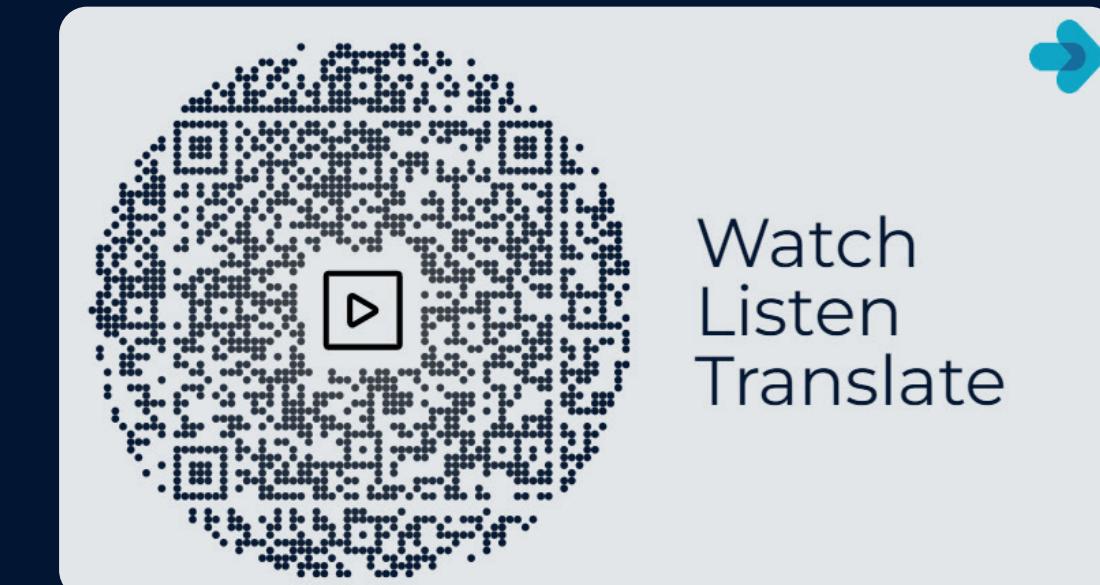


Evaluating the Role of Societal Perspectives in the EU Joint Clinical Assessment Framework and in EU-27 Health Technology Assessment Guidelines

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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

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 either¹.

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

| Key: | Required | Recommended | Mixed approach |
|--|---|--|--|
|  Denmark² | <p>The DMC employs a “limited” societal perspective as reference case</p> <p>This includes patient/relative time and transport costs but excludes productivity loss</p> |  Finland³ | <p>Primary perspective is the publicly funded health and social care system</p> <p>A full societal perspective is not required in base case; however, inclusion of broader costs can be considered in sensitivity analyses</p> |
|  Hungary⁵ | <p>The national healthcare system perspective is mandatory as the base case</p> <p>A societal perspective analysis is recommended in addition if a significant portion of costs or benefits lies outside the healthcare system</p> |  Ireland⁶ | <p>The reference-case perspective on costs is the publicly funded health and social care system</p> <p>A broader societal perspective is allowed as a supplementary analysis, especially if an intervention has significant non-healthcare costs or benefits</p> |
|  Romania⁸ | <p>A scoring system for drug HTA that considers clinical and economic factors is used</p> <p>Cost-effectiveness is assessed using both the third-party payer and societal perspectives in the scoring model. Detailed guidelines are not published; evaluations largely reference international assessments</p> |  Spain⁹ | <p>Societal perspective is recommended as the reference case in Spain</p> <p>All costs and consequences to society (not just the health system) should be considered in economic evaluations</p> |
|  France⁴ | <p>The reference case is a “collective” perspective, covering all costs regardless of payer within the health system</p> <p>In practice, this means including costs to all public payers (and patient co-pays) but excluding broader societal costs like productivity</p> |  Netherlands⁷ | <p>The Dutch guidelines mandate a societal perspective as the base case for all evaluations</p> <p>All relevant costs and benefits “irrespective of who bears them” must be included. (A separate analysis from healthcare perspective is also typically reported for decision-makers)</p> |
|  Sweden¹⁰ | <p>Sweden employs a societal perspective in cost-effectiveness analyses</p> <p>All relevant costs regardless of payer (national, regional, municipal) are included. In recent practice, TLV applies a “limited” societal perspective – excluding some elements for consistency with ethical principles</p> | | |

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