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National Perspectives on the European Joint Clinical Assessment: Insights From HTA Stakeholders in Four Countries

HTA20

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Background & Objective

- In 2025, Joint Clinical Assessment (JCA) will start for oncology drugs and advanced therapy medicinal products (ATMPs) according to the European Health Technology Assessment (HTA) regulation[1].
- This standardized comparative assessment of the clinical evidence valid for all European member states (MS) will eliminate the need for multiple submissions and assessment of the same evidence across Europe.
- To explore the potential impact of JCA on health authorities and health technology developers (HTDs), as well as a potential variability in JCA adoption across Europe, stakeholder interviews with current or former members of HTA bodies, ministries or payers were conducted in four countries.

Methods

- Current and former representatives from HTA agencies, national payers or health ministries in France, Germany, Italy, and Poland were interviewed (1-2 per country).
- The 30-min free-flowing yet structured interview followed a questionnaire focusing on expected effects of JCA with respect to their own countries and other member states. Main areas of interest were the impact of JCA on health authorities and HTDs, potential necessary national process adjustments, as well as commonalities or differences between countries' views on JCA and potential divergent conclusions drawn by individual member states.
- Table 1 provides an overview of the interview questions.
- A qualitative analysis of key findings and comparative summary of responses are being presented.

Table 1: Interview questions on expected JCA impact

Methodology	Market Access	Reimbursement
Where do you see the strengths and weaknesses of JCA? Either from a HTA body or payer perspective.	Do you think that JCA will impact patients' access in your country?	Will limited evidence in rare diseases impact JCA negatively and hence restrict reimbursement later?
Will any comparator from the EU HTA PICOs be accepted in your country in the future?	Do you expect that in countries without established HTA system, JCA will enhance access to new treatments?	Do you expect changes in the reimbursement processes and timelines in your country due to JCA?
Do you expect discrepancies between member states regarding the interpretation of the assessment outcome for the national appraisal?	Do you expect manufacturers to launch earlier in your country than before JCA?	Do you expect an impact on pricing of drugs?

Results

- A single submission for standardized clinical assessment is perceived as a benefit.
- High-quality reports being available early will allow faster processes.
- Either higher workload or a shift in workload that will require more resources and experts is expected, and existing laws will have to be followed.
- PICOs need to match national requirements; otherwise, amendments will be requested.
- Translation of JCA outcomes into national/regional appraisals may result in discrepancies between member states due to different focuses of the healthcare systems.
- Stakeholders highlighted that JCA could be particularly beneficial in countries lacking robust evaluation systems.
- Successful application will depend on
  - PICOs being manageable and amendable to national rules
  - Raising awareness of JCA requirements among HTDs, especially outside of Europe
  - Timely adaptation of processes within national HTA agencies, including resourcing
  - Addressing HTD's concerns regarding absence of a formal arbitration process

Legend

JCA: Joint Clinical Assessment
HTA: Health Technology Assessment
HTD: Health Technology Developer
PICO: Population, Intervention, Comparator(s), Outcomes
QALY: Quality Adjusted Life Year

Results (continued)

Methodology

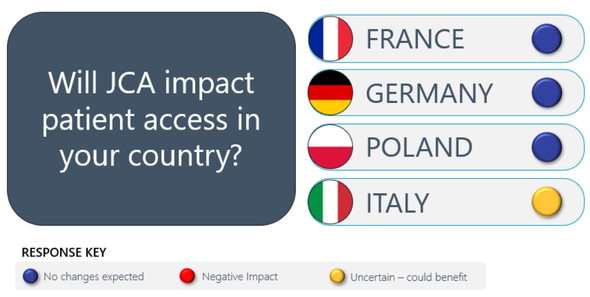
Are discrepancies expected in national appraisals and what would be the reasons?

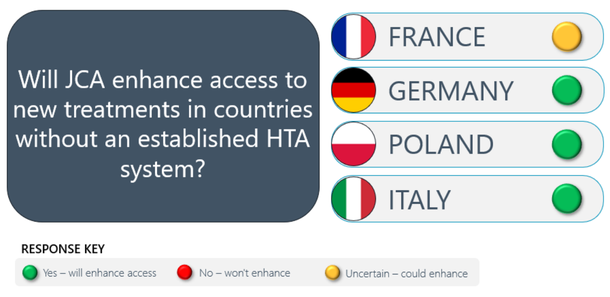
FRANCE	GERMANY	POLAND	ITALY
Yes – member state discrepancies expected	**Yes** – member state discrepancies expected	**Yes** – member state discrepancies expected	**Yes** – member state discrepancies expected
A therapeutic advance may not translate into an added benefit in France, and vice versa	Example: Chosen endpoint is not relevant to patient population	A favorable JCA assessment would likely prevail	Example: PICOs proposal may not fully reflect national needs and might not be accepted
	No differences in evidence assessment; therapeutic advance may not translate into an additional benefit, the opposite is very unlikely		
Some countries may regroup populations for price negotiations	Cultural differences, e.g., focus on QALY vs medical impact	A less favorable JCA might be viewed differently	Diverse healthcare landscapes and varying priorities in member states may lead to differences

- Respondent perspectives on their own countries and other member states as it relates to discrepancies with respect to the interpretation of a JCA outcome for national appraisal.

Market Access

Are there any impacts on patient access to be expected?

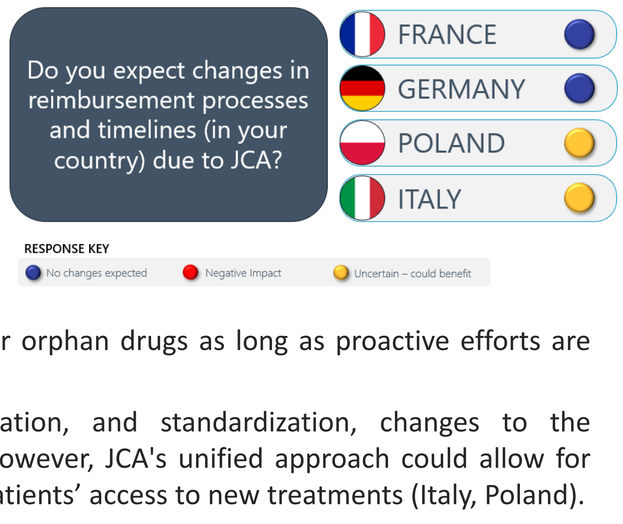




- Interviewees do not expect changes with respect to patients' access in general; in Italy, potentially faster processes might grant access to new treatments earlier.
- To some extent, stakeholders foresee faster access in countries with limited HTA infrastructure, but restricted capacities, country-specific priorities and adaptation needs might hinder or delay the positive impact.
- For France and Germany, no impact on launch time is expected, but the early availability of the clinical assessment reports could lead to earlier drug launches in Poland and Italy.

Reimbursement

Are there any impacts on reimbursement to be expected?



- Interviewees don't expect a disadvantage for orphan drugs as long as proactive efforts are being taken to address evidence gaps.
- Apart from resource optimization, adaptation, and standardization, changes to the reimbursement process are not expected, however, JCA's unified approach could allow for faster decision-making and hence enhance patients' access to new treatments (Italy, Poland).
- JCA could also have an impact on pricing depending on the evidence and acknowledgement of innovation in Italy and Poland.

Conclusions

- JCA represents a significant step towards harmonizing and expediting access to new treatments across all European member states.
- Perceptions reveal potential influence on reimbursement and pricing processes, such as faster decision-making and evidence-based conclusions that may impact pricing.
- Despite positive perceptions of a single clinical assessment, integrating JCA within national frameworks induces some challenges.
- Different outcomes in national appraisals are expected due to diverse focuses of healthcare systems.
- Refinements to the JCA framework following the planned review phase are envisioned.

References

1. Regulation (EU) 2021/2282 of the European Parliament and of the Council Regulation - 2021/2282 - EN - EUR-Lex (europa.eu)

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