HTA154

From JCA to Local P&R: Evaluating the Impact Across Europe

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Background

- In December 2021, the European Parliament and the Council of the European Union adopted Regulation (EU) 2021/2282 on HTA (HTAR), establishing a permanent framework for EU-level collaboration in HTA.[1] This regulation replaces prior project-based initiatives and introduces structured cooperation through:
  - Joint Clinical Assessments (JCAs)
  - Joint Scientific Consultations (JSCs)
  - Identification of emerging technologies
  - Voluntary cooperation among Member States (MS).
- The HTAR amends Directive 2011/24/EU, entered into force in January 2022 and began applying in January 2025 for cancer treatments and Advanced Therapy Medicinal Products (ATMPs).
- JCAs aim to harmonize the clinical evaluation of new medicines and certain medical devices across the EU, reducing duplication, enhancing consistency, and facilitating faster and more equitable patient access to innovation.
- While clinical assessments are centralized, decisions on value judgement, pricing and reimbursement (P&R) – along with broader HTA components such as economic, ethical, and organizational evaluations - remain under national competence. This creates a dual-level system where EU-level assessments must be integrated into diverse national HTA frameworks, each with its own structures, capacities, timelines, and policy environments.
- MS are currently adapting their legal and policy frameworks to implement HTAR and ensure system readiness. Monitoring national implementation and adaptation to the JCA process is critical to identifying early challenges and informing strategies that support the successful rollout of HTAR - particularly in terms of improved patient access to innovation across Europe.

Objectives

- This study aimed to assess the anticipated impact of JCAs on national HTA and P&R processes, assessment methodologies, and timelines for patient access to innovative therapies. This analysis covers a range of European markets.

Methods

- A systematic assessment was conducted to evaluate the status of national implementation of the EU HTA Regulation across 14 European countries:
  - Austria (AUT), Belgium (BEL), Denmark (DNK), Finland (FIN), France (FRA), Germany (DEU), Ireland (IRL), Italy (ITA), the Netherlands (NDL), Norway (NOR), Poland (POL), Portugal (PRT), Spain (ESP), and Sweden (SWE).
- These countries were selected to ensure representation across:
  - HTA archetypes (e.g., relative clinical effectiveness, cost-effectiveness, budget impact)
  - Healthcare system organization (centralized vs. decentralized HTA decision-making models)
  - Geographic and procedural diversity (Northern, Southern, and Central Europe).
- A mixed-methods approach was employed, combining secondary research with structured primary data collection to assess response to the HTAR, local preparedness, and expected implementation challenges and opportunities.
- A desk review was performed using publicly available sources, including HTA body websites, health ministry communications, legislative documents, methodological guidelines, and implementation updates. Supplementary information was gathered from local trade associations, policy publications, and stakeholder consultation documents where available.
- A structured questionnaire was developed to complement the desk research and administered multiple times between May 2024 and May 2025 to local market access and policy leads at Bristol Myers Squibb (BMS) across the selected markets.
- The structured questionnaire explored key areas, including:
  - Anticipated changes to national HTA and P&R processes and methodologies
  - Readiness of national HTA bodies and MS.
  - Expected impact on time to patient access
- Follow-up semi-structured interviews were conducted with affiliate experts at BMS to capture additional updates and qualitative insights into expected impact and strategic considerations.

Results

- MS have taken concrete steps to align their national systems with the JCA process and broader EU-level coordination. Implementation progress varies across markets, with many initiating structural, legal, and procedural reforms, including:
  - Legal amendments to enable participation in EU-level HTA
  - Updates to national HTA guidelines and submission templates
  - HTA system reforms triggered or accelerated by HTAR alignment
  - Early involvement in JCAs as (co-)assessors or contributors.
- Our findings *(as of Sep 2025)* revealed significant variation in national preparedness, policy adaptation, and procedural alignment across the 14 markets, with some markets still navigating a rapidly evolving landscape.
- At the legislative level, the implementation of EU HTAR has triggered or accelerated legal reforms in AUT, BEL, and ESP including newly established HTA boards (e.g., AUT), updated national procedures (e.g., NDL), formal integration of JCA reports, patient perspectives, and EU HTA guidelines (e.g., BEL), and the introduction of new assessment criteria (e.g., ESP). Several markets, including AUT, the Nordic markets, ITA, POD, ESP, and NDL, have revised or are actively revising their local P&R systems, introducing new evaluation guidelines, dossier templates (e.g., NDL), and adapted local requirements and process timelines (e.g., AUT, ESP, POL, Nordic markets). Public authorities have initiated dialogue with HTDs, primarily via trade associations, to explore the implications of the JCA process.
- The anticipated impact of JCAs varies by HTA system maturity: minimal disruption is expected in mature systems (e.g., FRA, DEU), while higher or uncertain impact is anticipated in markets with less established HTA frameworks. The implementation approach that HTA bodies will adopt for JCA findings remains broadly uncertain, especially in contexts requiring local adaptations or economic modeling.
- Insights from the 14 markets (**Figure 1**) included in this study show:
  - Varying willingness among HTA bodies to engage early with HTDs on national PICO requirements, with openness for early engagement observed in DNK, DEU, SWE, and FIN.
  - Varying interest of HTA bodies in sharing local PICOs with HTDs. There is openness from HTA bodies to share PICOs in POL (during EU scoping), BEL (after EU scoping is finalized) DNM, DEU, SWE, NOR, FIN, and NDL post-submission of JCA dossier. No sharing expected by HTA bodies in AUT, FRA, ITA, PRT, and IRL.
  - Varying potential impact on procedural timelines. To avoid delays in national processes, DEU, FRA, ITA, BEL, and POL have confirmed that national dossiers may be submitted prior to JCA report publication. Conversely, DNK, AUT, PRT, and SWE anticipate starting national assessments only after the final JCA publication, which may introduce potential delays to the start of national processes. Notably, under Spain's draft Royal Decree, expected to be released in Q4 2025, the national timeline for clinical assessment may be shortened from 90 working days to 20 calendar days when a JCA is available, accelerating clinical assessment for products in scope of JCA.

Figure 1. Impact of JCA on the P&R procedure at local level across the 14 focus countries

	Austria	France	Poland	Denmark	Germany	Netherlands	Italy	Spain	Portugal	Sweden	Norway	Finland	Belgium	Ireland
PICO scoping discussion with HTD is possible	No	No	No	Yes	Yes	No	No	No	No	Yes	No	Yes	Yes	No
HTAb willing to share local PICOs with the HTD	No	No	Yes (during EU scoping process)	Yes (after JCA dossier submission)	Yes (publication on G-BA website during GER benefit assessment)	Yes (after JCA dossier submission)	No	No	No	Yes (after JCA dossier submission)	No	Yes	Yes (HTD can request after EU scoping is finalized)	No
HTAb expected to wait for final JCA report to start national assessment	Yes	No	No	Yes (potential delay)	No	Yes (submissions at CHMP can reference JCA dossier)	No	Yes (potential delay, but accelerated clinical assessment 20d vs 90d)	Yes	Yes	No	Yes	No	Partial (potential delay, submission at EMA approval possible)
Likely respondent to JCA PICO survey	GOEG/ AIHTA/ DV (for retail products)	HAS	AOTMiT	DMC	G-BA	ZIN	AIFA	AEMPS	INFARMED	TLV	NOMA	HILA (outpatient drugs), Fimea (hospital drugs)	NIHDI	NCPE

Key: Willingness to engage with HTD on PICO scoping / Flexibility to start national HTA ahead of JCA report; No willingness to engage with HTD on PICO scoping / No flexibility to start national HTA ahead of JCA report

- Further clarity on national integration is expected in 2026 with the anticipated release of P&R decrees, both in ESP and ITA.
- No major changes have been reported in national HTA methodological guidelines, except in POL and ESP, where authorities have confirmed alignment with the EU HTA framework. The German HTA body IQWiG has clarified that EU HTA methodologies will not be incorporated into its General Methods, as the EU HTA process falls outside national competence.
- Capacity constraints remain a key concern for HTA bodies in ITA, FRA, ESP, DNK, and PLD, with several bodies highlighting risks of delayed assessments for non-JCA assets.
- Of the 14 markets analyzed, 11 are actively participating as (co-)assessors for the first nine products undergoing JCA as of October 2025, indicating broad representation in the initial implementation wave of JCAs.

Discussion

- The introduction of the EU HTAR and the rollout of JCAs marks a transformative step towards greater harmonization and collaboration in the clinical evaluation of innovative therapies across Europe.
- Our multi-country analysis highlights that while MS are making measurable progress in adapting national frameworks, the diversity of national systems, legal requirements and methodological approaches continue to shape the landscape of JCA integration. Notably, many markets are proactively participating as (co-)assessors in the first wave of JCAs, demonstrating strong commitment to EU-level coordination and the success of HTAR.
- The initial implementation phase presents both opportunities and challenges for HTDs. The multiplicity of PICOs, reflecting diverse comparator and sub-population requirements across MS, increases complexity but also underscores the need for tailored engagement with national HTA bodies. Importantly, our findings show that the appetite for early engagement and transparent exchange regarding national PICOs is growing in several markets, facilitating alignment on evidence needs.
- Capacity constraints and procedural variations, such as the timing of national dossier submissions relative to JCA report publication, remain areas requiring close monitoring to prevent potential delays in patient access.
- To maximize the positive impact of JCAs, HTDs must continue to prioritize open communication and strategic partnership with both EU and national stakeholders. Early sharing of JCA dossiers with local affiliates, alignment on evolving evidence requirements, and active participation in consultation opportunities will be essential to navigating the complexities of the dual-level system and ensuring that patients benefit from timely access to new therapies.

Conclusion

- JCAs represent a major milestone in EU-level HTA coordination, with the potential to improve clinical assessment efficiency and accelerate patient access to innovation across Europe. Their impact on access and reimbursement will depend on the quality and usability of JCA reports, as well as the effectiveness with which MS integrate EU-level frameworks into their national systems.
- By fostering proactive dialogue and partnership with HTA bodies, HTDs can help deliver future clinical assessments that are both rigorous and responsive to the needs of patients and health systems. For HTDs it will be important to maintain ongoing global-to-local communication to anticipate emerging evidence requirements and support integration of JCA into national processes.
- Monitoring the initial wave of JCA reports - expected from Q2 2026 - will be critical to understanding their integration at the national level, assessing their impact on JCA and non-JCA assets, informing future best practices, and facilitating continuous improvement in the system.
- Ultimately, realizing HTAR's promise of improved patient access to innovative therapies across Europe will depend on the ongoing evolution of both the EU HTA framework and national HTA systems, alongside meaningful stakeholder engagement and collaboration.

References

1. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.

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