# The JCA is Coming: Will the EU Band Together?

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## INTRODUCTION

Health technology assessments (HTAs) remain the key regulatory process to inform the funding of new medicines in Europe, as a positive HTA evaluation is essential for successful access and reimbursement. Europe is pushing for increased HTA collaboration across countries to promote transparency/objectivity and streamline drug review.

## OBJECTIVES

A new pan-European HTA regulation established in January 2022 will require member states to give "due consideration" to joint clinical assessment (JCA) reports within their national HTA assessments starting in 2025. The JCA will focus on the clinical domain of HTAs but will not focus on economic assessments. Additionally, member states will remain free to conduct supplementary clinical and non-clinical analyses.

## METHODS

This regulation review considers the potential impact of widespread European adoption of the JCA as a new requirement for HTAs. N=8 ex-payer stakeholder interviews across Germany, France, Italy, and Spain (N=2 each) add a primary research perspective on the potential impact of the JCA on future drug reviews.

## RESULTS

### PERCEPTION OF JCA AND IMPACT ON EU ACCESS AND REIMBURSEMENT

- Payers across Germany, France, Italy, and Spain agree the JCA will have a positive impact on the access and reimbursement policies across the EU, with N=5/8 citing the standardization of regulatory procedures as the top driver of positive perceptions
  - These payers suggest the JCA will expedite the approval, pricing, and reimbursement decisions of new medicines and provide greater transparency in the assessment
- While German and French payers believe their country's clinical value priorities will be reflected in the JCA framework, Italian and Spanish payers are less certain (though not viewed negatively), and believe their countries will eventually adapt to the JCA standardized process (and forego their national assessment)
- At present, the JCA is expected to take effect in January 2025 (Figure 1), with full implementation (i.e., across all EMA-registered drugs) by 2030

**Figure 1 – Timeline of JCA Implementation**


** Coordination Group will include EMA and HTA body representatives, patient representatives, healthcare professionals, and potentially industry representatives.*

### FUTURE OF HEALTH TECHNOLOGY ASSESSMENTS POST-JCA

- Despite high confidence in the parameters and evaluation criteria within the JCA (Figure 3), payers still expect their countries to conduct their own supplemental clinical assessment
  - Rather than create redundancies in work, payers foresee the JCA inputs will feed into / enhance their country-specific evaluations
  - However, French, Italian, and Spanish payers expect some initial adoption inertia as they gain comprehension around the JCA's clinical assessment of new products vs. their own (i.e., countries may initially repeat full assessments to understand the differences that exist)
  - German payers, however, believe the incorporation of the JCA will be quick, with integration of the JCA dossier into their G-BA process already being planned
- Both Italian payers and N=1/2 Spanish payers believe that their countries may work towards implementation of a cost-effectiveness mode upon JCA implementation
  - These payers note current national limitations (e.g., inability to critically review indirect product comparisons) to effectively implement CE models within IT/ES

**Figure 2 – Top Pros and Cons of JCA Adoption in the EU** *(from the payer perspective)*

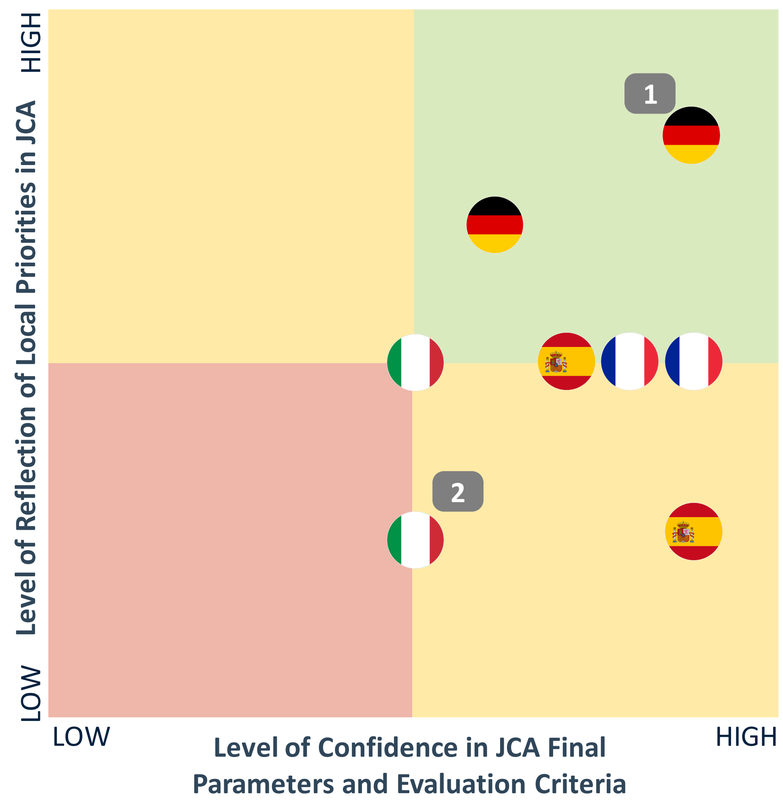
| | PROs | CONs |
|---|---|---|
| 1 | HTA Process Standardization Across EU | Increased Coordination Efforts |
| 2 | Expedited HTA Process | Lack of Reflection of Local Priorities |
| 3 | Improved Quality of Assessment *(IT / ES Payers)* | Potential Delays/ Redundancies |

> *"[We expect a supplemental clinical assessment even with the implementation of the JCA] at the beginning to check the overlap of what our agencies usually do and what the JCA will do. If we find a match between the two approaches, Italy could start to rely more on the JCA more and reduce the burden of country assessment."*
>
> *-Italian Payer*

> *"We will adjust our dossier template to allow integration of the JCA… The manufacturers will be able to use much of the JCA material to fill in the G-BA template."*
>
> *-German Payer*

> *"Currently the economic evaluation of new pharmaceutical products in Spain is very precarious and not transparent; therefore, there is a strong will to converge on the European evaluation. Health economists want to create a cost per QALY specific to Spain, but they find that it is a lot of work and there is not enough support currently."*
>
> *-Spanish Payer*

**Figure 3 – Payer Perceptions of the JCA by Country**




1. German payers believe that the JCA will generally reflect similar clinical priorities as the current assessment, with the potential exception of indirect comparison acceptance in G-BA
2. Believed the CE model of EU would slow Italy's uptake of JCA and limit its current reflection of clinical priorities

## DISCUSSION, LIMITATIONS AND CONCLUSION

### Discussion

Overall, payers interviewed believe the economic assessment of new products (post-JCA implementation) will evolve. Although it is still an open question as to what those changes will look like and when they will go into effect across each country individually, there is the potential for a more standardized European clinical assessment procedure. This may also enable shifts in economic considerations/assessments across Italy and Spain towards a cost-effectiveness (CE) model, as manufacturers will likely design their future clinical trials in compliance with JCA priorities (which will more closely reflect CE model priorities vs. budget impact).

> *"The main advantage is the degree of harmonization on a European scale, offering greater visibility for manufacturers. It will also make it possible to create a harmonized framework on a transnational basis. The limitations are that the assessment of efficiency is a contextual element, dependent on economic and political choices, and that the national level will continue to be required."*
>
> *-French Payer*

### Limitations

There is limited publicly-available information on the JCA currently, and payers as well as EU member states remain unclear on what the final implementation of JCA will look like. When looking towards past examples of multi-country assessments (e.g., EMA), payers believe it was successful on a regulatory level. However, as it pertains to the HTA process, payers are less certain of the outcome given the differences across country priorities, SoC and clinical guidelines, and even willingness to pay. Initial anticipated clinical assessment redundancies may hinder manufacturer regulatory ease (vs. enabling a smoother process as intended by the JCA).

> *"I think that the multi-country EU assessments for new product evaluation processes will create alignment and cohesion across countries with problem in the evaluation process of new products and their market access. In countries with strong processes and reference agencies, they may keep using their approach with no significant changes."*
>
> *-Italian Payer*

### Conclusion

A standardized European HTA process through the JCA is likely to enable high quality, quick clinical assessment of new pharmaceuticals. Standardization across countries is also meant to enable an easier regulatory process for manufacturers looking to launch new products in Europe. However, of the countries interviewed, Germany is the only country expecting relatively seamless integration of the JCA (likely due to the match in both local clinical priorities plus high confidence in JCA parameters). Overall, payers had positive perspectives regarding JCA implementation, though it will require the trust of both payers and manufacturers to become the sole HTA process across the EU.

> *"Due to close involvement of G-BA and IQWIG, I see a good chance that the JCA is the basis for the final HTA decision for Germany. It will not replace our HTA decision but will provide a relevant part of the evidence needed for a HTA decision for a new product [in Germany]."*
>
> *-German Payer*

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