# Implications of the European Joint Clinical Assessment on Pharmaceutical and Medical Technology Company Market Access and Evidence Generation Strategy

HTA401

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## Summary

- Familiarity and awareness of the JCA amongst the pharmaceutical, biotech, and medical device industries are high
- Market Access, HEOR, and RWE are highlighted as the functions with the highest level of involvement in JCA planning
- Most respondents believe that the JCA will open the door for industry to consider early entry in smaller / prior lower-priority markets
- There is not a consistent perception of the impact that the JCA will have on product preparation and launch and evidence-generation plans
- All respondents agree on the importance of increased internal cross-functional collaboration across global, regional, and local stakeholders
  This collaboration is key to ensuring access success and underscores the importance of each individual's contribution

## Introduction

Health Technology Assessments (HTAs) of pharmaceuticals and medical devices in Europe have historically been conducted in a decentralized manner[1]. The Joint Clinical Assessment (JCA) is set to streamline the HTA process to reduce duplication of work across HTA bodies and increase efficiency. Previously, the EU had three iterations of centralized HTA components, Joint Action 1-3 (JA1-3), though the low utilization and a lack of universal adoption of HTA content has limited their value [2,3].

The JCA is mandatory for all pharmaceutical and medical technology undergoing HTA and will be introduced for oncology and advanced therapy products in January 2025, orphan-designated drugs in 2028, and all EMA-registered drugs in 2030. JCAs will run in parallel with the EMA assessment and CHMP recommendation. JCAs will not provide any additional recommendations for member state HTAs; they will just provide a consolidated evidence package comprising an assessment and summary report[3].

The embedding of JCAs into member state HTAs presents a challenge, both for individual HTA bodies that may or may not want to rely on a centralized format for evidence submission and for pharmaceutical and medical device companies submitting HTAs for new assets, particularly in early years[3].

## Objectives

This study is designed to evaluate the extent to which the introduction of JCA requirements has influenced the preparedness of pharmaceutical and medical technology companies for their European launch. It also aims to gauge industry experts' expectations regarding the impact of JCA on strategic decisions.

## Methods

A 5-minute quantitative survey was distributed online with pharmaceutical, biotech, and MedTech industry professionals. The study aimed to quantify the impact of JCA on the time taken to enter EU markets, evidence generation plans, and the level of investment required for evidence generation, among other factors.

## Results

**Figure 1 |** Respondent background

N=10 professionals across the pharma, biotech, and MedTech industries responded to the survey

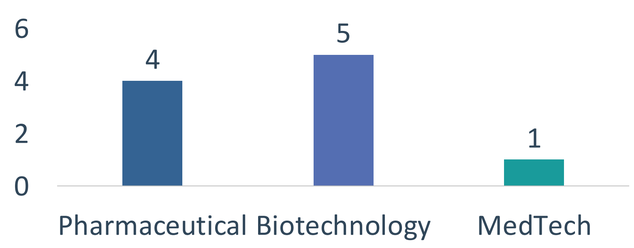



**Figure 2 |** Respondent familiarity with the JCA

All respondents rated their familiarity with the JCA as 3 or higher (scale from 1 [not familiar] to 5 [very familiar])

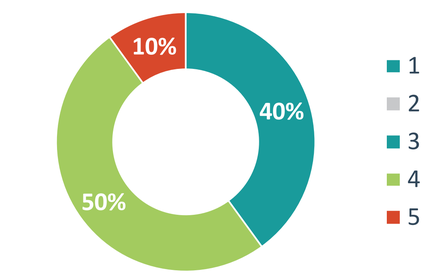



**Figure 3 |**
Which departments are involved in preparing for the JCA

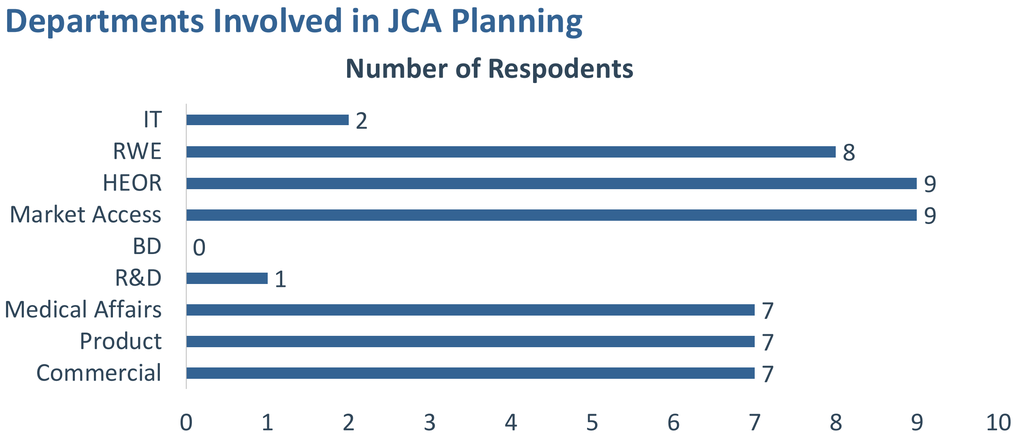



**Figure 4 |** Impact of JCA on product preparation and launch strategy

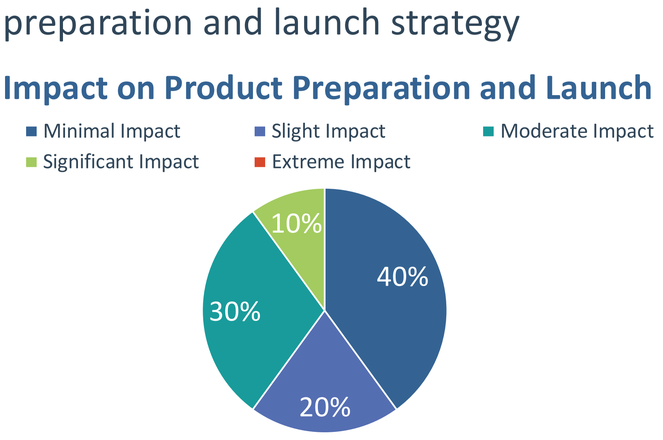



**Figure 5 |** Impact of JCA on evidence generation strategy

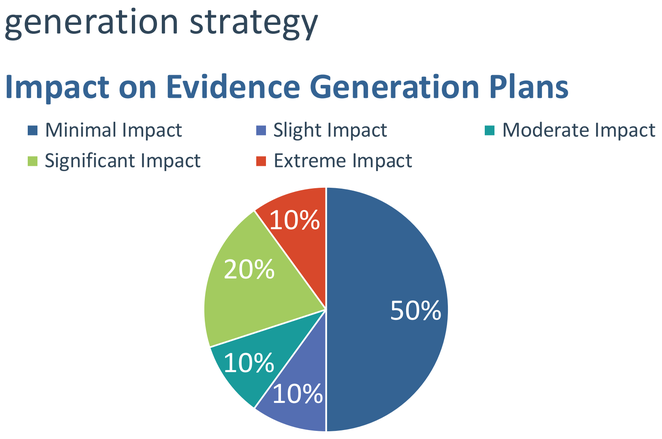



**Figure 6 |** Impact of JCA on EU market access

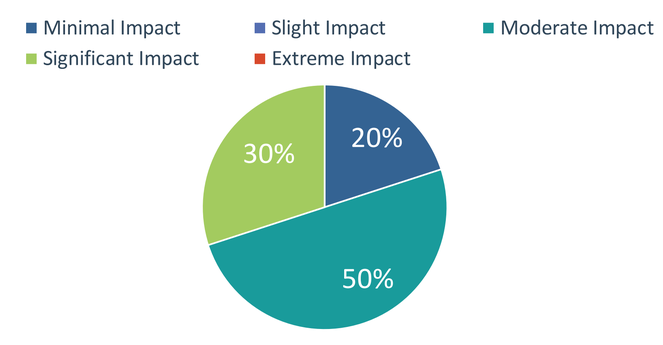
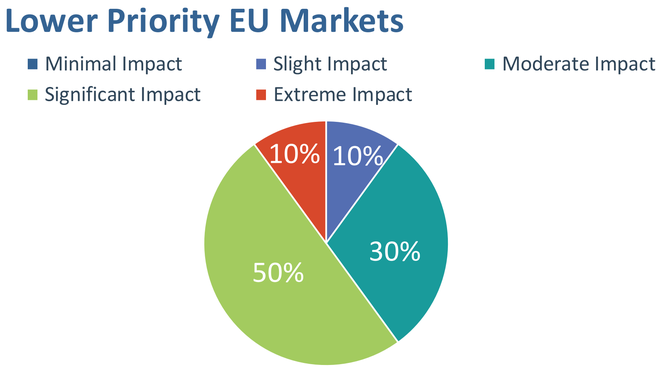



**Figure 7 |** Impact of JCA on access to smaller/previously lower priority markets




### Other Considerations

- More roles involved in process
- Resource challenges due to parallel regulatory and JCA, both requiring input from medical, stats and clinical
- JCA country-level adoption uncertainties
- Deprioritization of NICE process
- Increase overall the requirements for comparative effectiveness, which may increase burden of proof/evidence
- Planning and investment in local affiliates across smaller markets

## Conclusions:

Implementing the JCA has somewhat impacted the product planning and launch process. On the one hand, it is certain that the JCA will increase industry interest in entering smaller lower-priority markets – perhaps because the JCA will enforce a more robust process to prepare for launch in these markets compared to previous strategies for established markets. On the other hand, it is still unclear how investment in evidence generation, timeframes for product launch, and viability of market entry will be impacted. While the industry can hypothesize about the JCA's impact in the upcoming years, only the first assessments in 2025 will provide insight into the real-world value and challenges of the JCA implementation.

## References

[1] Mapping of HTA Methodologies in EU and Norway – The European Commission
[2] EU REA – Learnings From the First Three EUnetHTA Joint Action 3 Assessments – Charles River Associates
[3] Schuster V. EU HTA Regulation and Joint Clinical Assessment-Threat or Opportunity? J Mark Access Health Policy. 2024 May 13;12(2):100-104. doi: 10.3390/jmahp12020008. PMID: 38808311; PMCID: PMC11130920.

## Abbreviations

**BD**: Business Development
**CHMP:** Committee for Medicinal Products for Human Use
**EMA:** European Medical Agency
**HEOR**: Health Economics and Outcomes Research
**HTA:** Health Technology Assessment
**JA:** Joint Action
**JCA:** Joint Clinical Assessment
**PICO:** Population, Intervention, Comparator, Outcome
**R&D**: Research and Development
**RWE**: Real-world Evidence

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