate and the Scientific and Economic Commission (CSE) in related activities, which may include coordination with EU HTA groups, providing training on JCA, etc.

This reorganization aims to improve efficiency, transparency and coordination with national and European institutions.

The Netherlands

The Dutch National Health Care Institute (Zorginstituut Nederland, ZIN) has also been preparing to implement the new HTA regulation, with the aim of developing a national HTA process that supports the JCA and facilitates use of JCA reports at national level.

As part of these adaptation processes, the ZIN conducted a practical gap analysis, which identified six key domains for improvement: legal, information and knowledge, IT and templates, communication and stakeholder engagement, capacity and resources, and financial aspects.

In this context, the Dutch national HTA process expects some challenges, including:

- > Required integration of JCA evidence needs listed by Member States in the national pharmacotherapeutic report
- > Fast stakeholder (e.g., physicians and patient organizations) engagement needed to incorporate their input into national PICO scoping
- > Potential need to write national HTA reports in English to ease JCA integration, with the caveat that it would hinder public understanding and engagement from patient organizations (the current decision is to continue writing reports in Dutch)

- > Requirement for additional staff in the short term to handle the JCA inputs and prepare national reports, with provision of training on JCA procedures
- > Limited staff with the required deep expertise in clinical studies and outcomes to support the JSC

Despite the need for certain adaptations to national processes, the ZIN believes the approach and EU HTA collaboration will speed up access to real innovation, harmonize methods for clinical aspects and reduce work duplication.

Conclusion

Many EU member states are increasingly considering the impact of the JCA on existing National HTA processes, and have begun taking steps to ensure its smooth implementation. However, there is still significant uncertainty on the level of integration of both processes. With the first JCA processes expected to be completed in spring 2026, one could expect to observe further national process changes around that time, with national benefit assessments taking the JCA into account, and further organizational changes taking place.

Sources

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