How national HTA systems are being reshaped in response to EU HTA: A review of current reforms and early implementation

HTA56

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INTRODUCTION

- The EU Health Technology Assessment (HTA) Regulation (EU 2021/2282) introduced Joint Clinical Assessments (JCAs) to harmonise clinical assessment across EU Member States and reduce duplication of clinical evidence requirements.[1]
- The EU HTA Regulation establishes common obligations for national HTA bodies to give 'due consideration' to JCA reports and avoid duplication of clinical evidence requirements. However, countries retain discretion over how JCA is integrated into national HTA processes
- As JCA implementation progresses, the extent of convergence in national HTA processes, timelines and evidence requirements remains uncertain

OBJECTIVE

To compare early national implementation of the EU HTA Regulation across eight countries and identify areas of convergence and divergence in JCA integration, scientific advice interaction, dossier requirements and assessment processes

CONCLUSIONS

- Early implementation of the EU HTAR remains heterogeneous across Member States, with convergence most evident in avoiding duplication of EU-submitted clinical evidence requirements
- Differences persist in procedural readiness, interactions between JSC and national advice, and alignment of national HTA timelines with JCA availability
- These findings suggest that Member States are adapting existing HTA systems to the JCA framework in distinct ways rather than converging towards a single implementation model
- As national approaches continue to evolve, manufacturers will need to account for both EU-level requirements and country-specific processes when developing pan-European evidence and HTA strategies

METHODS

A structured comparative policy review, as visualised in Figure 1, was conducted to examine publicly available HTA bodies, government and official sources published up to 18/06/2026. Eight countries were included: Germany, France, Italy, Spain, the Netherlands, Sweden, Poland and Hungary. Data were extracted across four domains: legislative/procedural readiness, joint scientific consultation (JSC) national advice interaction, JCA integration and timeline alignment. Findings were compared to identify patterns of convergence and divergence in national implementation approaches

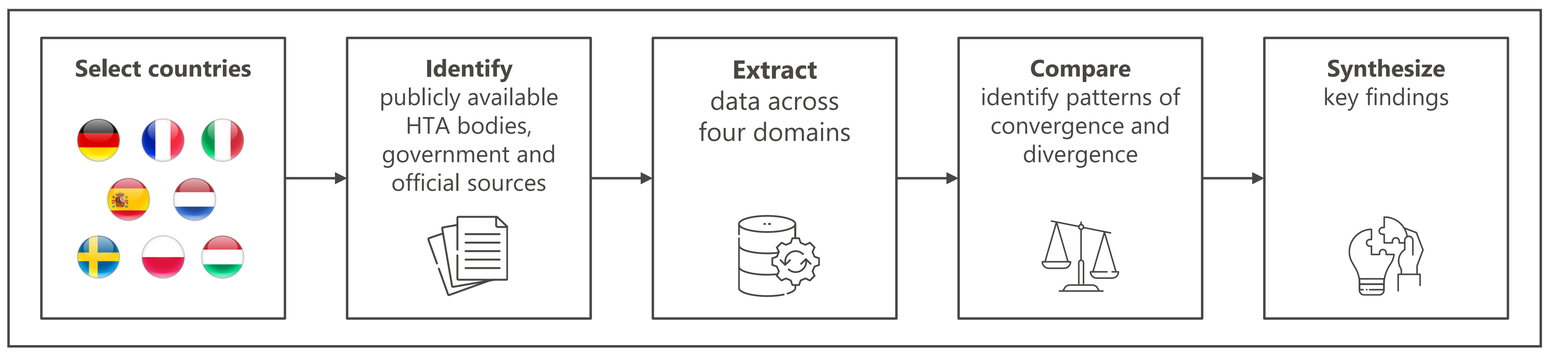


Figure 1. Overview of the research methodology

RESULTS

All eight countries have adapted their HTA processes in response to the EU HTAR, but implementation maturity differs (Table 1)

- Six countries (DE, FR, IT, NL, SE and HU) showed advanced procedural readiness through published manufacturer guidance
- ES and PL had legislated for HTAR alignment but lacked manufacturer-oriented procedural guidance

National dossier requirements persist despite reduced duplication of clinical evidence

- DE, FR, IT and NL require references to relevant EU dossier sections within the national dossier, while ES, HU, PL and SE allow data available through the EU portal to be simply omitted
- Across all reviewed countries, national HTA processes may still require additional country-specific evidence, such as economic analyses and relevant new data available after JCA completion

Beyond dossier handling, national approaches remain country-specific

- SE and NL require JCA report availability before HTA initiation, while in other countries national assessment initiation is not tied to JCA availability
- Explicit timeline alignment with JCA publication was uncommon, with ES being the only country specifying national clinical assessment publication within 15 days of JCA report availability
- FR was the only country where JSC participation precluded subsequent national early advice

Table 1. National approaches to JCA implementation across procedural readiness, advice pathways, dossier requirements and HTA timelines

	Legislative / procedural readiness	JSC vs national-level "scientific advice"	JCA integration into national HTA dossier*	JCA – national HTA timeline alignment
Germany[2-4]	Operational procedures in place	Parallel advice allowed; should avoid duplication	Cross-reference relevant JCA content within specific national dossier sections required	AMNOG starts at market launch; not contingent on JCA report publication
France[5]		Previous or parallel advice not allowed		National appraisal not contingent on JCA publication; JCA considered when available
Italy[6]		None identified		None identified
Spain[7]	Framework established; procedures developing	Parallel advice allowed; must avoid duplication	Data available in JCA to be omitted from national submission	The national clinical report is finalised no later than 15 days after JCA publication
Netherlands[8-9]	Operational procedures in place	None identified	Cross-reference relevant JCA content within specific national dossier sections required	Assessment starts once the JCA is final
Sweden[10]			Data available in JCA to be omitted from national submission	Limited early work may occur, but formal assessment starts once the JCA is final
Poland[11-12]	Framework established; procedures developing			None identified
Hungary[13-14]	Operational procedures in place			

***For all countries:** JCA report (if available) forms the basis of the national clinical assessment. Country-specific evidence/analysis still required

Key: ■ Defined / operational approach ■ Developing / partially defined approach ■ No changes to national process identified

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Abbreviations: AMNOG: Arzneimittelmarktneuordnungsgesetz (German Pharmaceutical Market Restructuring Act); DE: Germany; ES: Spain; EU: European Union; FR: France; HTA: health technology assessment; HTAR: Health Technology Assessment Regulation; HU: Hungary; IT: Italy; JCA: joint clinical assessment; JSC: joint scientific consultation; NL: Netherlands; PL: Poland; SE: Sweden

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