Bridging National and EU HTA Regulation: Policy Responses to the JCA Rollout

Authors: Kurt Neeser, MPH, PhD[1]; Katarzyna Lasota, PhD[2]; Andrea Bernardini, PhD[3]; Sanja Stanisic, MSc[4]; Elvira Mueller, MPH, PhD[1]

[1] Certara, Lörrach, Germany
[2] Certara, Kraków, Poland
[3] Certara, London, United Kingdom
[4] Certara, Milan, Italy

Background and Objective

- From 12 Jan 2025, JCA under the Health Technology Assessment Regulation (HTAR) is mandatory for new oncology and Advanced Therapy Medicinal Products (ATMPs); rollout extends to orphan drugs by 2028 and all new medicines by 2030, reshaping EU evidence assessment.
- JCA reduces duplication and methodological variation via a shared clinical assessment; pricing and reimbursement remain national.
- National agencies are aligning timelines, methods, and stakeholder processes with EU rules while preserving country-specific assessments, real-world evidence use, and value-based approaches.
- This research examines national policy responses and, where implemented, how they bridge domestic HTA with the new EU regulation.

Methods

- Conducted comprehensive desk-research of national HTA/ministry documents, published sources, and EU reports across 10 countries with the highest nominal Gross Domestic Product - Germany, France, Italy, Spain, Sweden, Norway, Netherlands, Belgium, Czech Republic, Poland – across EU4 and representative Northern and CEE HTA perspectives.
- Reviewed outputs from regional HTA collaborations (Joint Nordic HTA Bodies, BeNeLuxA, CEE HTA Network).
- Timeframe covered was from January 2023–October 2025. Screened for HTAR implementation strategies, procedural reforms, and integration of Joint Clinical Assessment (JCA) into national systems, enabling cross-country comparison of readiness and policy priorities.

Results

As of October 2025, EU member states show significant variation in their policy responses to the rollout of the JCA.

GROUP A: Outstanding for Leadership and Alignment

Germany achieved full implementation with the First Amendment to AM-NutzenV (March 7, 2025), establishing comprehensive guidance through the "referencing solution" (Verweislösung) and "delta dossier" mechanism. G-BA is fully operational and ready, representing the benchmark for seamless AMNOG-JCA integration. **Netherlands** completed full guidance implementation with new procedures and templates developed. The National Health Care Institute (ZIN) is fully ready and operational, having hired dedicated JCA assessors and conducting thorough gap analyses. ZIN aims to serve as (co-)assessor multiple times in 2025, demonstrating advanced readiness. **Belgium** achieved full guidance implementation in parallel to the 3rd edition of their economic evaluation guidelines. The country is fully ready and operational, with comprehensive methodological frameworks integrating European HTA standards while maintaining national cost-effectiveness criteria for Class 1 products (i.e., pharmaceuticals with demonstrated therapeutic added value compared to existing therapeutic alternatives).

GROUP B: Regional Collaboration and Advanced Coordination

Sweden achieved full guidance implementation through Joint Nordic HTA-Bodies (JNHB) with updated process guidelines. SBU and TLV is fully ready and operational, with ongoing refinement of methods throughout 2025. Strong Nordic collaboration enables focus shift to health economic assessment while JCA provides clinical foundation.

Results (ctd)

Group B (ctd)

Norway achieved full guidance implementation with national working group established and NOMA representing Norway across all JCA/JSC sub-groups. The country is fully ready and operational through JNHB collaboration, with HTAR integrated into "New Methods" framework and active participation from four Regional Health Authorities.

GROUP C: Large-Market Adaptors: Maintaining Strong Local Autonomy

France achieved full guidance implementation through HAS, maintaining established processes while integrating JCA as reference points. The country is fully ready and operational with early scientific advice streamlined to written format and clear JSC prioritization protocols. HAS retains dual-commission system (TC and CEESP) for national economic/ethical assessment. **Italy** has partially implemented guidance with the Scientific and Economic Committee for Medicines (CSE) operational, and Working Group established (April 2025). However, readiness faces constraints: P&R Dossier not yet updated for JCA requirements, resources not allocated in 2025 Financial Law [3a]. AIFA demonstrates policy commitment but operational capacity lags behind guidance development. **Spain** has not yet completed guidance implementation. Royal Decree under final review. The AEMPS-led governance structure with 21-member Council is designed and EUnetHTA nine-domain framework adopted, but operational implementation awaits regulatory approval.

GROUP D: Emerging Implementation and Capacity Development

Czech Republic has implemented legislative changes but does not yet have existing guidelines. SÚKL self-assessed as ready and on schedule but faces capacity constraints: dual JCA/national workload challenges, HTA expert recruitment difficulties, and stakeholder contracts still in development with patient organizations. Readiness demonstrates commitment but acknowledges realistic operational limitations. **Poland** has implemented process with amendment of Reimbursement Act published in (July 2025. AOTMiT initially self-assessed as not yet ready but demonstrates active engagement. Readiness status: developing. The country maintains multi-stage process a national methodological priorities while working toward full JCA integration.

Further details on country-specific initiatives are summarized in Table 1.

Conclusions

- European countries are making steady progress in aligning their national HTA processes with the EU JCA framework, with the overarching goals of streamlining submissions, reducing duplication, and enhancing transparency.
- All ten countries analyzed (100%) have either issued formal guidance or are in the process of drafting policies to synchronize assessment content, procedural steps, and timelines with the JCA. This signals broad political and institutional commitment to incorporating EU-level evaluations into national decision-making.
- While intensive work is ongoing, and remaining gaps are expected to narrow in the coming years, differences in timing, regulatory culture, and institutional capacity may continue to influence the speed and depth of integration.
- Challenges such as constrained assessor resources, managing compressed timelines, and ensuring effective stakeholder engagement remain non-trivial and could affect uniform implementation.
- Looking ahead, the JCA rollout has the potential not only to harmonize evidence requirements, but also to reshape reimbursement negotiations and stimulate deeper collaboration among countries, ultimately paving the way for a more unified European approach to patient access and innovation adoption.

Table 1: Summary of the ten countries

Country	Status of adaptation of national guidance and processes		Country specific barriers	Country	Status of adaptation of national guidance and processes		Country specific barriers
	Policy Implemented or announced? (month/year)	Guidelines available aligning JCA and national assessment?			Policy Implemented or announced? (month/year)	Guidelines available aligning JCA and national assessment?	
DE	Yes (March, 2025) [1]	Yes, main topics: • Dual assessment approach • Referencing solution ("Verweislösung") • "Delta dossier" for German specific request (AEs, PRO, etc) • No suspension mechanism if JCA report is missing	• Must provide JCA dossier within 3 days if report not yet published	NO	Yes (June, 2025) [6]	Yes, and Norway part of the HTACG	• Resource conflicts on national level managing JCA participation
FR	Yes, (October 15, 2025) [2]	Yes, main topics [2a, 2b] • Similar to Germany , France implemented most of the necessary internal processes • Medicines that undergo or plan to undergo JSC at EU level are not eligible for early scientific advice at national level	• National early scientific advice now written format only - no meetings	NL	• Yes, (February, 2025) [7]	Yes, ZIN deeply involved in JCA process	• Some capacity and resource constraints expected
IT	In progress [3]	No	• Unclear how AIFA will integrate stakeholder input for scoping	BE	• Yes, (June, 2025) [8]	• Yes	• Potential for delayed national reimbursement despite JCA availability
ES	Under approval (October 10, 2025 [4]	Yes, the new decree aims to • Create a NICE-like governance structure • Adopt the EUnetHTA nine-domain framework • Use clinical domains from JCA evidence and non-clinical domains (economic, ethical, etc.) remain nationally appraised	• Dual assessment system - clinical from JCA, 5 non-clinical domains national	CZ	• Yes (2025) [9]	• No, (not adapted or published yet)	• SÚKL's capacity limitations in managing dual JCA and national workloads
SW	Yes (March, 2025) [5]	Yes • JNHB published updated process guideline	• Increased short-term administrative burden on TLV	PL	• Yes (July, 2025) [10]	• Update is expected	• Multi-stage reimbursement process maintained

Legend

AEMPS: Agencia Española de Medicamentos y Productos Sanitarios; **AOTMiT**: Agencja Oceny Technologii Medycznych i Taryfikacji (Agency for Health Technology Assessment and Tariff System); **ATMP**: Advanced Therapy Medicinal Products; **CEESP** = Commission d'Évaluation Économique et de Santé Publique; **CSE**: Scientific and Economic Committee; **HAS**: Haute Autorité de Santé; **HTACG**: HTA Coordination Group; **HTAR**: Health Technology Assessment Regulation; **JNHB:** Joint Nordic HTA Bodies ; **MA:** Market Access; **NOMA**: Norwegian Medical Products Agency; **P&R:** Pricing and Reimbursement; **SUKL**: Státní ústav pro kontrolu léčiv (State Institute for Drug ; Control); **TC**: Commission de la Transparence (Transparency Committee); **TLV**: Tandvårds- och läkemedelsförmånsverket (Swedish Dental and Pharmaceutical Benefits Agency; **ZIN**: Zorginstituut Nederland

References

1. Early benefit assessment of medicinal products in Germany – first adaptions to AMNOG implementing the EU HTA Regulation 18 March 2025 (https://www.hoganlovells.com/en/publications/early-benefit-assessment-of-medicinal-products-in-germany-first-adaptions)
2. Règlement Européen sur l'évaluation des technologies de santé (https://www.has-sante.fr/jcms/p_3545447/en/reglement-europeen-sur-l-evaluation-des-technologies-de-sante);
2a How Will the EU JCA Change the HTA Process in France? (How Will the EU JCA Change the HTA Process in France? » Partners4Access); **2b** COMMISSION IMPLEMENTING REGULATION (EU) 2024/3169 of 18 December 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level (Implementing regulation - EU - 2024/3169 - EN - EUR-Lex)
3. Severens H, et al. Paving the road for a successful EU HTA Reform implementation. Glob Reg Health Technol Assess. 2025 Aug 29;12:194-197; 3a. Gazzetta n. 160 del 12 luglio 2025, AIFA Determina 9 luglio 2025 (https://www.quotidianosanita.it/allegati/allegato1752498628.pdf), **4.** The Draft Royal Decree on Health Technology Assessment (https://www.cuatrecasas.com/en/spain/life-sciences-healthcare/art/health-technology-assessment-royal-decree); **5.** Welcome to the Nordic collaboration JNHB (Joint Nordic HTA-Bodies); **6.** Directoratet for Medisinske Producter: EU- HTA regulation 18.06.2025 (https://www.nyemetoder.no/49dceb/siteassets/informasjonsmote-om-htar-18.-juni-2024---presentasjon-fra-dmp.pdf); **7.** Nieuwe werkwijze beoordeling van geneesmiddelen, 24.01.2025 (https://www.zorginstituutnederland.nl/documenten/2025/01/24/nieuwe-werkwijze-beoordeling-van-geneesmiddelen); **8.** BELGIAN GUIDELINES FOR ECONOMIC EVALUATIONS AND BUDGET IMPACT ANALYSES: THIRD EDITION. KCE REPORT 400. (https://kce.fgov.be/sites/default/files/2025-05/KCE400_Method_guidelines_economic_evaluations.pdf) 18 June 2025; **9.** CZECH REPUBLIC Recent and planned developments in pharmaceutical policies 2025(Czech Republic_Country_Poster_PPRI Lisbon_0.pdf); **10.** DZIENNIK USTAW RZECZYPOSPOLITEJ POLSKIEJ. Warszawa, dnia 28 sierpnia 2025 r. Poz. 1192 (z dnia 25 lipca 2025 r.). (https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20250001192/O/D20251192.pdf)

Want to learn more?
<< Scan Here