

# Evaluating the Role of Societal Perspectives in the EU Joint Clinical Assessment Framework and in EU-27 Health Technology Assessment Guidelines



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## Background

- + Health Technology Assessment (HTA) in Europe increasingly recognises that the value of new interventions extends beyond clinical patient outcomes to include caregiver burden, productivity impacts, and wider societal costs.
- + These considerations are especially relevant in rare diseases, where indirect effects on families and health systems can be substantial.
- + Yet approaches remain inconsistent: some HTA bodies provide explicit guidance on societal perspectives, while others offer little direction.
- + At the European level, the Joint Clinical Assessment (JCA) framework offers only limited scope for broader value, raising concerns about alignment with national requirements and the risk of divergent assessments.
- + Greater clarity on how broader value is addressed across the European Union (EU) is needed to support methodological development and harmonisation.

## Objectives

- This study aimed to:
- + Map how broader value elements—caregiver burden, productivity, and other societal costs — are addressed in the EU JCA dossier and in all EU27 national HTA guidelines.
  - + Summarise 2019-2025 peer-reviewed evidence on methodological challenges, data gaps and potential solutions.

## Methods

- + A targeted literature review in EMBASE and PubMed (2019-2025) and a comprehensive review of guideline documents from the European Medicines Agency (EMA), European Network for HTA (EUnetHTA) and every national HTA agency website was performed.
- + AI-assisted data extraction with full human quality control was performed to capture required perspective, caregiver burden, productivity, and any additional broader value references. Narrative synthesis identified recurring challenges and proposed remedies.

## Conclusions

- + Broader value is recognised in principle across Europe but operationalised inconsistently. The current JCA process provides minimal mechanism to capture societal benefits, risking divergent national decisions and undervaluation of technologies with substantial caregiver or productivity effects.
- + Embedding an optional structured “broader value module” in the JCA dossier, harmonising definitions of societal perspective, and investing in cross-country data infrastructure - especially for rare diseases - would facilitate more consistent, comprehensive value assessments.

## Results

- + Twenty-four guidelines were reviewed; HTA guidelines were not identified for Cyprus, Luxembourg, or Malta.
- + Nine guidelines require or strongly recommend a societal perspective (Figure 1).
- + Productivity impacts are explicitly referenced in 16 guidelines, while caregiver burden or family spillover effects in 14. Three guidelines do not address either<sup>1</sup>.

Figure 1. EU Member States Referencing Societal Perspective in National HTAs



- + The JCA template confines assessment to clinical domains; consideration of broader value is limited to a brief qualitative “organisational and societal impact” paragraph, with no structure for quantitative inputs<sup>11</sup>.
- + Methodological differences occur due to concerns around double counting and differing definitions: measurement of productivity using human or friction cost, and definition of societal perspective<sup>12</sup>.
- + Emerging solutions include caregiver-specific instruments, real-world registries, and transferability adjustment factors, but uptake remains limited.

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**Abbreviations:**

EU: European Union; HTA: Health Technology Assessment; JCA: Joint Clinical Assessment; EUnetHTA: European Network for HTA; DMC: Danish Medicines Council; TLV: Swedish Dental and Pharmaceutical Benefits Agency