Exploring stakeholders' perceptions of the EU Health Technology Assessment Regulation and access to innovative medicines in Europe and the Netherlands: opportunities, challenges, and recommendations

Poster # **HPR29**

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INTRODUCTION

- The new EU Health Technology Assessment Regulation (EU HTAR) (2021/2282) marks a major shift in how innovative medicines are evaluated for access across Europe.[1]
- The regulation introduces the Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC), establishing centralized assessments of clinical effectiveness.
- Significant delays and disparities in access to innovative medicines persist across Europe, particularly affecting high-need areas such as oncology and countries with limited resources or complex reimbursement pathways.[2]
- By replacing fragmented, country-specific reviews with EU-wide HTA processes, the regulation aims to reduce duplication, enable evidence-based decision making, and ensure more timely and equitable patient access.
- While the new regulation promises greater efficiency and equity, its implementation brings fresh challenges and uncertainties for healthcare systems and stakeholders.
- This research explored stakeholder perceptions of the JCA and JSC and investigated their potential impact on access to innovative medicines in Europe.

METHODS

- A qualitative exploratory design was used to understand stakeholders' perceptions of the JSC and JCA.
- Stakeholders from diverse healthcare organizations across six EU countries were recruited through purposive sampling, including referrals, online outreach, and direct contact at the World EPA Congress in Amsterdam.[3]
- Eligibility required participants to have direct or indirect involvement with the EU HTAR and basic knowledge of these procedures; non-EU stakeholders were excluded.
- Semi-structured interviews (conducted online and in person in April-May 2025) explored (expected) opportunities, challenges, and impacts related to the JSC and JCA, guided by five dimensions of access: awareness, accessibility, accommodation, affordability, and acceptability.[4]
- A total of 17 interviews were conducted, with representatives from pharmaceutical companies, health insurance companies, consultancy firms, patient organizations, healthcare providers, and policy institutions. (Table 1)
- Interviews were audio-recorded (with consent), transcribed, anonymized, and analysed using thematic analysis in ATLAS.ti, employing both inductive and deductive coding to identify patterns and themes.
- Sampling and interviewer biases were considered and minimised by transparent recruitment and objective questioning; data saturation was reached with no new themes emerging in final interviews.
- All participants gave informed consent, data was securely managed and anonymized, and institutional ethics were followed.

RESULTS

Six key themes were identified from stakeholders' perceptions of the JSC and JCA. (Figure 1, Table 2, Figure 2)

- **Awareness**: Most stakeholders are familiar with the JSC and JCA initiatives, but the level of understanding often remains concentrated within certain individuals or departments due to limited internal information flow.
- **Accessibility & equity:** There are mixed views on acceleration or delay of access to new medicines by the JSC and JCA. Optimism on timely access and equity is highest for countries with less developed HTA systems.[5]
- **Integration & preparedness:** Readiness to adapt to the JSC and JCA varies widely. Larger and more experienced organizations have made more progress than smaller and less experienced organizations due to resource constraints and lower familiarity. Unclear procedural guidance and demanding data requirements were reported by almost all stakeholders as significant challenges.
- **Stakeholder collaboration:** Transparent and inclusive cooperation is vital to success; e.g. strong internal teamwork, cross-country collaboration, and active involvement of patients and HTA bodies, with proactive knowledge sharing especially important for supporting less experienced countries.
- **Trust & acceptability:** While there is cautious optimism about the potential benefits of harmonization, stakeholders stress the need for practical, user-friendly processes that avoid unnecessary bureaucracy. National trust and collaboration are crucial for the new procedures to deliver real value but varied widely across countries.
- **Learning & reflection:** Continuous learning, sharing of experiences, and ongoing adaptation are considered essential. Stakeholders prefer real time evaluation and improvement based on feedback to ensure rapid, practical progress, instead of waiting for formal reviews.

Only 24% of stakeholders expected the EU HTAR to improve time to access and equity across Europe, others were concerned about delays and were uncertain or had mixed views. (Figure 3)

Figure 1. Key themes in stakeholders' perceptions of the JSC and JCA implementation

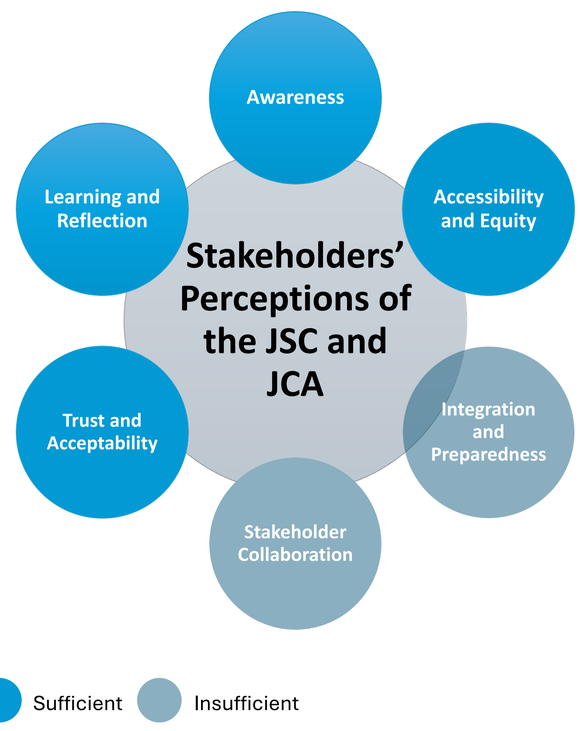


Table 1. Overview of interviewees

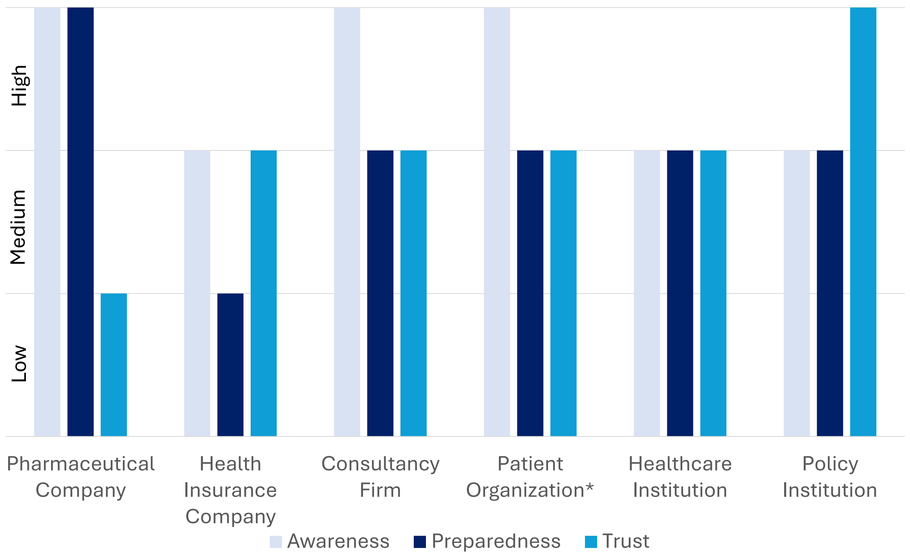
Participant	Organization	Country	Recruitment	HTA Experience
1	Consultancy Firm	Netherlands	World EPA congress	High
2	Consultancy Firm	Netherlands	Referral	Medium
3	Consultancy Firm	Netherlands	Referral	High
4	Health Insurance Company	Netherlands	Referral	Medium
5	Health Insurance Company	Netherlands	Referral	High
6	Healthcare Institution	Netherlands	Referral	Low
7	Healthcare Institution	Netherlands	Referral	Low
8	Patient Organization	Netherlands	Online outreach	High
9	Pharmaceutical Company	Hungary	Referral	High
10	Pharmaceutical Company	Nordics	Referral	High
11	Pharmaceutical Company	Multi-country (EU)*	Referral	High
12	Pharmaceutical Company	Spain	Referral	High
13	Pharmaceutical Company	Netherlands	Referral	High
14	Pharmaceutical Company	Multi-country (EU)*	Referral	High
15	Pharmaceutical Company	Netherlands	Referral	High
16	Policy Institution	Netherlands	Referral	Medium
17	Policy Institution	Italy	World EPA congress	High

Based in Switzerland; role covers EU-level activities rather than Swiss national focus

Table 2. Perceived sufficiency across key implementation themes

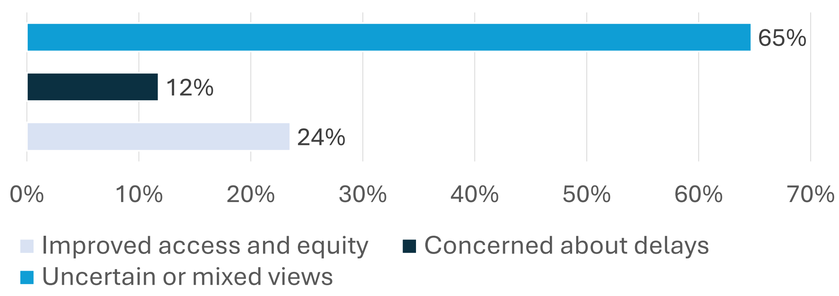
Themes	Sufficient	Insufficient
Awareness The level of knowledge and understanding of the JSC and JCA	83.4%	17.6%
Integration and preparedness The extent to which organizational adaptations have been made to meet the new requirements of the JSC and JCA	52.9%	47.1%
Collaboration The perceived quality of relationships between stakeholders within and across countries	58.8%	41.2%
Trust and acceptability The extent to which stakeholders regard the JSC and JCA as valuable	70.6%	29.4%
Learning and reflection The degree to which ongoing learning and critical reflection are actively prioritized and embedded in practice	76.5%	23.5%

Figure 2. Comparing awareness, preparedness, and trust by organization type



Only one patient organization was interviewed, so the findings may not be representative of all patient organizations

Figure 3. Expected impact on equity and time to access



DISCUSSION

- This study revealed several critical findings in the early implementation of the EU HTA regulation. Although individual stakeholder awareness is high, poor internal communication limits organizational readiness and coordinated action.
- There is cautious optimism about narrowing access gaps, particularly for countries with less mature HTA systems, but concerns persist about procedural complexity, duplicated assessments, and the risk of additional delays in established systems. Most organizations, regardless of size, face overwhelming requirements and unclear guidance.
- The level of trust and collaboration varies significantly across countries, highlighting the urgent need to actively share best practices. Persistent gaps in collaboration and transparency among countries and stakeholder groups continue to threaten unified progress. Building trust and securing buy-in from all stakeholders will depend on delivering genuine practical value rather than adding more bureaucracy.
- Key strengths of this study include its timely capture of early perceptions and in-depth cross-stakeholder analysis, but limitations such as overrepresentation of pharmaceutical companies and lack of HTA agency input may skew perspectives. Future research should expand stakeholder diversity and incorporate quantitative measures.
- Ultimately, continuous adaptation, clear communication, and a strong EU-wide commitment will be essential to transform promise into true progress for timely and equitable access.

KEY FINDINGS & CONCLUSIONS

- Awareness of the JSC and JCA is high, but information and communication gaps persist within organizations.
- There are mixed expectations about the impact on medicine access; optimism is greatest for countries with less developed HTA systems.
- Unclear procedural guidance and demanding data requirements are the most reported expected barriers.

Action Points

- Build open, transparent collaboration, and strong trust among all stakeholders, with additional support for less experienced nations.
- Cultivate an EU-wide culture of learning and commitment.
- Keep patient benefit at the core by prioritizing a practical process over bureaucracy, using stakeholder input to drive real-time improvements.

LIST OF ABBREVIATIONS

EU	European Union
EU HTAR	EU HTA Regulation
HTA	Health Technology Assessment
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
World EPA congress	World leading healthcare evidence, pricing and access congress

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DISCLOSURES

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References 1) European Union. (2021). Regulation (EU) 2021/2282. **2)** EFPIA. (2022). The root cause of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines. **3)** Terrapinn Holdings Ltd. (2025). World EPA Congress. **4)** Penchansky, R., & Thomas, J. W. (1981). The Concept of Access: Definition and Relationship to Consumer Satisfaction. Medical Care, 19(2). **5)** Frontier, A. M., Visintin, E., & Kanavos, P. (2021). Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. PharmacoEconomics - Open, 6(3), 315–328.