The EU Joint Clinical Assessment:

A harmonised approach to clinical assessments across the European Union

Aitken, D.

HEOR

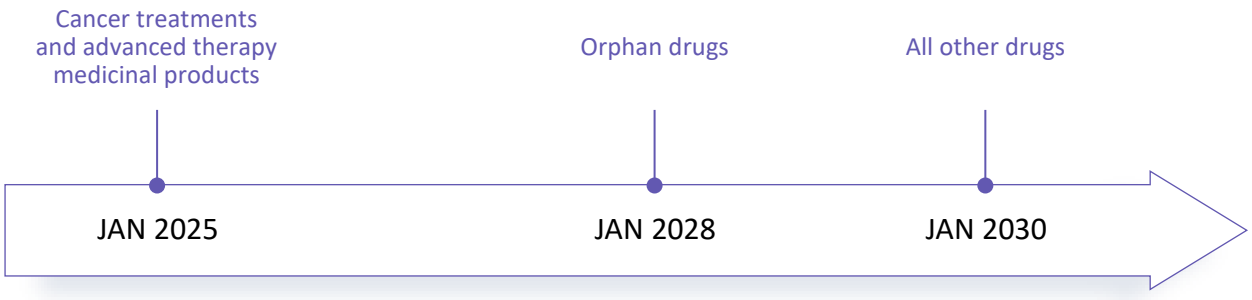
Contents

Background

In January 2022, the European Commission published a milestone regulation enforcing a joint approach to clinical assessments across the European Union (EU). Whereas EU nations currently assess the clinical evidence for a medication according to their own framework, a joint clinical assessment (JCA) aims to reduce multiplicative efforts across individual EU HTA bodies and accelerate patient access to treatments. The JCA will produce a single report on a new treatment's clinical benefit which will form the basis of decision making for all 27 EU member states. This new approach will replace the voluntary EUnetHTA 21 consortium, a project-based collaborative health technology assessment (HTA) network, which ceased operations on 16th September 2023.

Commencing in January 2025, the JCA process will start by evaluating cancer therapies, before assessments of orphan drugs begin in January 2028 and remaining drug classes in January 2030 (Figure 1).

Figure 1. Timelines for the commencement of JCAs across therapeutic areas



What does the JCA process involve?

Recently published timelines reveal the JCA process will run concurrently with the European Medicines Agency (EMA) marketing authorisation process as outlined in Table 1.[1]

Table 1. The JCA process is proposed to run concurrently with the EMA process. Scenario 1 is performed for new chemical entities whereas scenario 2 is performed for the JCA of new indications of already approved drugs or accelerated approval. Table adapted from published timelines.

Standard EMA procedure	**JCA Scenario 1** (new chemical entities)	**JCA Scenario 2** (Type II variation, accelerated approval)
Start of procedure: **01.01.2023**	Start of procedure: **18.02.2023**	Start of procedure: **01.01.2023**
Day 120 List of questions: **26.04.2023**	Assessment scope available: **07.05.2023**	Assessment scope available: **26.03.2023**
Day 180 List of outstanding issues: **20.09.2023**	Dossier submission **04.08.2023**	Dossier submission **23.06.2023**
CHMP opinion: **20.11.2023**	1. Draft JCA: **09.11.2023**	1. Draft JCA: **29.09.2023**
European Commission approval: **05.01.2024**	2. Draft JCA: **15.12.2023**	2. Draft JCA: **04.11.2023**
	Final version JCA: **10.01.2024**	Final version JCA: **30.11.2023**
	Endorsement by HTA Coordination Group: **04.02.2024**	Endorsement by HTA Coordination Group: **22.12.2023**

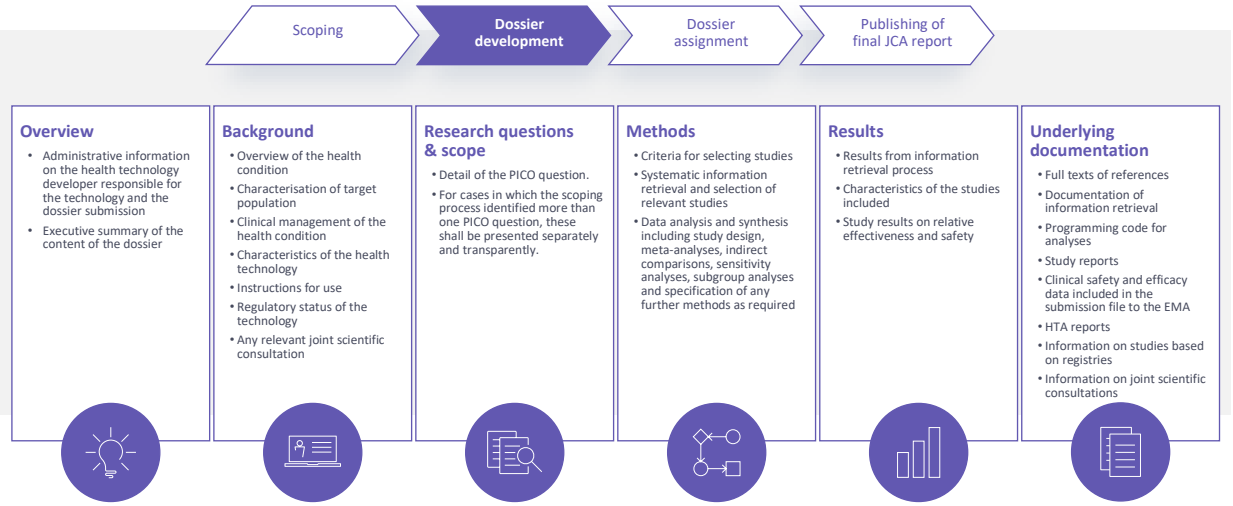
Scoping

The JCA process begins with the scoping phase in which all member states are invited to complete a 'Population, Intervention, Comparator, Outcome' (PICO) survey, resulting in up to 27 PICOs returned. These are consolidated by an assessor and co-assessor who ensure that the needs of member states are translated into the lowest number of PICO(s) possible which forms the scope for the JCA.

Dossier development

Following finalisation of the scope, companies begin development of the JCA dossier. This process is estimated to take around 6 months, with submission required at least 45 days prior to publication of the Committee for Medicinal Products for Human Use (CHMP) opinion by the EMA. Guidance on the content for the JCA dossier has been published and largely focuses on the disease background, details of the intervention, systematic retrieval and selection of studies, and presentation of clinical efficacy and safety (Figure 2).[2]

Figure 2. The proposed JCA process with key focus on dossier development.



Assessment of the dossier

Assessors and co-assessors from different member states are then invited to evaluate the dossier before the final JCA report is published up to 30 days following EMA approval. The report will not be legally binding and will allow individual countries the authority to appraise the clinical evidence and request further evidence from the submitting company at their reimbursement stages as required. Non-clinical assessments including economic evaluations and consideration of organisational, societal or ethical aspects remain the responsibility of individual member states.

What are the benefits of a joint approach to clinical assessments?

1. **Potentially reduced duplication of work** - A harmonised approach to clinical assessment across the EU can reduce the duplication of work across HTA bodies in areas where there are consistent evidence needs.
2. **Accelerated patient access** – The JCA process will be performed in parallel with EMA marketing authorisation, potentially accelerating patient access as the delay between marketing authorisation and clinical assessment is reduced.
3. **Reduced pressure on less developed HTA infrastructures** - A harmonised approach to assessing clinical efficacy reduces the strain on countries with less developed HTA expertise as this burden can be shared among nations with more developed infrastructures. Between 2018 – 2021, 147 medicines were granted reimbursement in Germany compared with ten in Turkey.[3] The same study revealed that the time between marketing authorisation and reimbursement ranged from 128 days in Germany to 918 days in Romania.
4. **Increased equity of product launch** - An EU-wide approach might simplify product launches in Europe, improving the equitability of treatment access for many EU patients in typically less attractive markets.

What are the drawbacks of a joint approach to clinical assessments?

1. **Potentially large number of PICOs** - The standard of care for a condition varies between healthcare systems which might increase the complexity of a submission. An analysis in non-small cell lung cancer indicates that the EUnetHTA guidelines could initially lead to >10 different PICOs.[4] For the JCA, all PICOs relevant for a single population can be clustered into one chapter in the report. Each relevant comparator is then assessed sequentially.
2. **Potential for smaller markets to be dominated** – At both the PICO consolidation stage and downstream, larger markets might dominate the process or decision making. Whether the JCA represents a truly harmonised approach or will instead be dominated by larger markets will merit future investigation following its implementation.
3. **Heterogeneity in methodological priorities of member states** – Currently there exists a large disunity in how member states reach reimbursement decisions. Some nations favour a cost-effectiveness approach and will require clinical evidence to feed into their framework whereas other member states will not. Further, Germany, clinical efficacy results are the main drivers of value and are more heavily scrutinised. Though EunetHTA guidance provides methodological clarity, Germany's HTA body is notoriously rigorous and rejects 71.5% of ITCs.[5] Therefore, despite lacking legal basis, endorsement of an ITC within the final JCA report could make this difficult to reject on a national level.
4. **Delays to patient access at national levels are not eliminated** – Despite an accelerated authorisation and clinical assessment process, patient access might still be delayed in some countries relative to other member states if that nation requires manufacturers to submit additional evidence or complementary clinical analyses at the reimbursement stage.

Next steps

The advent of this harmonised approach presents a fresh challenge for all stakeholders, with ongoing preparations forming the basis of discussions at ISPOR Europe 2023. At HEOR, we already adopt a harmonised approach within our global value dossiers and value communications. We look forward to using this experience to support our clients in strategically navigating this new landscape and aiding patient access to life-changing medicines.

Further details on the JCA approach can be found on the EUnetHTA website.

At HEOR, our fully integrated HTA teams are experts in developing and critiquing evidence submissions for health technology agencies around the globe. We provide end-to-end strategic consultancy and reimbursement support, navigating our clients through the complex policies and processes in their target markets.

If you want to see how we can support you prepare for the JCA process or have other questions regarding HTA strategy, **reach out to Beverley Jones, Director of Value & Access (beverley.jones@heor.co.uk)**.

References

1. EUnetHTA. D5.4 JCA timelines v0.1. 2023. Available at: https://www.eunethta.eu/wp-content/uploads/2023/06/EUnetHTA-21-D5.4-Timelines-JCA.pdf [Accessed November 2023].
2. EUnetHTA. D5.1 Submission Dossier Guidance. 2023. Available at: https://www.eunethta.eu/wp-content/uploads/2022/12/EUnetHTA-21-D5.1-Submission-Dossier-Guidance-v1.0.pdf [Accessed November 2023].
3. IQVIA. EFPIA Patients W.A.I.T. Indicator 2022 Survey. 2023. Available at: https://www.efpia.eu/media/s4qf1eqo/efpia_patient_wait_indicator_final_report.pdf [Accessed November 2023].
4. van Engen A, Kruger R, Ryan J, et al. HTA97 Impact of Additive PICOs in a European Joint Health Technology Assessment. a Hypothetical Case Study in Lung Cancer. Value in Health. 2022;25(12):S315.
5. Ecker T, Kandola S, Musiolik K, et al. Implications of EU HTA on Acceptance of Indirect Treatment Comparisons in National Assessments (HTA55). 2023.

Rhymney House, Unit A Copse Walk, Cardiff Gate Business Park, Cardiff, CF23 8RB

+44 (0)2920 399146 | enquiries@heor.co.uk