The impact of the EU-JCA throughout European Healthcare Systems

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Introduction and methods

The introduction of the European Joint Clinical Assessment (EU-JCA) in 2025 for cancer therapies and ATMPs will mark the inauguration of an attempt to centralise HTA for new medicines in Europe. In 2028, the EU-JCA will be introduced for orphan medicinal products, and from 2030 will be routinely used for all centrally approved medicines.

A primary research programme was conducted in September-October 2022 with a sample of national payers from the EU4, Belgium, Poland, Hungary, and Portugal. The objective was to understand the perceived impact of the implementation of the EU-JCA for patient access to medicines at the member state level and the associated implications for manufacturers.

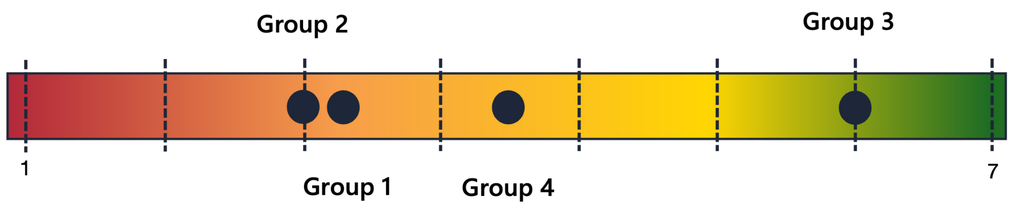
Different European member states were grouped according to population and purchasing power, to explore the way in which different market archetypes perceive the EU-JCA and the predicted implications for their national HTA processes. The member state groups are explained in the table below:

	Countries	Purchasing power	Population size
Group 1	France, Germany, Italy, Spain	High	High
Group 2	Belgium	High	Low
Group 3	Poland	Low	High
Group 4	Hungary, Portugal	Low	Low

Results

Payer perception to JCA value to support national HTA

Figure 1. Payer perception of the value that the EU-JCA could have with respect to patient access to medicines. ***(1 = no additional benefit versus current HTA process; 7 = significant additional benefit versus current HTA process)***



Payers from countries with lower purchasing power believe the EU-JCA will have a beneficial impact on patient access to medicines. For these countries, the centralised joint assessment is expected to provide a transparent and consistent assessment of the clinical evidence and incremental value of new therapies close to the time of marketing authorisation, to directly support timely national level decision making. In particular this will be valued for complex therapies where there is uncertainty on the incremental/long term clinical value (e.g., cell and gene therapies). In these cases, high levels of analytical rigor will be required to determine the potential long-term value of disease modifying therapies that could change the natural history of generic disorders. A robust evaluation of the dataset with alignment across member states will likely increase payer confidence in the potential clinical value of new therapies, and therefore promote patient access.

Additionally, one centralised report to inform the clinical value of new therapies and data quality should reduce disparity in access, particularly with respect to rare diseases and cancers, which can currently be seen across Europe.

Payer representatives from countries with higher purchasing power consider that the EU-JCA will provide less additional value in the national assessment process, as this is expected to be largely based on the methodologies and evidence assessment standards that they are already using. Furthermore, unless there are parallel initiatives to centralise economic value assessment and pricing negotiations, variability in patient access and reimbursement restrictions are predicted to continue due to financial disparities between healthcare systems.

Predicted additional data requirements at the member state level

Figure 2. Likelihood of member states to request additional data during the Joint Clinical Assessment process

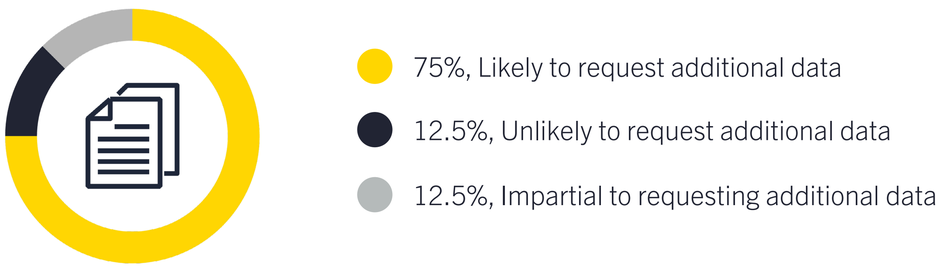


Table 1. Types of data likely to be requested by member states during the Joint Clinical Assessment process.

1	Indirect treatment comparison for a new therapy vs. current SoC in the country (if this comparison is not demonstrated by the pivotal trial)
2	A definition of the MCID for any outcome measures used in the pivotal trial (ensuring this is validated and patient relevant)
3	Validation of any endpoints that are not considered acceptable at national level
4	A definition of the target patient population (including estimated national patient numbers and a definition of current treatment/unmet needs within the country)

The most frequently mentioned additional evidence request at the member state level is an ITC for the investigational product vs. SoC (if this is not available from the pivotal trial, or provided as part of the EU-JCA assessment). Delays in patient access are predicted if the comparator used for the EU-JCA does not align with current clinical practice at the member state level, and the public consultation on the methods guideline on comparators and comparisons, has shown that ITCs are likely to become an integral part of the EU-JCA (to reflect the potential for multiple different relevant comparators across countries). To avoid this need for additional data submission at the member state level and potential delays to patient access, payers across markets state that high quality ITCs should be available as part of the EU-JCA process where there is variation in the comparator; this should be performed in line with academic best-practice.

Implications for national level assessment

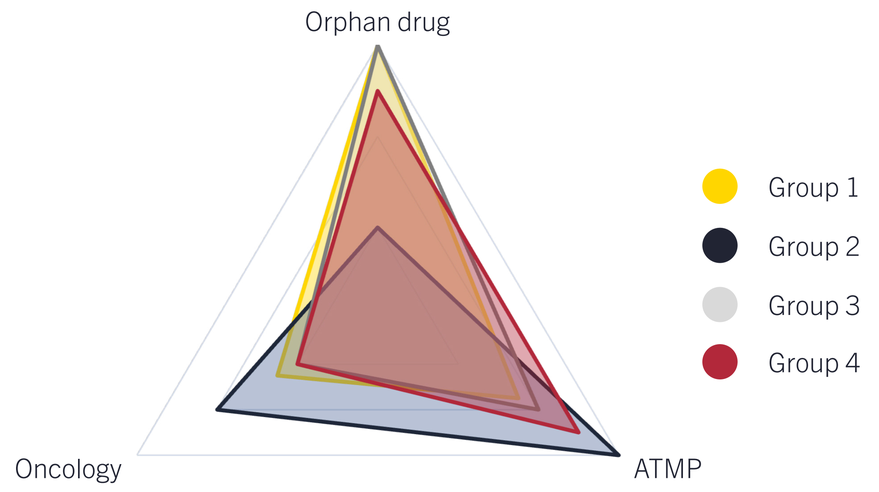
The current representation of HTA bodies supporting the development of the JCA methods is considered acceptable, however payers from smaller European countries believe the significant representation of France and Germany across 'hands on groups' developing the methods and processes for evaluation will mean a high level of influence on the assessment standards. It was noted that more representation from central/Eastern Europe would have been beneficial to ensure the needs of these healthcare systems are reflected.

Figure 3. Does the availability of the centralised Joint Scientific Consultation procedure reduce the need for early engagement at the member state level?

Payers predict the new centralised Joint Scientific Consultation procedure will reduce the need for early engagement at the member state level to inform the clinical development strategy. However, there is still likely to be value in local HTA engagement to clarify potential requirements for additional data submission/analysis at the member state level (e.g. where health economic evaluation is required, which falls outside of the JCA)

Priority therapies for JCA evaluation

Figure 4. Payer perception of the therapy types that will benefit the most from a centralised clinical assessment

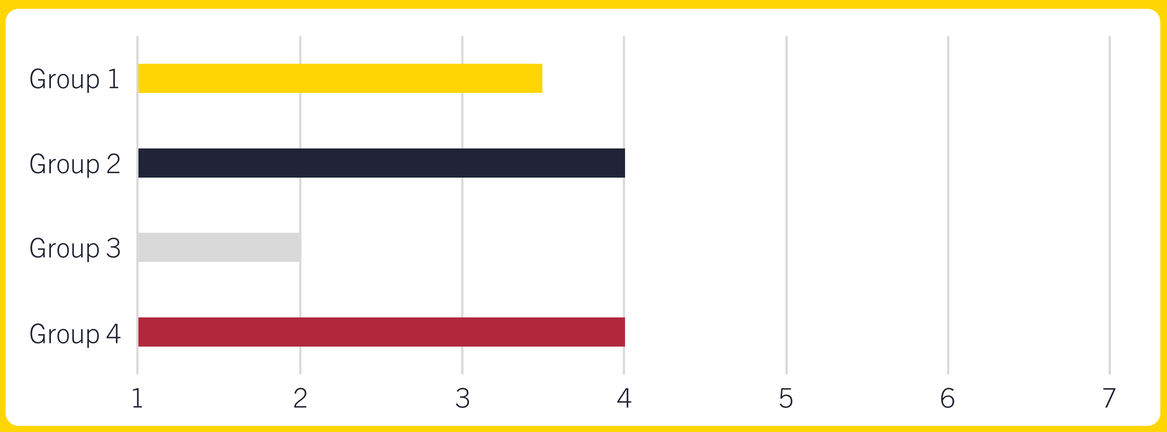


Across country archetypes, payers associate the greatest value of the EU-JCA process with orphan drugs and ATMPs. This results from the delegation of the clinical assessment to countries with the most expertise within the relevant therapy area/technology type, which should result in a higher quality assessment. This particularly applies to rare diseases, where clinical expertise may be scarce. Furthermore, analytical resources and clinical experts could support with the identification of subgroups where products provide increased clinical value, which will allow payers across Europe to make more informed decisions on the reimbursement of new therapies.

With particular reference to Germany, one payer explained that the launch of the EU-JCA, in parallel with the upcoming reforms to the AMNOG process, is likely to make the HTA landscape more challenging in Germany for orphan designated products.

Conclusion and implications for manufacturers

Figure 5. Payer perception of the overall impact of the EU-JCA on the national HTA



Overall, payers across Europe expect routine use of the EU-JCA within member state decision making on the incremental clinical value of new medicines from 2025, however current frameworks and metrics for the quantification of clinical value and the uncertainty in available data are expected to remain.

The greatest practical impact is expected in member states with less resources for HTA at present, where availability of the EU-JCA report close to the time of marketing authorisation will likely reduce the resource burden for assessment and accelerate the time for evaluation.

Despite the potential for progress towards accelerating patient access and reducing variation, member state level responsibility for the negotiation of pricing and reimbursement is likely to mean continued divergence between member states depending on purchasing power. Furthermore, post-launch requirements for additional data generation to inform country level re-evaluation could also lead to divergent requests (and growing administrative complexity for manufacturers) to meet national level conditions for reimbursement.

Table 2. Key considerations for manufacturers submitting dossiers to the EU-JCA in 2025

1	Early engagement through the Joint Scientific Consultation process should ensure pivotal trial design and wider evidence analysis/synthesis planning are aligned with evolving requirements of the EU-JCA
2	Direct engagement with HTA authorities in priority member states should address any potential additional data requirements outside the EU-JCA (e.g. additional clinical/economic evidence to inform national decision making)
3	Detailed analysis on the current SoC for target patients across the EU should inform the likely relevant clinical comparator(s) for the EU-JCA process. Where there is heterogeneity in the SoC across countries, ITCs should be prepared in line with academic best practice to demonstrate the incremental clinical value vs. the range of possible comparators

Abbreviations. AMNOG: Arzneimittelmarkt-Neuordnungsgesetz; ATMP: Advanced Therapy Medicinal Product; EU4: France, Germany, Italy, Spain; HTA: Health Technology Assessment; ITC: Indirect Treatment Comparison; MCID: Minimum Clinically Important Difference; SoC: Standard of Care