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Background +

- ✚ The European Union's (EU) new Joint Clinical Assessment (JCA) requires manufacturers to submit a harmonised clinical dossier within 100 days of filing with the European Medicines Agency (EMA).
- ✚ This initiative aims to provide all 27 EU Member States with simultaneous access to identical clinical evidence, thereby streamlining decision-making and potentially reducing disparities in access to innovative therapies.
- ✚ While the JCA is positioned as a mechanism to promote health equity, its practical implications and effectiveness in addressing existing inequities remain unclear.

Objectives +

This study aims to:

- + Review how health equity is considered in national health technology assessments (HTAs) across the EU Member States.
- + Evaluate the potential of the JCA framework to support the generation and use of equity-relevant clinical evidence.

Methods +

A targeted review was conducted to assess how health equity is addressed in EU-level and national HTA processes. This included:

1 EU-JCA documents

19 key regulatory and guidance documents were analysed, including:

- Regulation 2024/1981 on JCAs
- Guidance on Outcomes
- Guidance on Filling the JCA Dossier
- Draft Procedural Guidance on Scoping and Subgroup Analyses

2 National HTAs

HTA guidance documents
from 24 of the 27 EU Member
States were reviewed

3 Literature Review

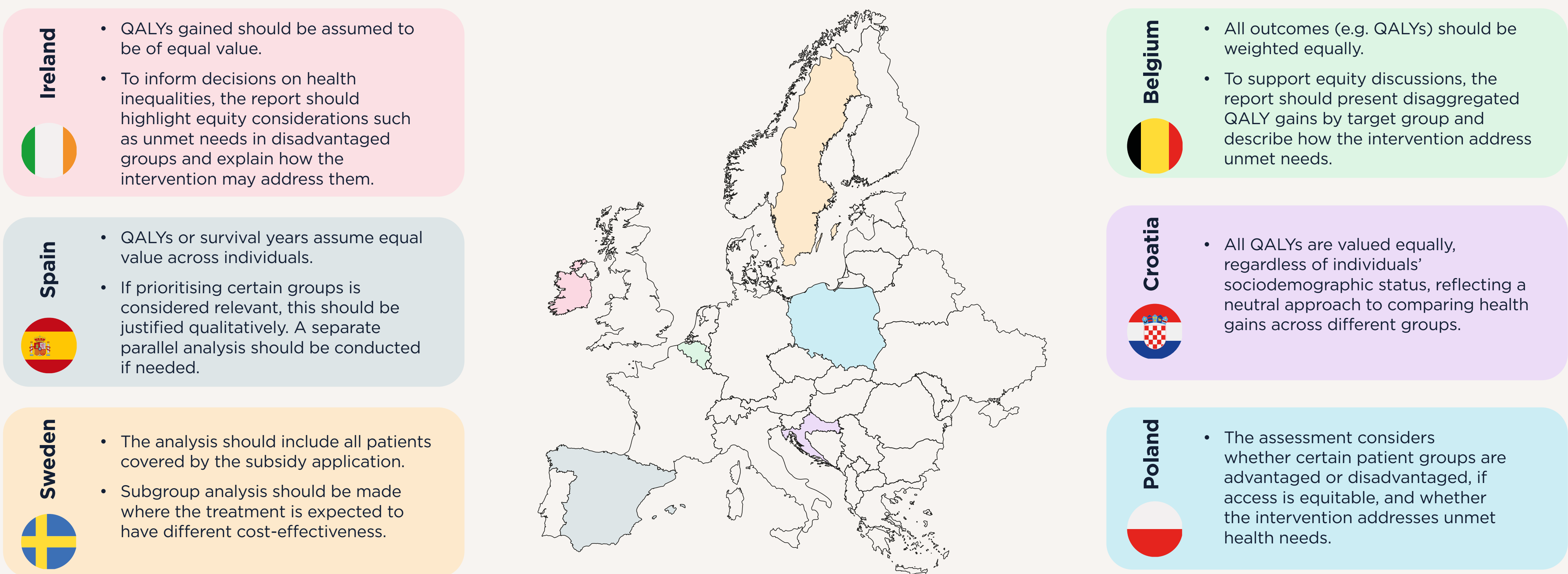
A systematic search on PubMed (n=9) and EMBASE (n=2) identified publications on how health equity is addressed in JCA and national HTA (2020–2025).

Results

- Among the 24 Member State HTAs reviewed, Belgium, Croatia, Ireland, Spain, Sweden and Poland explicitly consider health equity in their HTA guidelines (Figure 1).
- Belgium, Croatia, Ireland, and Spain maintain the standard assumption of equal quality-adjusted life years (QALYs) across populations and encourage supplementary reporting on unmet needs in underserved groups. Sweden considers quantitative subgroup analysis to identify patient groups that may benefit most from an intervention, while Poland adopts a qualitative approach.



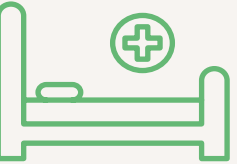







Quality Control: External verification with Avşar et al. (2024) confirmed guidance consistency but highlighted disparities in how health equity is integrated into the HTA guidelines across several markets, particularly Denmark, Hungary and Germany. Data elements were manually screened and extracted, followed by quality control performed on a representative sample, with internal verification confirming 100% consistency across the reviewed dataset.

Figure 1: EU Member States Referencing Health Equity in National HTAs



- ✚ The EU guidance on JCA outcomes requires a full range of clinically and patient-relevant outcomes, along with pre-specified subgroups, where meaningful heterogeneity exists, ensuring the evidence base aligns with equity concerns. However, the JCA dossier template treats these as optional, not mandatory (Table 1).
- ✚ Rare diseases lack dedicated provisions, and Member States remain free to interpret or supplement the joint evidence differently.

Table 1: JCA Outcome Requirements as outlined in the JCA Outcomes Guidance and the JCA Dossier Template Guidance

Guidance on outcomes for JCA			Required	Optional
1		Clinician-reported outcomes		
2		Patient-reported outcomes		
3		Observer-reported outcomes		
4		Subgroup pre-specification (e.g. age, sex, genetic markers)		
Guidance on filling in the JCA dossier template			Required	Optional
1		Subgroup outcomes		

Conclusions

- + Although the JCA aims to promote equitable access, systematic inclusion of equity considerations within its assessment framework is not mandated.
- + Responsibility for identifying and addressing health disparities remains with individual Member States through their national HTA processes, leading to variation in how equity is incorporated across the EU.

Abbreviations

JCA - Joint Clinical Assessment
EU - the European Union
HTA - Health Technology Assessment
QALY - Quality-Adjusted Life Years

[illegible]