WORKSHOP REPORT

Navigating National Decision Making Post Joint Clinical Assessment (JCA): Enablers, Barriers and the Path Forward

27th November 2025
Renaissance Amsterdam Schiphol Airport Hotel, The Netherlands

Utrecht University

CIRS Centre for Innovation in Regulatory Science

Executive summary

Background

The implementation of Joint Clinical Assessment (JCA) under the EU Health Technology Assessment Regulation (HTAR) marked a significant evolution in the European health technology assessment (HTA) landscape. As of 2025, national HTA bodies and stakeholders have been actively adapting to a new era of collaborative clinical assessment for medicines. The aim is to reduce duplication, improve consistency, and enhance efficiency across Member States. However, the successful integration of JCA outputs into national decision-making pathways remains an evolving challenge.

In June 2024, CIRS conducted a multi-stakeholder workshop that brought together representatives from the European Medicines Agency (EMA), European Commission, EU HTA agencies, industry, patient groups, academics and payers. The workshop explored system readiness for JCA and focused on designing effective and efficient processes for JCA. A key outcome was the recognition that national-level adaptation strategies will be essential to fully realise the intended benefits of JCA. CIRS' annual metrics, which track the timing and outcomes of regulatory and HTA decisions across jurisdictions, provide a valuable baseline to monitor the impact of JCA on national access to new medicines. These data allow stakeholders to evaluate whether improvements in efficiency, alignment, and timeliness are being achieved, and where key gaps or misalignments remain.

Building on the insights from the 2024 workshop, this workshop looked more deeply at the challenges of post-JCA transition at the national level. It was co-developed with Utrecht University, combining CIRS' metrics research, tools, and policy insights with Utrecht's academic expertise in pharmaceutical policy, HTA methodology, and evidence-based decision making.

Workshop objectives

- Examine the role of HTA agencies in the JCA process — focusing on both process inputs and outcome outputs, as well as how agencies and companies are adapting their processes to integrate JCA outputs into decision making.
- Identify key challenges and capacity-building needs for effective JCA implementation, including resource constraints, methodological and timeline alignment, and stakeholder engagement.
- Facilitate multi-stakeholder discussions and develop recommendations, bringing together HTA agencies and industry to explore practical implementation of JCA outputs and identify actions to improve efficiency and alignment in national decision making.

GRAPHIC SUMMARY

Navigating National Decision Making Post Joint Clinical Assessment

A CIRS-Utrecht University workshop explored different stakeholders' early experiences of Joint Clinical Assessment (JCA), considering practical implementation of JCA outputs into national decision making.

Key learnings and recommendations

PICO coordination

- Developers require earlier and broader PICO discussions, with clearer communication of national needs.
- JCA reports should transparently reflect uncertainties, such as evidence gaps for informing specific PICOs and potential lack of robust or recent clinical trials.

EMA-HTA collaboration

- EMA shares major clinical objections with JCA subgroups without narrative commentary.
- Operational and evidence level collaboration will continue to be strengthened through workshops, daily coordination with the HTA Secretariat, and follow up work with the HTA Coordination Group.

Capacity building

- Maturing HTA agencies continue to strengthen internal JCA capability by leveraging external expertise and receiving Commission technical support to update national HTA processes and methods.
- HTA Regulation training and capacity building for all stakeholders should be implemented and regularly updated.

Feedback loops

- Systematic evaluation of early JCA experiences is needed to refine methods, guidance, and address challenges.
- Trust and transparent communication between stakeholders are key.
- CIRS research will continue to quantify timelines from regulatory approval to patient access.
- The official HTA Regulation evaluation by the Commission is expected by January 2028.

Key points from the plenary sessions

Session 1: Input into the JCA process

HTA agency perspectives

All JCA procedures begin with Population, Intervention, Comparator, and Outcomes (PICO) scoping, which can potentially generate multiple PICOs from Member States. The short timeline for PICO preparation is a common challenge across HTA agencies, putting pressure on internal resources and external stakeholder engagement.

The Dutch HTA agency's experience as a JCA co-assessor demonstrated the complexity of consolidating the lowest number of PICOs while still reflecting Member State needs. Consolidation involves distinguishing between "need to have" and "nice to have" Member State requirements through bilateral discussions on the online HTA platform. When it comes to deciding whether to be involved as a JCA assessor or co-assessor, the Dutch agency has found that this decision must occur much earlier than its national agenda-setting process.

Maturing HTA agencies continue to build their internal capacity and capability to facilitate implementation of JCA, leveraging external expertise through networks and partnerships. The Greek and Slovenian agencies secured technical support from the European Commission to strengthen their national HTA systems by updating processes and methods. In addition, evaluators from the Slovakian agency have participated in internships at the German agency (IQWIG).

Legislation changes have been necessary in several Member States to facilitate implementation of the HTA Regulation. For example, Spain, Greece, Slovenia and Slovakia have implemented or are undergoing legislative reform to align their HTA frameworks with the EU HTAR.

Another challenge for some HTA agencies has been lack of awareness of JCA among national decision makers. In Slovakia, this has necessitated emphasis on JCA reports' significance for broader EU project involvement.

Company perspectives

The delivery of each JCA has considerable financial implications for companies, alongside significant staffing and analytical demands. Cross-functional collaboration, particularly involving local affiliates, is key. The compressed timeline from final scope receipt to submission means there is insufficient time for companies to complete the intensive preparatory work required, including systematic literature reviews and indirect comparisons. Therefore, companies must 'over-predict' PICOs, increasing workload, and be prepared to quickly pivot their evidence compilation strategy once the final scope is received. Timely sharing of national PICOs helps companies to prepare their national submissions more efficiently and effectively.

Utilisation patterns of JCA outputs so far suggest that not every Member State uses all the extensive analyses conducted, raising efficiency concerns. Nevertheless, the potential to accelerate decision making and reduce duplication offers significant long-term benefits for EU patient access.

Patient perspectives

Early experiences of patient involvement in JCA processes highlighted insufficient guidance to engage effectively and a lack of transparent feedback loops. While progress is being achieved through stakeholder collaboration, there must be systematic integration of patient input at relevant JCA stages from PICO definition to final JCA reports. Capacity building, transparent communication and monitoring progress are key.

Clinician perspectives

Continued collaboration between clinical societies, regulators and HTA agencies offers opportunities for improved evidence evaluation and decision-making processes. For example, The European Society of Medical Oncology (ESMO) developed the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) to address concerns about differential cancer drug access across Europe and globally. It provides clinical perspective on evidence assessment, facilitating discussions about meaningful effect sizes whilst adapting to evolving regulatory and HTA landscapes.

Role of the EMA

While maintaining clear separation of regulatory and HTA remits, the European Medicines Agency (EMA) and HTA Secretariat closely collaborate at operational and evidence levels. Three key operational areas require ongoing attention: notification processes, timeline communication, and question sharing during centralised procedures. A joint position paper published in April 2025 provides recommendations to developers to address evidence challenges and manage uncertainties.

EMA shares major clinical objections with JCA subgroups without narrative or commentary whilst providing relevant information for PICO impact assessment. This process is expected to undergo review in 2026.

Planned initiatives include continued operational collaboration through regular workshops and daily coordination with the HTA Secretariat. Evidence-level collaboration will build on the April 2025 position paper and other initiatives, working with the HTA Coordination Group (CG) and Subgroups to enhance EU-level success in evidence development and evaluation.

Session 2: Output from the JCA process into national decision making

Company perspectives

A key challenge for industry lies in understanding how JCAs will be implemented at the national level. Company mapping exercises are assessing local HTA preparations such as legal reforms, dossier adaptation, visibility of PICOs, timelines, and inclusion of local stakeholders in JCA processes. The landscape remains highly fragmented, with countries at different preparation stages and varying levels of clarity regarding JCA integration into national frameworks.

Success of the JCA requires not only high-quality European procedures, dossiers, and outputs, but also clear, predictable national implementation pathways. Trust and transparent communication between industry and HTA agencies is key.

Agency perspectives

Various HTA agencies shared how they intend to integrate JCA outputs into their national decision-making processes. For example, in the Netherlands, the JCA report will be the starting point for national appraisal, and a shortened effectiveness report will be produced referencing the JCA PICO chapter. Belgium has mandated combining JCA outputs with national assessments in a single bilingual report, with consideration of added therapeutic value assessments from France and the Netherlands, when available. The Beneluxa partnership presents opportunities for informal exchange during JCA processes and enhanced collaboration in post-JCA national procedures.

Because JCA represents only a small component of Norway's overall assessment process—which includes comprehensive cost-utility analyses—it may be less impactful than in countries that conduct clinical benefit

assessments, such as France and Germany. This variation stems from the different types of uncertainty each HTA system addresses and the extent to which JCA outputs align with national requirements.

For those countries that perform comprehensive cost-utility analyses, the limitations of JCA outputs relative to comprehensive economic evaluations may raise questions about resource allocation and opportunity costs. Success will depend on developing complementary processes that maximise JCA value whilst acknowledging the substantial additional work required at national levels.

There are concerns that JCA reports could become outdated for countries where market launches can be delayed for years following EMA approval, such as in Eastern Europe. Furthermore, in rapidly moving therapeutic areas like oncology, national HTA processes may require the latest clinical data, potentially limiting the relevance of JCA reports.

Session 3: Ensuring a future proof HTA landscape in Europe and beyond

In the final session of the workshop, a multi-stakeholder panel reflected on the transformative nature of the HTA Regulation, positioning it within broader healthcare policy evolution in Europe and worldwide.

The current EU landscape presents significant change and opportunity through multiple regulatory initiatives including the pharmaceutical reform, targeted evaluation of the Medical Devices Regulation, and Critical Medicines Act. The EU HTA Regulation has elevated HTA to higher prominence within the wider healthcare ecosystem, and JCA should be viewed as part of addressing healthcare sustainability challenges. Building trust and learning through experience are essential. Official evaluation of the HTA Regulation will be shared by the European Commission by January 2028.

For companies, JCA requires significant investment and unprecedented coordination for global market access, demanding new approaches to evidence generation, submission preparation, and stakeholder engagement across multiple jurisdictions simultaneously. To ensure success, approaches to evidence evaluation must be flexible, and company-agency interactions during JCA need to shift from information exchange to active dialogue.

Consideration is being given for how JCA outputs can be leveraged beyond the EU. For example, the UK National Institute for Health and Care Excellence (NICE) envisages the JCA report (if available) being a key literature component in its evaluations. International collaboration remains key to addressing HTA methodological issues, beyond JCA.

European payers recognise the potential benefits of JCA but remain focused on maintaining national decision-making capabilities and ensuring healthcare system sustainability. The intense pressure on public budgets, combined with competing policy priorities and political pressures, creates an environment where HTA's future depends on demonstrating clear value in guiding wise investment decisions.

Recommendations from the breakout discussions

Navigating national HTA processes in the context of JCA

- The HTA CG and industry should work together to conduct practical workshops sharing learnings of the JCA process and define future training for industry.
    - Questions remain about commercial sensitivity limitations and implementation timing whilst procedures continue.
- Industry should implement policy changes internally to enhance processes and collaboration, such as improving communication between regulatory and HTA departments and leveraging expertise from national affiliates.
- CIRS should explore the impact of JCA at the EU level, globally, and on clinical guidelines.
- Research is needed to evaluate whether the availability of national PICOs is timely enough for national submissions.

Methodological alignment between JCA and national processes

- HTA agencies could work more closely together to align and enhance guidance on interpreting evidence from subpopulations or small patient populations.
- HTA agencies should consider how to enhance communication on PICOs. An option could be to broaden the remit of PICO explanation meetings and have them earlier in the process.
- HTA agencies should aim for the published JCA report to provide sufficient detail on the uncertainties, such as evidence gaps for informing specific PICOs and the potential lack of robust or recent clinical trials.
- Companies and HTA agencies should collect lived experiences of using the JCA guidance issued by the HTA CG – are all stakeholders using the same language and interpretation?
- All stakeholders should reflect on JCA methodological learnings after the first four or five JCAs have been completed.

Stakeholder collaboration for effective JCA implementation

- The European Commission and HTA Stakeholder Network should implement and continuously update training and capacity building activities on the HTA Regulation for all stakeholders.
- CIRS should conduct research into how best to measure timelines from regulatory approval to patient access (e.g. prescriptions), so that the impact of JCA and national decision making can be quantified.
- Research is needed to track the evolution of human resource available in national HTA agencies for JCA and Joint Scientific Consultation (JSC) activities.

Workshop programme

Session 1: Input into the JCA Process: Learnings from National HTA Agencies and Companies	
08:50	**Chair's welcome and introduction – Prof Wim Goettsch,** Professor HTA of Pharmaceuticals, WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht University, The Netherlands
09:00	**Year one of JCA - Reflections from national HTA agencies** **Dr Lisette Vernooij,** Senior Advisor, European JCA of Medicinal Products, National Health Care Institute, The Netherlands **Dr Tomas Tesar,** Director, National Institute for Value and Technologies in Healthcare, Slovakia **Prof Flora Bacopoulou,** Head, HTA Committee, Ministry of Health, Greece
09:30	**Discussion**
09:45	**Aligning for preparation: Industry's consideration on internal coordination, preparation and readiness for JCA submission** **James Ryan**, Director, Global HTA Policy, HTA and Modelling Science, AstraZeneca, UK
10:00	**Discussion**
10:15	**Panel discussion: Reflections on future optimisation: What areas require better coordination, enhanced collaboration and iterative learnings from stakeholders?** **EMA perspective**: **Dr Michael Berntgen**, Head of Scientific Evidence Generation Department, EMA **HTA agency perspective: Belén Torres Garrido**, Therapeutic Positioning Report and Health Technology Assessment Area at Medicines for Human Use Department, AEMPS, Spain **Patient perspective: Antonella Cardone**, CEO, Cancer Patients Europe, Belgium **Clinician perspective: Prof Elisabeth de Vries**, European Society for Medical Oncology (ESMO)
11:00	**Break**
Session 2: Output from JCA Process into National Decision Making: Processes, Methodologies and Strategic Considerations	
11:30	**What can the EU HTAR Learn from the EMA's path to harmonisation?** **Francine Brinkhuis,** PhD Candidate, Utrecht University
11:40	**Discussion**
11:45	**Utilising JCA output for jurisdictional submission, adjusting submission strategies for timely local market access - What are the considerations from industry?** **Eelko Den Breejen**, Senior Director, Global Access & Value, Head of Oncology Portfolio & Market Engagement Team, Pfizer, The Netherlands
11:55	**Discussion**
12:00	**National HTA development and capacity building to operationalise JCA outputs** **Dr Katarina Beravs Bervar**, HTA Unit, Ministry of Health, Slovenia
12:10	**Aligning JCA clinical outputs with cost-effectiveness and methodological criteria** **Dr Anja Schiel,** Senior Adviser; Lead Methodologist in Regulatory and Pharmacoeconomic Statistics, NOMA, Norway
12:20	**What are the impacts and implications of national payer in the context of JCA uptake?** **Dr Marc Van de Casteele,** Chair Domain Task Force HTA Beneluxa, Coordinator HTA Pharmaceuticals, Belgian Health Care Institute (RIZIV-INAMI)
12:30	**Discussion**
12:55	**Introduction to the breakout session – Dr Neil McAuslane,** Scientific Director, CIRS
13:00	**Lunch**

Session 3: Breakout discussions	
13:45	**Breakout A: Navigating National HTA Processes in the Context of JCA** *How jurisdictions are adapting timelines, procedures, and resources to align with JCA while preserving national priorities* **Chair: Niklas Hedberg,** Chief Pharmacist, TLV, Sweden and co-chair of the EU HTAR CG **Rapporteur: Anne Willemsen**, Co-Chair of the HTA Subgroup on JCA, and Senior Advisor, National Health Care Institute, The Netherlands **Breakout B: Bridging Methodological Differences: From JCA to National Application** *Exploring challenges and solutions for methodological alignment, including PICO adaptation and post-JCA national assessments* **Chair: Dr Christine Leopold,** Assistant Professor of Drug Regulatory Science, Utrecht University **Rapporteur: Dr Antonia Morga,** Head, New Product Planning, Global Value Evidence, Medical Affairs, Astellas Pharma Europe Ltd **Breakout C: Collaboration for Effective JCA Implementation** *Engaging agencies, companies, clinicians, patients, and payers to support coordinated and transparent decision making* **Chair: François Houÿez**, Director of Treatment Information and Access, EURORDIS – Rare Diseases Europe, France **Rapporteur: Dr Peter Pemberton-Ross**, Head, HE & HTA Strategy, Biogen, Switzerland
13:45	**Break**
16:10	**Feedback from breakout discussions**
16:30	**Panel discussion: Ensuring a future-proof HTA landscape to enable patient access to innovative medicines** *Leveraging horizon scanning, early scientific advice, and collaborative thinking in Europe and beyond* **Agency perspective**: **Dr Nick Crabb**, Chief Scientific Officer, NICE, UK **Industry perspective**: **Shane Kavanagh**, Vice President Johnson & Johnson, Belgium **Policy perspective**: **Maya Matthews**, Head of Unit Health Technology Assessment, implementing the EU HTA regulation, European Commission **Payer perspective**: **Yannis Natsis**, Director, European Social Insurance Platform (ESIP) - European Health Forum Gastein Board member
17:30	**Next steps and close of meeting**

Session summaries

Please note that the following summaries represent the views of the individual presenters and do not necessarily represent the position of the organisation they are affiliated with. Included slides are attributed to the individual presenters and have been reproduced with their permission.

Session 1: Input into the JCA Process: Learnings from National HTA Agencies and Companies

Year one of JCA - Reflections from the Dutch HTA agency

Dr Lisette Vernooij, Senior Advisor, European JCA of Medicinal Products, National Health Care Institute, The Netherlands

Introduction to the Dutch HTA system

The National Health Care Institute (ZIN) is an independent governmental body with various responsibilities, including managing the basic healthcare package through HTA and appraisals. There are four package criteria for health technology evaluation. The effectiveness criterion serves as the primary 'knockout' criterion, requiring new technologies to demonstrate equal or superior effectiveness compared to standard treatment for reimbursement consideration. Following positive effectiveness assessment, three additional criteria are evaluated: necessity, cost-effectiveness, and feasibility. The EU JCA contributes to the effectiveness component of this framework, specifically the established medical science and medical practice assessment.

National PICO scoping

Upon the start of a JCA, national PICO (Population, Intervention, Comparator and Outcome) scoping takes place. In the Netherlands, national PICOs are primarily defined based on national clinical guidelines, with input from patient and clinical experts recruited through patient organisations and clinical societies, respectively. Confidentiality agreements are essential during this consultation process.

All Member States have the opportunity to express their national PICO requirements through the EU PICO survey. PICO consolidation is then carried out by the JCA assessor and co-assessor.

Experience as an assessor

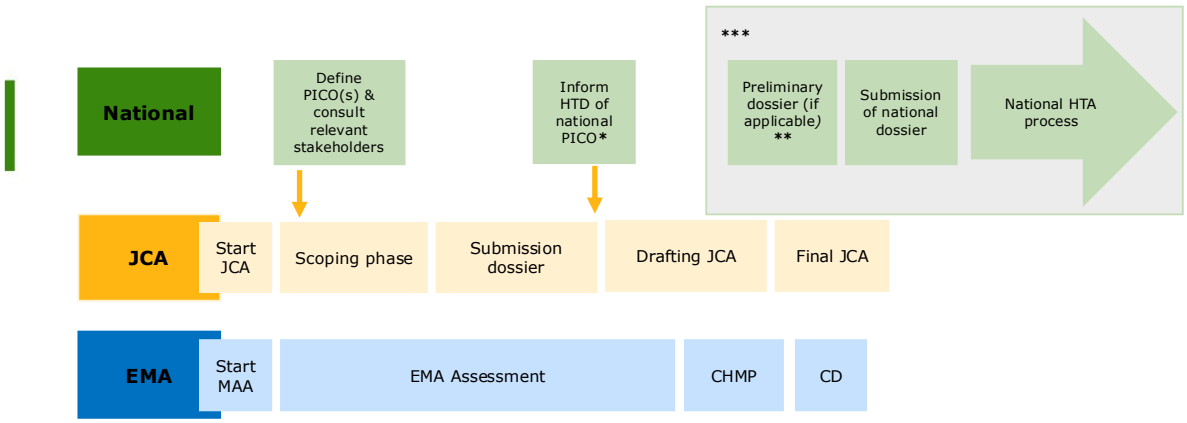
ZIN's experience as a JCA assessor on a product for bladder cancer demonstrates the complexity of consolidating the lowest number of PICOs while still reflecting Member State needs. Consolidation involves distinguishing between "need to have" and "nice to have" Member State requirements through bilateral discussions on the online HTA platform.

When it comes to deciding whether to be involved as a JCA assessor or co-assessor, ZIN has found that this decision must occur much earlier than its national agenda-setting process. ZIN can only take on an assessor role for certain medicinal products, such as high-cost hospital pharmaceuticals with high budget impact (i.e. pharmaceuticals in the 'lock procedure'). Therefore, ZIN must gauge, at an early stage, whether a product is likely to be within its scope.

National implementation of JCA outputs

EU law mandates due consideration of JCA reports, therefore national appraisal commences only after JCA report publication. However, preliminary national dossiers may be submitted following positive CHMP opinions to accelerate timelines (see figure below).

National reimbursement dossiers remain necessary for the assessment of all package criteria. ZIN will produce shortened assessment reports referencing relevant JCA PICO chapters, whilst outlining therapeutic value conclusions and reimbursement advice.



Abbreviations: EMA=European Medicines Agency; CHMP=Committee for Human use of Medicinal Products; CD=Commission Decision on Marketing Authorization; HTD=Health Technology Developer, JCA=Joint Clinical Assessment; MAA=Marketing Authorization Application; PICO= Patient, Intervention, Comparator(s) and Outcome(s);
*: only upon request by the HTD
**: may include a renewed national scoping, this may especially be relevant when the HTD submits much later as the treatment landscape could have changed
***: it should be noted that this figure presents the earliest timepoints possible for these steps, however, the exact timelines will depend on the national submission by the HTDs.

Willemsen A, Rutten-van Mölken M, Al Dulaimi R, Schelleman H, Goettsch W, Timmers L. Preparing for the EU HTA Regulation: Insights from the Dutch Perspective. *J Mark Access Health Policy*. 2025;13(3):35. Published 2025 Jul 24. doi:10.3390/jmahp13030035

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Implementation challenges

Key challenges include short PICO scoping timelines and earlier decision-making requirements compared to national horizon scanning processes (Willemsen et al. 2025). In addition, there is a potential risk that the national scope may require alterations following publication of the JCA report; this is dependent on indication changes, launch strategies, therapeutic landscape evolution, or data availability changes.

Conclusion

The Dutch implementation of JCA demonstrates pragmatic adaptation whilst maintaining national assessment frameworks. The JCA offers opportunities for process acceleration, improved evidence quality, and reduced duplication across Member States. Nevertheless, timeline management remains a challenge, suggesting that successful implementation of JCA requires careful balance between European coordination and national decision-making needs.

Year one of JCA - Reflections from the Slovakian HTA agency

Prof Tomas Tesar, Head, National Institute for Value and Technologies in Healthcare, Slovakia

Introduction to the Slovakian agency

The National Institute for Value and Technology in Healthcare (NIHO) was established in 2022 as Slovakia's independent national HTA agency. Its role is to bring transparency to decision making in the field of health, especially in the reimbursement decision of new technologies (mainly medicines and medical devices). NIHO has actively contributed to JCA evaluations by developing and reviewing guidelines, regularly attending meetings of JCA subgroups, participating in PICO surveys, and collaborating with the Germany agency, IQWIG, on preparing a JCA report.

JCA challenges and solutions

NIHO faced significant capacity challenges during the first JCA, due to a shortage of analysts and the substantial workload required from national processes. Changes to internal procedures and new HTA guidelines have since been implemented. In addition, to help enhance capability within NIHO, two evaluators participated in internships at IQWIG.

Another challenge was limited awareness of JCA among national decision makers. This necessitated emphasis on JCA reports' significance for broader EU project involvement e.g. ASCERTAIN and EU4MEDTECH projects.

New methodological guidelines

New HTA methodological guidelines for Slovakia were developed and presented in September 2025, representing a crucial step in JCA implementation. These guidelines have been integrated into Slovak legislation, establishing that applicants need not submit data already provided through JCA frameworks, with JCA reports forming the basis for national decisions under a special regulation.

Regional market access delays

Market launches in Central and Eastern Europe can be delayed for years following EMA marketing authorisation (see right, examples from Slovakia). This raises critical questions about the utility of JCA reports for these countries, as PICOs may no longer be relevant.

Will PICO still be relevant after two, three or five years from the authorization of the medicine by the European Commission for Central and Eastern Europe countries?

NIHO Národný inštitút pre hodnotu a technológie v zdravotníctve

Example from Slovakia:

Name of medicinal products	Therapeutic area	Marketing authorisation issued	Submitted application for reimbursement from public health insurance
Voxzogo	Achondroplasia	26.08.2021	30.07.2024
Trodelvy	Breast Neoplasms	22.11.2021	31.07.2023
Zolgensma	Muscular Atrophy, Spinal	18.05.2020	31.10.2022

Conclusion

Slovakia's experience illustrates the opportunities and challenges facing newer HTA agencies in implementing JCA. Whilst progress has been achieved in capacity building and legislative alignment, regional market access delays raise concerns about the utility of JCA reports for Central and Eastern European contexts.

Year one of JCA - Reflections from the Greek HTA Committee

Professor Flora Bacopoulou, Head, HTA Committee, Ministry of Health, Greece

Introduction to the Greek HTA system

The Greek HTA Committee, launched in 2018, operates under the Ministry of Health's oversight, alongside a Negotiation Committee for medicinal products. The HTA Committee has 11 members, a legal counsellor, and approximately 100 external experts (mainly doctors and pharmacists).

Technical Instrument Support initiative

Greece secured Technical Instrument Support (TSI) from the European Commission in 2024, collaborating with the World Health Organisation (WHO) and the Greek Ministry of Health to strengthen the national HTA system and build capacity for implementation of the EU HTA Regulation (HTAR). The initiative aims to ensure access to innovative and cost-effective health technologies through improved HTA processes and methods.

The TSI initiative in Greece followed a structured three-phase approach:

1. Situation analysis to understand alignment and identify gaps between the Greek HTA system and HTAR.
2. Development of HTA guidance on methods and processes, informed by situation analysis, stakeholder input, and insights from other HTA agencies.
3. Pilot testing of the new draft guidance and refinement based on practical experience (ongoing).

Building capacity and capability

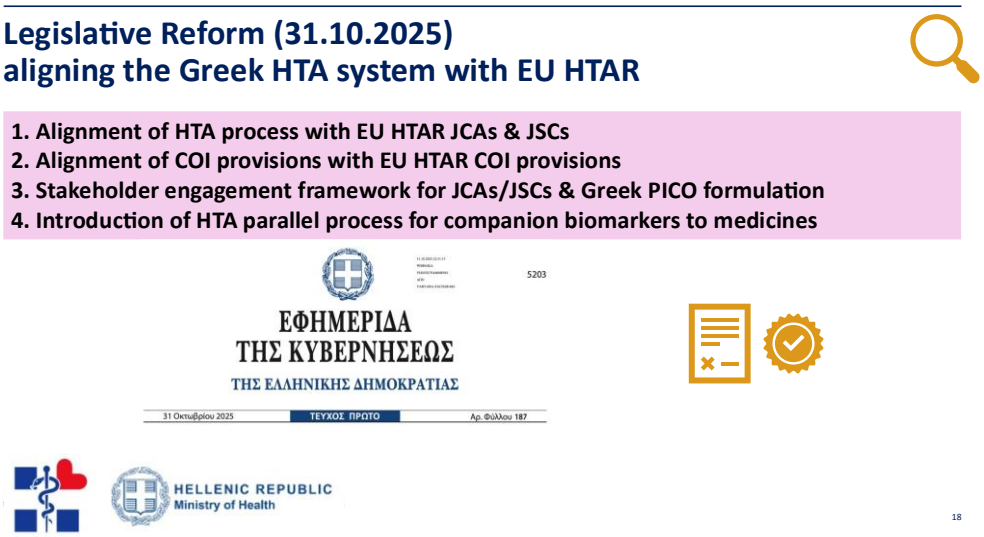
Greek assessors have participated in various HTA training sessions, for example, on the PICO framework, clinical assessment and economic assessment. They have also visited and met virtually with experienced HTA agencies including AIFA (Italy), AGENAS (Italy), HAS (France), and INFARMED (Portugal), providing practical learning opportunities from established HTA systems.

Legislative reforms

Legislative reforms in October 2025 achieved partial alignment of Greek HTA processes with European requirements for JCA and JSC (see below). Key achievements include alignment of conflict-of-interest frameworks with European standards, development of stakeholder engagement frameworks, and introduction of HTA procedures for companion biomarkers to medicines.

Next steps

Greece will continue building national capacity for assessors, co-assessors, and experts to support the centralised JCA and JSC procedures. Representatives from national member organisations (primarily universities) will be nominated to participate in subgroups of the Member State Coordination Group on HTA, pending approval from the HTA Secretariat and European Commission. A two-year fellowship programme for HTA in medicinal products and medical devices has received initial approval from the National and Kapodistrian University of Athens Medical School, with implementation planned for 2026 or 2027.



Conclusion

Greece demonstrates comprehensive preparation for HTAR implementation through structured capacity building, HTA method and process refinement, legislative alignment, and stakeholder engagement. The Technical Support Instrument initiative was key to enhancing Greece's HTA system, establishing foundations for European HTA collaboration and continued national capacity-building efforts.

Industry's considerations for internal coordination, preparation and readiness for JCA submission

James Ryan, Director, Global HTA Policy, HTA and Modelling Science, AstraZeneca, UK

AstraZeneca developed a comprehensive "5P approach" to JCA, encompassing planning, partnering, predicting, producing, and pull-through phases.

Planning for JCA

Planning commenced in 2021 with senior leadership engagement across R&D, commercial, and local affiliate functions, recognising the significant organisational change and investment required for successful JCA implementation. New capabilities were developed, for example, in German and French teams for clinical assessment expertise, whilst other countries required training in cost-effectiveness methodologies. Project management skills and patient experience data expertise, particularly in patient-reported outcomes, were also expanded.

Partnering across functions

JCA demands extensive internal collaboration across HEOR, regulatory affairs, EU local affiliates, clinical, patient experience science, biometrics, statistics and programming, medical affairs, market access, and commercial teams. Regulatory has emerged as a key partner to HEOR, given the regulatory-HTA alignment required for JCA processes.

Predicting PICOs

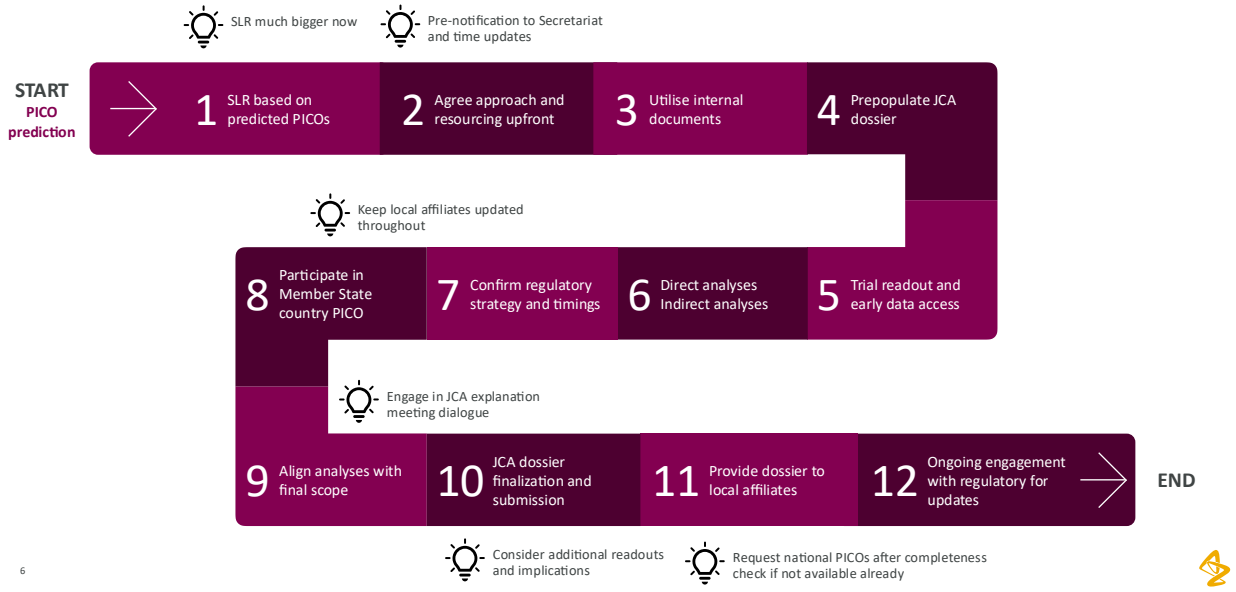
The compressed timeline from final Population Intervention, Comparator, and Outcomes (PICO) scope receipt to submissions means there is insufficient time for companies to complete the intensive preparatory work required, including systematic literature reviews and indirect comparisons. Therefore, companies must 'over-predict' PICOs, increasing workload, and be prepared to quickly pivot their evidence compilation strategy once the final scope is received.

PICO prediction employs evidence-based approaches considering claimed indications, clinical trials, clinical guidelines, clinical practice, regulatory information, and HTA decision patterns. Once consolidated, PICOs are then validated with local affiliates, clinical input, and real-world evidence analysis.

Producing JCA submissions

The final PICOs inform the scope of the systematic literature review (SLR) search and subsequent indirect comparisons (see below). The SLR scope for JCA submissions is much bigger due to over prediction of PICOs, extracting substantially more data than for non-JCA submissions. Parallel statistical teams support global regulatory submissions, requiring senior leadership commitment during critical regulatory phases.

4. Produce – our recipe to success



Pull-through from JCA to national decision making

Internal collaboration with local affiliates is essential, requiring early engagement, continuous updates and transparency regarding European submissions. Timely sharing of national PICOs by agencies helps improve the efficiency and effectiveness of national dossier preparation.

Utilisation patterns of JCA outputs so far suggest that not every Member State uses all the extensive analyses conducted, raising efficiency concerns. Furthermore, in rapidly moving therapeutic areas like oncology, national HTA processes may require the latest clinical data, potentially limiting the relevance of JCA reports.

Conclusion

The delivery of each JCA has considerable financial implications for companies, estimated to range from 0.5-1.0 million dollars per JCA, alongside significant staffing and analytical demands. Cross-functional collaboration, particularly involving local affiliates, is key. Whilst utilisation patterns of JCA outputs so far raise efficiency concerns, the potential for accelerated decision making and reduced duplication offers significant long-term benefits for patient access across Europe.

Panel discussion: Reflections on future optimisation of JCA processes

European Medicines Agency (EMA) perspective

Dr Michael Berntgen, Head of Scientific Evidence Generation Department, EMA

While maintaining clear separation of regulatory and HTA remits, the EMA and HTA Secretariat closely collaborate at operational and evidence levels, with daily contact on various HTAR implementation aspects.

Operational collaboration

Three key operational areas require ongoing attention: notification processes, timeline communication, and question sharing during the Centralised Procedure. Company awareness of notification processes is improving, with trade associations playing an important role. Timeline predictability remains complex due to variable assessment durations based on applicant response times and question complexity.

The EMA shares clinical major objections with JCA subgroups without narrative or commentary, whilst providing relevant information for PICO impact assessment. This process is expected to undergo review in 2026 to evaluate its usefulness versus administrative burden.

Communication alignment between the EMA, HTA Coordination Group and European Commission is key to ensuring coordinated public information release and consistency in European-level reporting.

Evidence collaboration

A joint EMA-HTA position paper published in April 2025 provides recommendations to developers to address evidence challenges and manage uncertainties. Collaborative workshops addressing technical topics, such as external controls and disease-specific registries, are open to payers as well as HTA bodies.

Future collaboration opportunities

Planned initiatives include continued operational collaboration through regular workshops and coordination with the HTA Secretariat. Evidence-level collaboration will build on the April 2025 position paper and other initiatives, working with the HTA Coordination Group and subgroups to enhance European-level success in evidence development and evaluation.

Research on the impact of regulatory decisions

The EMA recently conducted research on products addressing unmet medical needs through conditional marketing authorisation and/or PRIME designation, analysing regulatory decisions against national access outcomes. This research aims to understand the downstream impact of regulatory decisions, which could inform potential benchmarks for future JCA process evaluation.

Conclusion

EMA's role in JCA implementation focuses on maintaining an effective regulatory-HTA interface while supporting evidence development and operational coordination. The collaborative approach emphasises learning through experience at the same time as maintaining appropriate separation of regulatory and HTA remits, contributing to the success of HTAR.

HTA agency perspective

Belén Torres Garrido, Therapeutic Positioning Report and HTA Area, Medicines for Human Use Department, Spanish Agency of Medicines and Medical Devices (AEMPS), Spain

Background

Since 2013, AEMPS has developed therapeutic positioning reports as a tool for Ministry of Health negotiations. These national HTA reports focus on clinical assessment of safety and efficacy, whilst the 17 regions maintain competencies for regional-level access decisions. On the European level, AEMPS has participated in EUnetHTA21 since 2016 and actively engaged in HTA Regulation (HTAR) preparation through the Comitology Committee, HTA Coordination Group, and its subgroups.

JCA scoping challenges

The JCA PICO scoping process involves development of the assessment scope by assessors and co-assessors, followed by Member State PICO survey responses and consolidation by European assessors. Timeline pressures are notable, with standard procedures allowing 14 days for European assessment scope proposals and 21 days for Member State responses, whilst accelerated procedures reduce these to seven and 14 days respectively.

It became apparent early on in 2025 that Member States need the following information for national consultations during the scoping process: therapeutic area, medicinal product names, active substance, and claimed therapeutic indications. In addition, some Member States may need to share the frequency or mode of administration of the medical product. Therefore, confidentiality agreements are required between national HTA agencies and the external stakeholders they are consulting.

Stakeholder engagement process

Building on existing stakeholder relationships, AEMPS contacts patient organisations and medical societies in parallel to JCA process initiation. Confidentiality agreements and conflict-of-interest statements enable information sharing and expert identification. Patient and clinical experts complete questionnaires based on EUnetHTA21 frameworks, providing feedback for the national response to the European PICO survey.

Legislative developments

Spain receives support through the Technical Support Instrument initiative managed by the European Commission to implement HTAR. A Royal Decree for HTA is in progress, having undergone consultation in 2024. This new legislation sets out the national HTA framework, including responsibilities of the different bodies and collaboration with different stakeholders.

Conclusion

The HTAR presents opportunities for single market improvement, innovation stimulation, and Member State assistance in maintaining sustainable healthcare systems. Spain continues to implement HTAR systematically through established national processes, active European participation, and ongoing legislative development.

Patient organisation perspective

Antonella Cardone, CEO, Cancer Patients Europe, Belgium

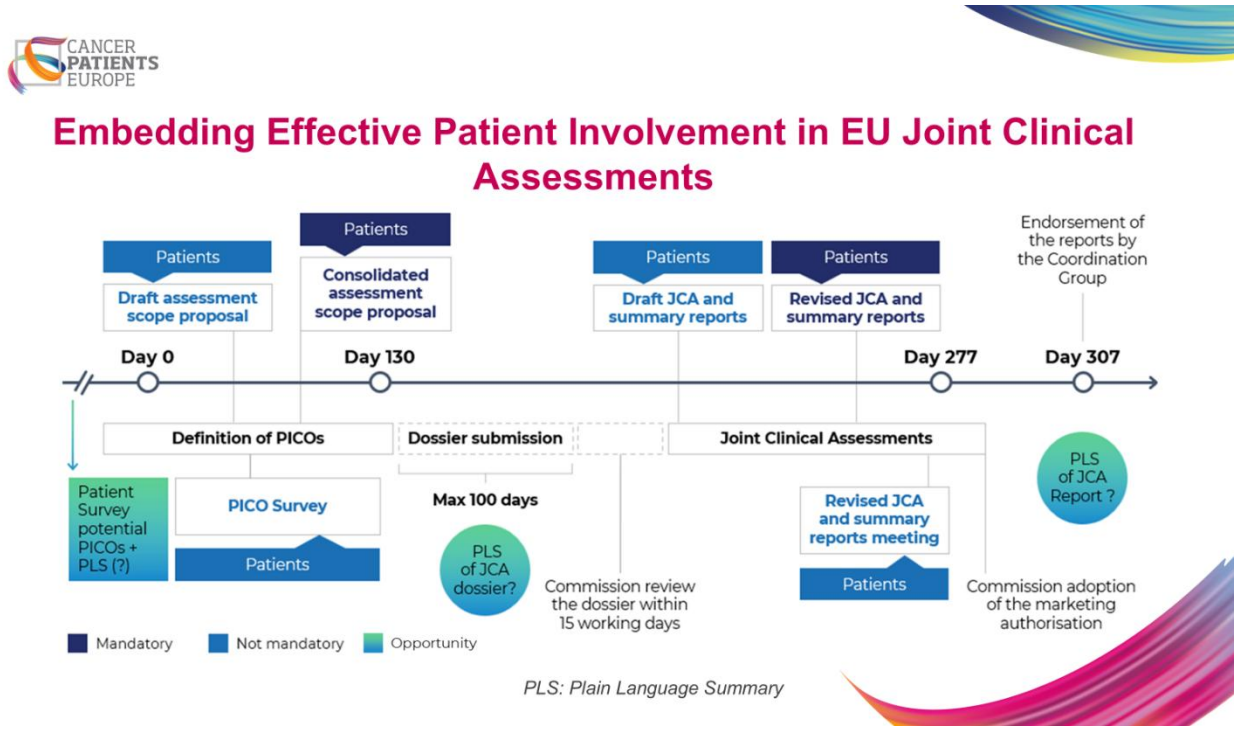
Cancer Patients Europe has played a key role in preparing patients for the HTA Regulation through various activities including webinars and parliamentary events, some in collaboration with other patient organisations. In addition, Cancer Patients Europe co-leads two projects under the HTA International Patient and Citizen Involvement Interest Group: plain language summaries facilitating patient involvement, and supporting patient input in JCA processes.

Experience of JCA participation

As part of the EU HTA Stakeholder Network, Cancer Patients Europe works closely with the European Commission to identify patient experts for JSC and JCA processes. Cancer Patients Europe has participated in three requests and nominated 28 patients, with five or six recruited as of October 2025. Survey and focus group feedback highlighted insufficient guidance for effective patient engagement during JSC and JCA, including a lack of clear explanations of the HTA process, PICOs, and national contexts. While this issue is being addressed thanks to open dialogue with the European Commission and HTA Secretariat, there remains a need for more predictable information on how patients' input is used in JCA.

Systematic patient involvement in JCA

Patient input should be integrated systematically at relevant JCA stages, from the definition of PICOs to final reports (see below). Patient PICO input at the very beginning, before draft assessment scope proposal, is key to ensuring patient perspectives inform EU-level decision-making processes.



Remaining challenges

Key challenges to patient involvement in JCA include misalignment of patient input in PICOs across Member States, lack of transparent feedback loops for patient recruitment and participation, and ad hoc training approaches. In addition, there can be silos between company patient engagement functions and HTA teams, creating delays and missed opportunities. Early company engagement with patient organisations is essential, particularly for informing societal impact assessment and indirect cost evaluation.

Conclusion

Early experiences of patient involvement in JCA processes highlighted insufficient guidance for patients to engage effectively and a lack of transparent feedback loops. While progress is being achieved through stakeholder collaboration, there must be systematic integration of patient input in JCA, particularly early on when PICOs are being defined. Capacity building, transparent communication, and monitoring progress, are key to optimising patient involvement in JCA.

Clinical society perspective

Prof Elisabeth de Vries, European Society for Medical Oncology (ESMO)

ESMO Magnitude of Clinical Benefit Scale

The ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) was developed to address concerns about differential cancer drug access across Europe and globally. It assesses clinical benefit in both curative and non-curative settings, focusing on survival, toxicity, and quality of life.

Concerns about evidence quality

Over 50% of non-curative setting studies scored since 2017 do not achieve substantial benefit scores, whilst approximately 30% of recently approved drugs rely on single-arm studies. These trends create significant challenges and uncertainties for decision making in both regulatory and HTA contexts.

Practical application

The ESMO-MCBS demonstrates practical utility through multiple applications:

- Pharmaceutical companies are using the tool during trial design to optimise for substantial benefit achievement and facilitate evidence development planning.
- ESMO includes the MCBS scores in its clinical guidelines.
- Multiple HTA bodies globally consider the MCBS in their assessments.

Comparative analysis

ESMO is currently comparing ESMO-MCBS scores with national HTA body decision making across several European countries, examining differences and learning opportunities for mutual benefit. A similar analysis of post-JCA decisions is planned, recognising differences between individual trial assessment (which is the focus of the ESMO-MCBS) and comprehensive HTA decisions incorporating multiple European comparators.

Conclusion

The ESMO-MCBS tool provides valuable clinical perspective on evidence assessment, facilitating discussions about meaningful effect sizes whilst adapting to evolving regulatory and HTA landscapes. Continued collaboration between clinical societies, regulators, and HTA agencies offers opportunities for improved evidence evaluation and decision-making processes.

Session 2: Output from JCA Process into National Decision Making: Processes, Methodologies and Strategic Considerations

What can the EU HTA Regulation learn from the EMA's path to harmonisation?

Academic perspective

Francine Brinkhuis, PhD student, Utrecht University, and Pharmacotherapeutic Assessor, National Healthcare Institute, The Netherlands

Study background and methodology

A comprehensive study was conducted comparing the historical and policy developments of harmonising EU medicines regulation and HTA in Europe, which led to the EMA and the EU HTA Regulation (HTAR), respectively. The research employed a two-step approach: a narrative literature review focusing on EMA and EU-HTAR developments, followed by five focus group sessions with policy and regulatory experts to gather stakeholder insights on EMA's evolution and draw comparisons with the HTAR.

Historical overview

The EU medicines regulation journey began in the 1960s, triggered by safety concerns that highlighted gaps in pre-market evaluation. Key milestones included the 1965 marketing authorisation legislation, the 1975 multi-state procedure introduction, and ultimately the establishment of the EMA in 1995. In contrast, EU HTA collaboration began in the 1990s with several voluntary projects, progressed through EUnetHTA initiatives, and culminated in the adoption of the HTAR in 2021, after approximately 30 years of development.

Similarities and differences

Both the EMA and HTAR aim to reduce duplication and centralise clinical assessments, involving broadly similar stakeholders and employing dual co-assessor models. However, several differences exist: EMA has decades more experience, operates in a different geopolitical context, issues binding decisions rather than recommendations, relies on industry fees rather than public funding, and functions as a formal agency rather than a collaborative framework.

Key lessons for HTAR

Acknowledging and leveraging national diversity

Three critical lessons for HTAR emerged from EMA's experience. First, acknowledging and leveraging national diversity is essential, as harmonisation inevitably creates tension with national autonomy. The JCA's "due consideration" approach allows for national interpretation, so uptake will inevitably vary across Member States. Differences in Member State experience and maturity should be viewed as strengths rather than obstacles to overcome.

Trust as critical infrastructure

Secondly, trust enables collaboration, though the development of trust requires time and cannot be enforced. Experience from the EMA shows that trust can be improved through effective communication, shared platforms, and mutual recognition of differences.

Iterative learning and feedback loops

Both the EMA and HTAR started with phased scope implementation, allowing gradual uptake and learning from early cases. The ability to critically assess and adjust procedures through iterative learning, as demonstrated by EMA, is crucial for building an efficient joint system.

Conclusion

The HTAR is following a similar harmonisation journey to EU medicines regulation, but currently at an earlier stage. The EMA's experience shows that leveraging national diversity, building trust, and iterative learning, are key. Success of HTAR may require the EU HTA community to embrace a dual role as both enabler of access to effective treatments and protector from ineffective ones, combining scientific excellence with timeliness, partnership, and openness.

Conclusion

- EU medicines regulation evolved from fragmented national systems to a centralized framework, balancing EU oversight and national autonomy.
- EU HTA is on a similar journey, with MS maintaining authority over value judgments and reimbursement.
- The EMA's experience shows that leveraging **national diversity**, **building trust**, and **iterative learning** are key.
- Challenges remain, such as differing national capacities and legal frameworks

Some final takeaways:

- EMA embraced the duality of its role:
  - EMA as **enabler**: ensuring timely access to effective and innovative treatments.
  - EMA as **protector**: safeguarding public health from medicines with unproven or unsafe profiles
- A similar role is beginning to take shape for the EU HTAR, with national HTA acting as a 'backstop'
- Time, patience & willingness to adapt are critical

Universiteit Utrecht Pharmacoepidemiology & Clinical Pharmacology

Utilising JCA outputs for jurisdictional submissions, adjusting submission strategies for timely market access – What are the considerations from industry?

Eelko den Breejen, Senior Director, Head of Oncology Portfolio and Market Engagement, Global Access Strategy and Pricing, Pfizer, The Netherlands

National implementation uncertainties

Companies must balance the clear potential benefits of Joint Clinical Assessments, i.e harmonisation, high-quality decision making, and efficient resource use against the considerable resources needed for JCA preparation. A key challenge lies in understanding how JCAs will be implemented at the national level, requiring clarity on local HTA body guidance, implementation processes, and the relationship between JCA outputs and national procedures.

Information gathering and mapping

For companies, it's critical to understand national preparedness levels, legal framework changes, local HTA adaptations, stakeholder involvement, and PICO requirements across Member States. The landscape remains highly fragmented, with countries at different preparation stages and varying levels of clarity regarding JCA integration into national frameworks. Individual country engagement is often required to understand specific implementation approaches and timelines.

Quality and trust foundation

Success of the JCA depends fundamentally on delivering high-quality evidence, procedures, and outputs. High-quality JCA reports should build trust in the system, enabling faster national decision making based on confidence in European-level assessments. Companies need predictability alongside quality to support effective evidence generation and procedure implementation.

Conclusion

The fragmented JCA preparation landscape across Member States creates significant challenges for companies seeking to leverage JCA benefits for patient access, emphasising the need for improved coordination and clarity at both European and national levels. Success of the JCA requires not only high-quality European procedures, dossiers, and outputs, but also clear, predictable national implementation pathways. Trust and transparent communication between industry and HTA agencies is key.

What are the industry considerations for local HTA and market access strategies?

Legal framework	Have there been any changes to the principles of the local HTA framework?
Local HTA dossier adaptation	What are the detailed changes to the local HTA process to incorporate the JCA report?
Information on PICO survey	Will there be visibility on local PICOs?
Timelines (submission, time to access)	What are the implications for time to patient access?
Inclusion of stakeholders in HTA process	How will local stakeholders (patients and clinicians) be included in the JCA process?

National HTA development and capacity building to operationalise JCA outputs

Dr Katarina Beravs Bervar, Director, HTA Unit, Slovenian Quality and Healthcare Agency (JAKZ), Slovenia

Establishment of national HTA infrastructure

Slovenia has only recently implemented a formal HTA system, building on its experience within EUnetHTA. Following the establishment of the Slovenian HTA Sector within the Ministry of Health in mid-2024, the Law on Quality Assurance in Healthcare was adopted, which mandated the creation of a new agency. The Slovenian Quality and Healthcare Agency (JAKZ) was established in June 2025, featuring three pillars: quality, patient safety, and HTA. The HTA Unit within JAKZ is currently focusing on capacity building, methodology development, governance structures, and international collaboration.

Capacity building

In July 2025, Slovenia transferred its HTA unit from the Ministry of Health to the JAKZ and expanded its workforce to two full-time HTA experts. With this addition, Slovenia met the minimum capacity requirements to apply for the JCA co-assessor role, a significant learning opportunity. Becoming a JCA co-assessor alongside Germany's IQWiG was a key achievement in Slovenia's HTA journey.

National network development

Slovenia continues to expand its expertise by building a national HTA network to identify and engage HTA expertise across the country, part of a broader strategic effort to ensure sustainable HTA implementation. A three-day educational workshop was conducted in November 2025 for healthcare developers, academia, and patients to build broader understanding of HTA rationale and economic modelling.

Integration with national reimbursement processes

Active discussions are underway with the Slovenian National Health Insurance Fund (NHIF), the body responsible for medicine HTA assessments and reimbursement decisions, to integrate JCA outputs effectively. The current proposal is that JCA reports should be accepted as the clinical assessment component of dossiers, streamlining the assessment process and avoiding duplication of effort.

European-level support

Slovenia has been awarded an EU Technical Support Instrument (TSI) project to develop national HTA capacity, enhance governance mechanisms and role clarity across institutions, and update HTA methodologies to ensure alignment with JCA outputs. The country actively participates in various EU-level HTA networks and projects to access peer support and build expertise.

Conclusion

Slovenia's HTA development demonstrates that rapid progress is possible even with minimal capacity. Continued focus on national capacity building, methodology development, governance structures, and international collaboration is key to successful implementation of JCA in Slovenia.

Several preparatory activities improved the national HTA framework:

UPDATING **NATIONAL HTA METHODOLOGY** TO ALIGN WITH EU HTAR STANDARDS.

STRENGTHENING **GOVERNANCE STRUCTURES** FOR COORDINATION BETWEEN MINISTRY OF HEALTH (MOH), NATIONAL HEALTH INSURANCE FUND (NHIF), AND EXPERT GROUPS AND OTHER STAKEHOLDERS.

ESTABLISHING MECHANISMS FOR **SYSTEMATIC USE OF JCA OUTPUTS** IN NATIONAL DECISION-MAKING WITH NHIF.

JAKZ JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA KAKOVOST V ZDRAVSTVU

National HTA development and capacity building to operationalise JCA outputs

Dr Anja Schiel, Senior Adviser, Lead Methodologist in Regulatory and Pharmacoeconomic Statistics, Norwegian Medical Products Agency (NOMA), Norway

Understanding HTA's role in decision making

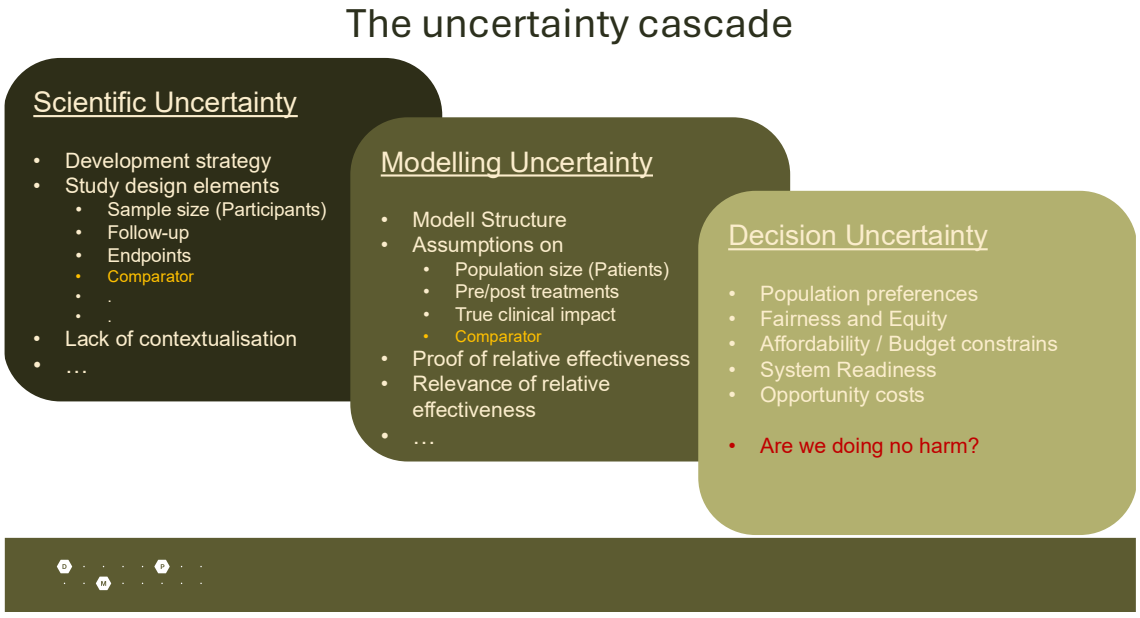
HTA serves as a tool to inform decisions rather than make them directly. It provides evidence synthesis that feeds into appraisal processes where decision makers incorporate additional elements like preferences, budget constraints, and equity considerations. This distinction is key to understanding where JCAs fit within national decision-making frameworks.

Differential impact across HTA systems

The impact of JCAs is likely to vary depending on national HTA approaches. Because JCA represents only a small component of Norway's overall assessment process—which includes comprehensive cost-utility analyses—it may be less impactful than in countries that conduct clinical benefit assessments, such as France and Germany. This variation stems from the different types of uncertainty each system addresses and the extent to which JCA outputs align with national requirements.

Uncertainty cascade and JCA positioning

Three types of uncertainty affect HTA processes: scientific uncertainty (addressed by both EMA and HTA bodies), modelling uncertainty (specific to economic evaluations), and decision uncertainty (context-dependent and related to opportunity costs). JCAs primarily address scientific uncertainty but have limited impact on the modelling and decision uncertainties that affect cost-utility analyses.



Opportunity costs

Every assessment activity incurs opportunity costs, and the value proposition of JCAs must be evaluated against these costs. For countries conducting extensive cost-utility analyses, the additional effort required to participate in JCAs may not be justified by the limited impact on national decision-making processes. Nevertheless, there may be future opportunities where the impact of JCA is greater, such as for Type-II variations.

Conclusion

The integration of JCAs into national economic assessment processes presents significant challenges, particularly for countries like Norway that rely on cost-utility analysis. The limited scope of JCA outputs relative to comprehensive economic evaluations may raise questions about resource allocation and opportunity costs. Success will depend on developing complementary processes that maximise JCA value whilst acknowledging the substantial additional work required at national levels.

What are the implications for national payers in the context of JCA uptake?

Dr Marc van de Casteele, Chair, Domain Taskforce HTA, Beneluxa, and Coordinator, HTA Pharmaceuticals, Belgian Health Care Institute (RIZIV-INAMI)

National integration of JCA outputs

Belgium has mandated combining JCA outputs with national assessments in a single bilingual report, with consideration of added therapeutic value assessments from France and the Netherlands, when available. The JCA output will be presented in English, while the Belgian component will be in Dutch or French, depending on company preference. The Belgian part of the report will address three key areas not covered by JCAs: Belgian epidemiology of the disease, added therapeutic value assessment, and comprehensive cost-effectiveness and economic evaluations.

Considerations for national processes

Belgium will adapt EU HTA methodology subgroup guidelines and merge them with the EUnetHTA methodology guidelines that have been used nationally for years. Post-JCA appraisal criteria will remain the same, ensuring consistency in national decision-making approaches. If evidence remains insufficient despite JCA completion, or if pricing is excessive, reimbursement may be refused based on national appraisal criteria.

Beneluxa collaboration opportunities

The Beneluxa partnership presents opportunities for informal exchange during JCA processes and enhanced collaboration in post-JCA national procedures. Given the significant investment of time, money, and personnel in JCA processes, leveraging this knowledge and investment in subsequent national procedures is key.

Company engagement

Companies will be able to access Belgian PICO information once EU PICOs are officially established and communicated, enabling preparation for national submissions. While Belgium does not offer formal early dialogue, companies can engage in informal pre-submission discussions with the Commission of Reimbursement of Medicines.

Resource investment

Experience so far shows that the JCA process does not reduce staff hours or timelines in Belgium. Additional investment has been required in staff training, participation in the HTA Coordination Group and its subgroups, and potential assessor roles. To ensure the value of such investments, companies must promptly proceed with national procedures following JCA completion, as delays could render JCA reports outdated. Metrics to track national reimbursement submissions and decision making will be useful for understanding the impact of JCA.

Conclusion

Belgium's approach demonstrates systematic integration of JCA outputs into existing national frameworks whilst maintaining established appraisal standards and procedures. Success depends on timely company submissions and effective resource allocation to support both JCA implementation and national requirements.

Session 3: Breakout discussions

Workshop participants were assigned to a breakout group and provided with a background document developed by CIRS, containing background information and suggested questions for discussion. The Chairs and Rapporteurs of each breakout were asked to facilitate and document the discussion, respectively. The Rapporteurs then fed back to all workshop participants in the main plenary session.

Breakout A: Navigating national HTA processes in the context of JCA

Chair: Niklas Hedberg, Chief Pharmacist, TLV, Sweden

Rapporteur: Anne Willemsen, Co-Chair of the HTA Subgroup on JCA, and Senior Advisor, National Health Care Institute, The Netherlands

Background

With the ongoing implementation of JCA in the EU, Member States are determining how to meaningfully integrate JCA reports into their national decision making. This transition presents both opportunities and challenges. Opportunities include potential improvements in efficiency, capacity building and cross-jurisdictional learning, while differences in timelines, context-specific evidence needs, and resource capacity may pose barriers.

This breakout group – comprised of both industry and HTA agency representatives - examined how jurisdictions are adapting their timelines, procedures, and resources to align with JCA while preserving national priorities.

Adapting national procedures

The group discussed the extent of legal changes needed to integrate JCA outputs into national HTA processes. This ranged from no changes required to substantial legal modifications, like in Spain where a new Royal Decree was required. Questions arose regarding JCA report utilisation when national HTA bodies don't assess all products, where other peers may be involved. More clarity is needed on how JCA reports would be used in this case.

There were mixed views as to when national PICOs can and should be communicated. Investigation is needed to determine whether the current timing of national PICO sharing allows industry adequate time to prepare national dossiers.

Industry representatives shared that they are mapping JCA dossier templates against national dossiers to identify potential overlaps and resource-saving opportunities. However, greater clarity is needed regarding how Member States are adapting their national assessment reports.

Trust was highlighted as an important aspect to implementing JCA successfully. Building trust between stakeholders, including HTA bodies and industry, has been somewhat challenging so far, but is key to mutual understanding and confidence in the JCA process and its implementation at the national level.

There was concern that JCAs may become outdated if launches in certain markets are delayed. Further discussion is needed on how to manage this issue.

Organisational considerations

It was suggested that companies should establish European-focused teams or centres to facilitate JCA submissions effectively. This would help to address gaps in European-level expertise in dossier development, as currently most experience lies with national affiliates.

The current shortage of biostatistical expertise was raised as a pressing concern for both HTA bodies and industry. There may be an opportunity for HTA bodies to pool biostatistical expertise across Europe and leverage expertise from other research areas.

Stakeholder engagement

Changes to clock stops during EMA assessment was highlighted as an important scenario requiring stakeholder interaction, between HTA bodies and companies as well as between regulatory and HTA teams within companies.

It was noted that clinical societies are considering using JCA outputs in their work. This may be an area to monitor as part of the evaluation of JCA impact.

Sustainability and evolution

The group agreed that a sustainable financing model needs to be created to support the future of JCA. More thought also needs to be given on how to systematically capture feedback, ideally transferring learnings from the oncology and ATMP fields to orphan drugs and vaccines. This systematic learning approach will enhance overall JCA effectiveness.

Recommendations for further work and research

- The HTA CG and industry should work together to conduct practical workshops sharing learnings of the JCA process and define future training for industry.
    - Questions remain about commercial sensitivity limitations and implementation timing whilst procedures continue.
- Industry should implement policy changes internally to enhance processes and collaboration, such as improving communication between regulatory and HTA departments and leveraging expertise from national affiliates.
- CIRS should explore the impact of JCA at the EU level, globally, and on clinical guidelines.
- Research is needed to evaluate whether the availability of national PICOs is timely enough for national submissions.

Breakout B: Methodological alignment between JCA and national processes

Chair: Dr Christine Leopold, Assistant Professor of Drug Regulatory Science, Utrecht University, The Netherlands

Rapporteur: Dr Antonia Morga, Head, New Product Planning, Global Value Evidence, Astellas, UK

Background

While JCA provides an objective assessment base for clinical evidence, methodological expectations at the national level continue to vary, particularly regarding PICO definition, comparator relevance, and analytical approaches. As national HTA bodies maintain responsibility for contextual appraisal and reimbursement decisions, questions remain about how JCA outputs will be interpreted and adapted in practice.

This breakout group, comprised of representatives from industry and HTA agencies, explored how methodological differences may influence national use of JCA reports, where alignment may be feasible, and how structured dialogue and company preparation can support efficient post-JCA national processes.

PICO considerations

The group agreed on three key considerations for the PICO framework for JCA. The first being that PICOs should reflect Member State needs by answering national-level questions. Secondly, there should be recognition that PICOs are policy driven, shaped by national priorities and not just methods. Finally, PICOs should foster Member State independence and autonomy through a framework that supports local HTA decisions. Supplementary analyses will be inevitable for some countries to meet national evidence needs.

Methodological challenges

Compared to the outcomes guidance issued by the HTA Coordination Group, the guidance for identifying comparators and relevant subpopulations requires more clarity. In addition, there are challenges around the identification of the 'best available standard of care', as this may be defined differently across Member States. This creates uncertainty for health technology developers in anticipating and accounting for such variations.

Industry representatives expressed concerns about the lack of transparency in PICO consolidation processes. Communication about PICOs should be earlier and in more depth to facilitate preparations for dossier submission.

Another challenge is the potential for divergences in estimands versus PICOs. Research questions captured at the trial level in the estimands may not always align with policy questions expressed in PICOs from JCA.

Recommendations for further work and research

Short term recommendations

- HTA agencies could work more closely together to align and enhance guidance on interpreting evidence from subpopulations or small patient populations.
- HTA agencies should consider how to enhance communication of PICOs. An option could be to broaden the remit of PICO explanation meetings and have them earlier in the process.
- HTA agencies should aim for the published JCA report to provide sufficient detail on the uncertainties, such as evidence gaps for informing specific PICOs and the potential lack of robust or recent clinical trials.

- Companies and HTA agencies should collect lived experiences of using the JCA guidance issued by the HTA Coordination Group – are all stakeholders using the same language and interpretation?

Long term recommendations

- All stakeholders should reflect on JCA methodological learnings after the first four or five JCAs have been completed.
- Further research can be considered once there is more experience of JCA.

Breakout C: Stakeholder collaboration for effective JCA implementation

Chair: François Houÿez, Director of Treatment Information and Access, EURORDIS – Rare Diseases Europe, France

Rapporteur: Dr Peter Pemberton-Ross, Head, HE & HTA Strategy, Biogen, Switzerland

Background

The implementation of JCA requires coordinated participation across multiple stakeholders, including HTA agencies, companies, clinicians, patients, and payers. While the JCA provides a collaborative assessment base for clinical evidence, effective national application depends on collaborative interpretation, clear communication of expectations, and meaningful engagement through assessment and decision-making processes.

This breakout group comprised of representatives from industry, HTA agencies and patient organisations explored the challenges and opportunities for effective stakeholder engagement during JCA processes.

Patient and clinician engagement

The group highlighted the importance of providing clear incentives to encourage patient and clinician engagement in JCA, given the significant time investment involved. As they are potential users of the JCA report, raising awareness and participation among clinicians is essential. Beyond incentives, there must be clarity in the JCA process in terms of what is expected of patients and clinicians, how their input will be used, and the feedback they will receive.

When JCA starts to be applied to orphan products in 2028, patient and clinician engagement in JCA may become more challenging due to smaller pools of experts and higher likelihood of conflict of interest. However, ongoing JCAs in rare oncology indications have had high community engagement, providing optimism for a similar experience in rare diseases.

Training programmes were highlighted as essential for facilitating effective patient and clinician engagement in JCA. They require careful tailoring to emphasise differences between regulatory (EMA) and HTA engagement processes.

At the national HTA level, approaches to patient engagement vary, with some HTA agencies having very developed processes while some have none. There are also HTA agencies that prefer lay patients over patients with advocacy or HTA expertise. HTA agencies without patient engagement processes may need to be identified and further supported.

Communication with industry during JCA

Industry representatives in the group reported generally positive experiences of JCA submissions so far, despite some initial difficulties. Predictability is key given the tight timelines and complex requirements. More opportunities for discussion on PICO scoping and consolidation would be beneficial. The cost of undergoing JCA was raised as a potential barrier to entry for small and medium-sized enterprises (SMEs) and non-profits that may need further consideration.

Evolving role of JSC

The group agreed that Joint Scientific Consultation (JSC) provides an optimal pathway for preparing for JCA, although opportunities for JSC are limited. Introducing fees could provide additional resources but has faced resistance in the past and may not be a viable solution across all Member States. The consequence of JCAs without JSCs raises concerns about missing opportunities for evidence generation planning at appropriate times, such as before trial protocol filing. Therefore, the following questions need consideration:

- What is the next most valuable advice pathway for products that don't undergo JSC?
- Is there an opportunity for an alternative consultation process prior to JCA that can address information gaps?
- Could JSC be streamlined for non-novel products in disease areas with extensive previous scientific advice experience?

JSC also faces prioritisation challenges, as resource limitations may lead to HTA agencies focusing on mandatory JCA delivery over voluntary JSC provision. Many agencies also lack experience in providing scientific advice, contributing to capacity concerns. Nevertheless, the fundamental limitation is the current shortage of HTA professionals; career promotion and training opportunities are needed to ensure a sustainable pipeline of future assessors, particularly those with skills in biostatistics.

International collaboration on methodology

Another topic that arose from the group discussion was the importance of international collaboration in ensuring that HTA methodology keeps pace with evolving technologies and evidence paradigms. There may be opportunities for EU HTA agencies to renew relationships with non-EU agencies, extending beyond ongoing Horizon Europe methods projects.

Recommendations for further work and research

- The European Commission and HTA Stakeholder Network should implement and continuously update training and capacity building activities on the HTA Regulation for all stakeholders.
- CIRS should conduct research into how best to measure timelines from regulatory approval to patient access (e.g. prescriptions), so that the impact of JCA and national decision making can be quantified.
- Research is needed to track the evolution of human resource available in national HTA agencies for JCA and JSC activities.

Panel discussion: Ensuring a future proof HTA landscape in Europe and beyond

HTA agency perspective

Dr Nick Crabb, Chief Scientific Officer, National Institute for Health and Care Excellence (NICE), UK

With the first JCA reports nearing publication, it is an exciting time for the global HTA community. There is strong support for colleagues involved in JCA processes, both industry partners engaging with procedures and HTA colleagues developing reports. The historical EUnetHTA collaboration provided a valuable foundation for understanding HTA cooperation that built toward the EU HTA Regulation.

Impact of JCA on NICE work

The impact on NICE operations will largely depend on relative timing of the JCA report and NICE assessments. If NICE work precedes JCA report availability, direct impact may be limited. However, some influence is expected as the clinical evidence submitted to NICE is likely to be the same or similar to that in JCA submissions. The inputs and assumptions made in cost-utility analyses for NICE may also be informed by JCA work. This alignment is important for addressing healthcare system sustainability challenges, as different HTA evidence demands could mean additional pharmaceutical development costs.

If JCA reports are available at the time of NICE processes, they will be used as key literature components. The deliberative JCA process, where European colleagues have examined uncertainties and presented conclusions on clinical evidence, provides useful input for NICE committee deliberations.

Methodological evolution and collaboration

While current HTA frameworks are sufficient, they could benefit from evolution – and perhaps revolution in some aspects. Data infrastructure improvements in the UK and across Europe create opportunities for enhanced real-world evidence integration into HTA processes, including JCA.

NICE's HTA Innovation Laboratory provides a ‘safe space’ for addressing complex HTA problems in collaboration with system partners and stakeholders. NICE is keen to collaborate with former EUnetHTA partners beyond current Horizon Europe participation, perhaps with a focus on methodological development and value frameworks.

HEMA collaboration

The Health Economics Methods Advisory (HEMA) group represents an independent undertaking by NICE, Canada’s Drug Agency (CDA-AMC), and the US Institute for Clinical and Economic Review (ICER) to evaluate new HTA methods and processes. HEMA reports are targeted to the founding agencies rather than representing agency positions to the broader world. There could be opportunities for collaboration between European and HEMA initiatives.

Conclusion

Consideration is being given for how JCA outputs can be leveraged outside of the EU. NICE envisages the JCA report (if available) being a key literature component in its evaluations. Collaboration potential exists beyond EU boundaries, building on established relationships whilst developing new partnerships for addressing common HTA challenges, including methodological issues.

Industry perspective

Shane Kavanagh, Vice President, Health Economics and Real-World Evidence, Johnson & Johnson, Belgium

Increased coordination

JCA is a significant step change for companies, requiring substantially more resources than initial estimates suggested. The parallel nature of submissions with major regulators creates unprecedented coordination requirements, necessitating new approaches to evidence generation, submission preparation, and stakeholder engagement across multiple jurisdictions simultaneously.

Avoiding absolutism

HTA frameworks that continually increase evidence requirements can be viewed as absolutist, which may be problematic in a global pharmaceutical landscape dominated by the Most Favoured Nation (MFN) policy. HTA agencies should weigh uncertainties and assess plausibility within the totality of submitted evidence, rather than ruling out certain evidence. While there are examples of excellent guidance issued recently, it is important to recognise the 'catch-up' period between the issuing of old and new guidance, where older data predates new guidance requirements.

Enhancing communication

Current JCA processes involve notifications to industry rather than genuine dialogue. There is a pressing need to transition from information exchange to meaningful dialogue; this issue should be a priority, rather than waiting until a retrospective evaluation of initial submissions has taken place.

Global uptake of JCA outputs

Uptake of JCA outputs beyond Europe will depend on local standards of care, populations, and diagnostic availability. Timing of submissions will also be an important factor, as well as agencies' willingness to potentially trade an earlier decision with increased certainty from more mature data.

Conclusion

For companies, JCA requires significant investment and unprecedented coordination for global market access, demanding new approaches to evidence generation, submission preparation, and stakeholder engagement across multiple jurisdictions simultaneously. To ensure success, approaches to evidence evaluation must be flexible, and company-agency interactions during JCA need to shift from information exchange to active dialogue.

Policy perspective

Maya Matthews, Head of HTA Unit, European Commission

European healthcare landscape transformation

The current EU landscape presents significant change and opportunity through multiple regulatory initiatives including the pharmaceutical reform, targeted evaluation of the Medical Devices Regulation, and Critical Medicines Act. The EU HTA Regulation (HTAR) has elevated HTA to higher prominence within the wider healthcare ecosystem, requiring all EU countries to engage with HTA processes. The HTAR has spurred HTA reforms in many countries with exciting developments, like the creation of dedicated HTA agencies in Member States previously without them. The transition from EUnetHTA's project-based approach to a legislative framework brings HTA topics to European and global attention.

Innovation in collaboration

The current undertaking for JCA represents highly innovative work - a collaborative exercise and substantial change management initiative bringing together organisations with diverse working methods to jointly assess the clinical relative effectiveness of new health technologies. This process requires clear communication and building trust between all stakeholders, including the Commission, HTA agencies, health technology developers, patients and clinicians.

The collaborative process aims to produce high-quality reports contributing to health system sustainability - a critical consideration given ageing societies, highly innovative pipelines, and the need to address growing access gaps both between and within countries.

Evidence-based European cooperation

At the European policy level, there is strong belief in evidence-based work merit and bringing different stakeholders together to share expertise and avoid duplication. The focus extends beyond technical JCA details to encompass broader emphasis on evidence generation for policy making.

Feedback and evaluation

Feedback loops and learning from initial experiences are essential for process refinement. The HTAR includes built-in evaluation requirements, due by January 2028. There may be opportunities for collaboration between the European Commission and CIRS in terms of providing evidence and data for the evaluation process and sharing expertise on HTA and regulatory processes.

Conclusion

The HTAR represents a transformation, not only for the HTA community but also within broader European healthcare policy evolution. The innovative collaborative approach to HTAR implementation creates foundations for sustainable, evidence-based healthcare decision making across Europe. Building trust, enhancing communication, and learning through experience are key to success.

Payer perspective

Yannis Natsis, Director, European Social Insurance Platform (ESIP), and European Health Forum Gastein Board Member

European policy environment

The current EU policy environment is dominated by discussions around competitiveness, innovation, strategic autonomy, and security, as emphasised in the Draghi report. Legislators are discussing potentially expensive incentives for pharmaceutical companies through the Biotech Act, Critical Medicines Act, and General Pharmaceutical Legislation revision, raising fundamental questions about costs and accountability measures.

Healthcare system sustainability crisis

The European Social Insurance Platform (ESIP) represents a breath of statutory social security institutions across Europe, including major national payers, pension funds, and social protection providers. The unprecedented pressure on public budgets due to economic downturns and competing priorities is a major concern for these organisations.

Public money scarcity creates intense competition for limited resources, with defence spending currently receiving significant attention while other sectors face constraints. The budget for non-defence investments requires careful allocation decisions, making HTA's role in guiding investment decisions increasingly critical. HTA must demonstrate clear value proposition within this competitive environment to maintain political and financial support.

The Most Favoured Nation (MFN) policy in the US represents another significant challenge for public healthcare financing, requiring thorough consideration of international pricing implications and their impact on European healthcare system sustainability.

Threats to the future of HTA

There are concerning trends emerging in EU policy circles where 'omnibus' legislation packages simplify existing regulations, effectively leading to their elimination. There is a potential risk that this could happen to the HTA Regulation if it proves too cumbersome and costly. In addition, there have been questions raised by some policy makers over the necessity of HTA since the COVID-19 pandemic, during which systematic HTA processes were bypassed to accelerate procurement deals.

Conclusion

European payers recognise the potential benefits of the HTA Regulation but remain focused on maintaining national decision-making capabilities and ensuring healthcare system sustainability. The intense pressure on public budgets, combined with competing policy priorities and political pressures, creates an environment where HTA's future depends on demonstrating clear value in guiding wise investment decisions.

Conclusion

The workshop highlighted broad stakeholder support for the goals of JCA in reducing duplication and harmonising clinical evidence assessment across the EU. Nevertheless, there was acknowledgement that the extent to which these benefits can be realised will depend on how effectively JCA outputs are integrated into diverse national decision-making pathways, each with its own methodological expectations, policy priorities, and capacity constraints.

HTA agencies described the practical realities of implementing JCA, including short timelines for PICO scoping, the complexity of consolidating Member State PICOs, and continuing efforts to strengthen national HTA capacity. Several agencies outlined recent or ongoing reforms—ranging from updated HTA guidelines to legislative changes—designed to help meet the requirements of the HTAR.

Industry participants reflected on the operational demands associated with JCA preparation, noting the substantial coordination required and the resource implications of preparing comprehensive analyses within tight timelines. They recommended earlier and broader PICO discussions, with clearer communication of national needs, so that national dossiers can be prepared more efficiently.

Across all stakeholders, there was recognition of the importance of trust, transparency, and communication throughout the JCA process. Regular dialogue between HTA agencies, companies, patients, clinicians, the EMA and European Commission are essential to build confidence in emerging processes and support continuous improvement. There may be opportunities for research by CIRS and/or Utrecht University to support the JCA evaluation process.

Overall, the workshop concluded that JCA should be viewed as an evolving process situated within a wider transformation of the EU healthcare landscape. Its long-term success depends on continued HTA capacity building, iterative learning, and sustained collaboration to promote high-quality, efficient, and consistent clinical assessment in support of timely patient access to medicines across Europe.

List of attendees

Affiliations are stated as they were at the time of the meeting.

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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, and grants.

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