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# Analysis of Feedback Shared on the Draft Implementing Act of the Joint Clinical Assessment (JCA)

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## INTRODUCTION

- The **Joint Clinical Assessment (JCA)** is intended to be a streamlined process in which a single data submission addresses issues of relative effectiveness and relative safety.
- JCA **is non-binding and will not make value judgments or conclusions on added clinical value**.
- The ability to make value judgments and pricing and reimbursement decisions remain under the sovereignty of the member states.
- The JCA process is **overseen by the Member State Coordination Group** on Health Technology Assessment (HTA), which appoints both an assessor and co-assessor from different member states responsible for the clinical assessment, drafting of a report, and consultation with stakeholders.
- The Commission's Implementing Act on Joint Clinical Assessments for medicines for human use was finally adopted on 23 May 2024. JCA divides the process into four steps (**Fig. 1**): 1). The scoping phase, encompassing the development and validation of PICOS; 2). JCA dossier development phase; 3). JCA dossier assignment phase; 4). The publishing of the final JCA report

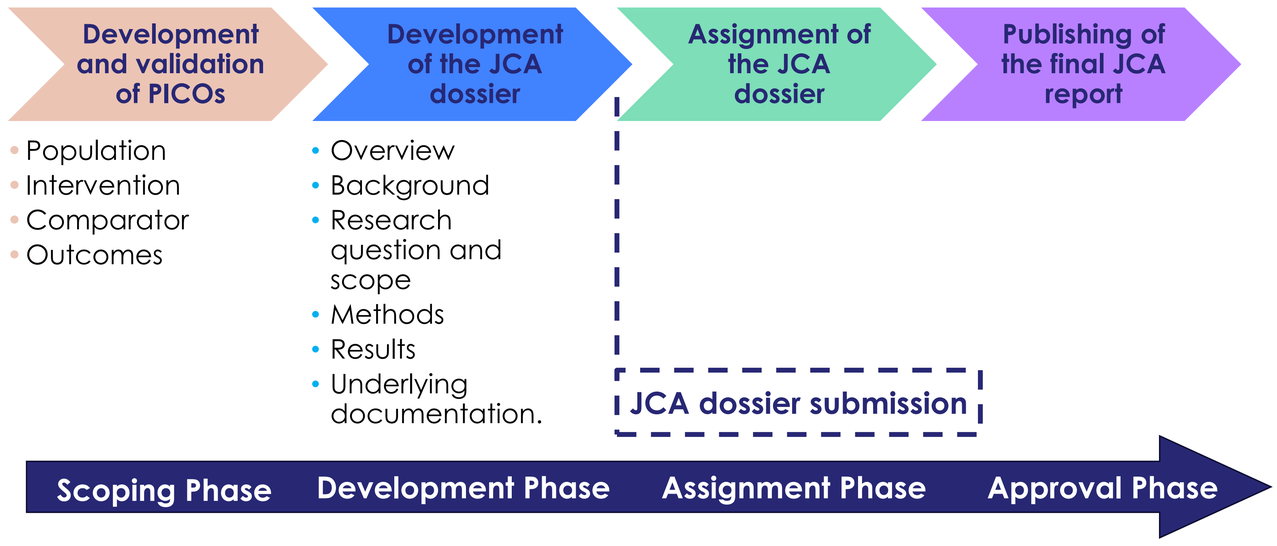



**Fig 1. Overview of the JCA process**
This figure illustrates outlines the steps involved in the JCA process.
Abbreviations: JCA: Joint Clinical Assessment

## OBJECTIVES

- JCA aims to accelerate patient access to innovative medicines with a single data submission on effectiveness and safety.
- The draft **Implementing Act** was released for feedback from March 5 to April 2, 2024. Our analysis evaluates this feedback to enhance the JCA process and improve patient access.

## METHODS

- We analysed 129 feedback statements on the draft Implementing Act for JCA collected from March 5 to April 2, 2024. Feedback from diverse stakeholders, including NGOs, companies, research institutions, and citizens, was categorized by organization type.
- Key themes identified included stakeholder engagement, timeline alignment with EMA processes, and data confidentiality.

## RESULTS

**Fig 2. Distribution of Feedback by Category of Respondent**

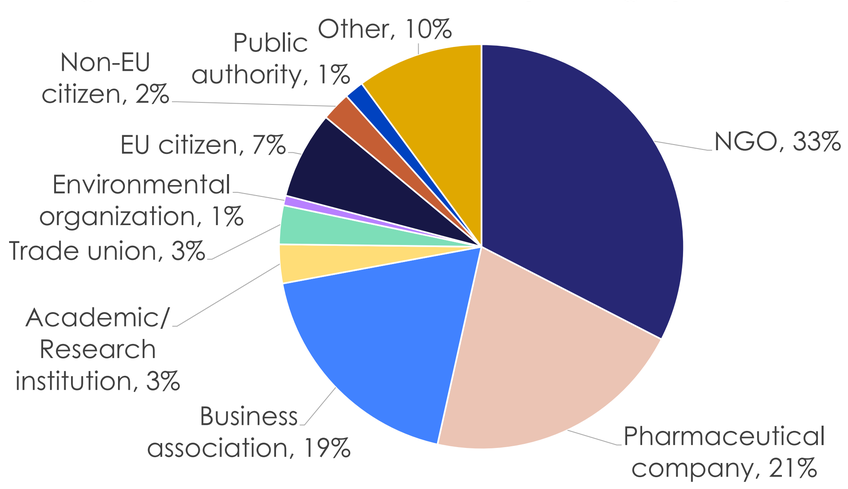
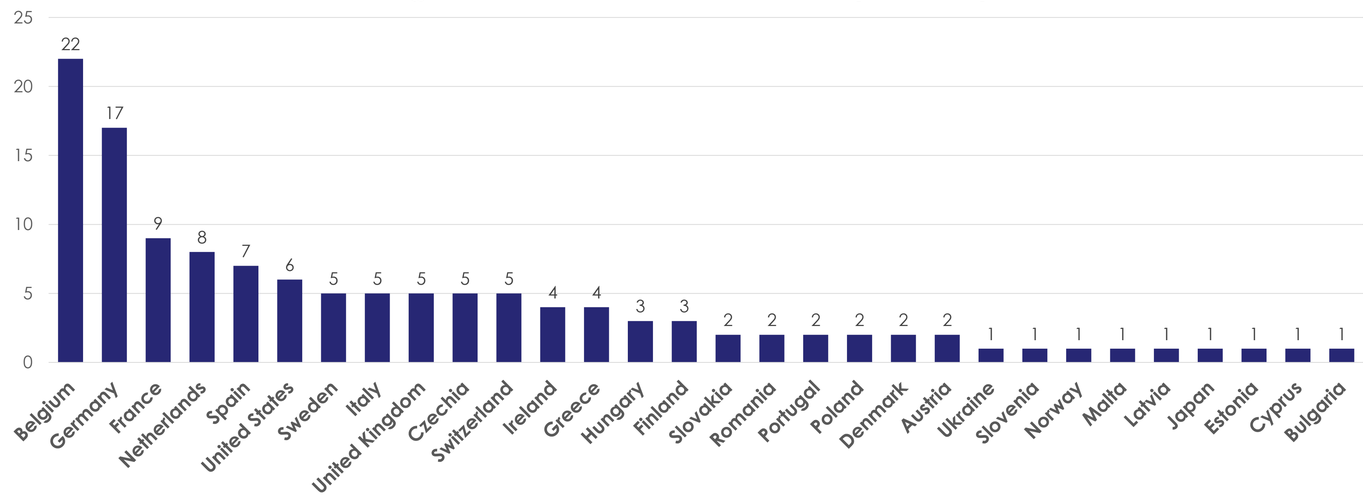



**Fig 3. Distribution of Feedback by Country**




Feedback shows that patient groups, clinicians, and industry across Europe are **highly engaged**, highlighting a **shared commitment to improving the JCA process**.

**Key Themes Identified:**

**Feedback was predominantly focused on Articles 2, 11, 12, 14, and 20 of the JCA draft.**

### 1 Stakeholder Engagement

- Involve HTA developers early in the scoping process for effective insight integration.
- Engage a diverse group of stakeholders, including patients and clinical experts, to improve the assessment process.
- Conduct mandatory scoping meetings to clarify roles and expectations.

### 2 Timeline Alignment

- Extending dossier preparation timelines allows for thorough analysis and better outcomes.
- Aligning timelines with European regulatory processes improves efficiency and reduces bottlenecks.
- Flexibility is essential to adapt to changes in populations or indications during assessment.

### 3 Confidentiality and Data Protection

- Robust frameworks are crucial for protecting sensitive information during assessments.
- Clear criteria for classifying confidentiality ensure transparency and consistency.
- Stakeholders need assurance that their data will be handled transparently, particularly regarding confidentiality requests.

### 4 Evidence Considerations

- Clear assessment guidelines and PICO development enable reliable evaluations.
- Including patient preferences and real-world evidence prioritizes patient-centred outcomes.
- The process should adapt to evolving evidence needs for relevance.

### 5 Transparency and Communication

- Clear communication and criteria during assessments build collaboration and trust.
- Keeping stakeholders informed about timelines and progress enhances engagement.
- Transparency in addressing "missing information" and clarifying methods improves assessment quality.

The feedback received demonstrates the necessity for refinements in the JCA process to enhance **transparency**, **efficiency**, and **protection of sensitive information**. Key stakeholder groups — including patient organizations, clinicians, and industry representatives — consistently pointed to improvements that could help ensure the JCA process **aligns with the needs of all involved parties**.

## CONCLUSIONS

- Overall, the feedback on the draft Implementing Act for JCA was consistent, emphasizing five key areas for revision: stakeholder engagement, submission timelines, management of commercially sensitive data, evidence considerations, and transparency & communication.
- Stakeholders stressed the need for early, ongoing involvement, alignment with EMA timelines, and stronger data protection frameworks. Addressing these concerns will ensure a smoother process, faster access to innovative treatments, and increased transparency. Implementing these revisions will improve collaboration, safeguard sensitive data, and optimize the JCA process to better meet patient and clinical needs.

## REFERENCES

1. European Commission - Have your say. (n.d.). European Commission - Have Your Say. Retrieved November 6, 2024, from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products/feedback_en?p_id=32560995; 2. Rudd, A. (2023, April 3). What is the joint clinical assessment and what does it entail? Remap Consulting. https://remapconsulting.com/hta/what-is-the-joint-clinical-assessment-and-what-does-it-entail/

## Disclosures

Authors have no conflict of interest to declare.

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