HTA178

How do National Systems take the JCA into Account? Navigating Specificities to Achieve Accelerated Patient Access

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Objectives

This research explores how European market access strategies must adapt to the requirements of the Joint Clinical Assessment (JCA) dossier, focusing on the integration of Member State PICO (Population, Intervention, Comparator, Outcome) input and national evidence requirements. The aim is to identify strategic approaches for dossier development that support accelerated patient access across diverse EU markets such as Germany, France, Netherlands, Belgium and Ireland.

Methods

A review of the JCA dossier template, recent regulatory guidance, and stakeholder perspectives was conducted to assess how launch strategies and evidence generation must align with JCA content requirements. Emphasis was placed on the operationalisation of PICO input, evidence selection, and the transparent justification of methodological choices within the dossier.

Results

Table 1: National JCA Relevance

	Germany (G-BA/IQWiG)	France (HAS)	Netherlands (ZIN)	Belgium (RIZIV/INAMI)	Ireland (NCPE)
Report mandatory for HTA Start	Not mandatory	Not mandatory	Not mandatory	Not mandatory	Not mandatory
Report mandatory for HTA Completion	Not mandatory; considered if available, extend depending on publication timing	Not mandatory; JCA annexed if available at CT opinion; national assessment unchanged	Unclear, expected that availability is required for assessment to be considered complete	Not mandatory; considered if available	Not mandatory; considered if available
Role of JCA Report/Dossier	Reference in Delta Dossier desirable; not mandatory; informs benefit assessment and price negotiation	Input to SMR/ASMR; HAS verifies comparators and methods; no national re-deposit of data; not used in early access	Dossier template specifies where to reference JCA submission dossier/report	Used to avoid duplication in clinical effectiveness assessment; economic review remains national	JCA dossier data may replace clinical inputs if relevant to Irish PICOs
Timing Considerations	Timing conflicts may impede integration; HTA proceeds; JCA annexed when available	Timing conflicts may impede integration; HTA proceeds; JCA annexed when available	Generally aligned with EU HTA timelines; reimbursement request possible only at EC decision	Submission at CHMP remains possible, inclusion of JCA report in the clinical assessment therefore challenging	Timing depends on company decision to submit National application; flexible timing allows integration when available
National PICO Disclosure	Yes, after national dossier submission; pre-submission advice meeting possible in addition	No disclosure forseen	Yes, possible before start of national HTA procedure	Yes, possible before start of national HTA procedure	Not confirmed

In accordance with Article 13 of Regulation (EU) 2021/2282, all analysed HTA bodies consider the JCA report or dossier when available. However, due to timing misalignments between EU and national procedures, integration is not guaranteed. National HTA processes may initiate or conclude independently of the JCA (except for the Netherlands), maintaining traditional assessment pathways. The use of the JCA varies, with some systems mainly aiming to mainly reduce duplication, while others will likely also use it to inform price negotiations. Disclosure of national PICOs remains inconsistent across analysed countries.

Table 2: Country-Specific Recommendations for JCA Dossier Evidence Presentation

	Germany (G-BA/IQWiG)	France (HAS)	Netherlands (ZIN)	Belgium (RIZIV/INAMI)	Ireland (NCPE)
Comparator/ Analysis Requirements	Use G-BA Appropriate Comparator Therapy; if no RCT evidence, include Bucher adjusted indirect comparison	Use "comparateur pertinent" per French practice; direct head-to-head comparison preferred; robust indirect comparisons accepted	Reflect standard of care (stand van de wetenschap en praktijk, incl; off label use); only peer-reviewed data accepted; direct head-to-head comparison preferred; robust indirect comparisons accepted	Compare against standard of care (incl. off label use) and/or reimbursed therapies	Include all relevant Irish alternatives; direct or indirect comparisons possible
Endpoint Presentation	Categorize endpoints: mortality, morbidity, QoL, adverse events (as specified); avoid unvalidated surrogates; use accepted MCIDs	Emphasize pre-specified primary endpoints per CT doctrine (mortality, morbidity, QoL, safety); justify contextualized surrogate endpoints; safety alone rarely sufficient	Outcomes ranked by importance (crucial vs. less important); predefined safety outcomes; MCID requested for every endpoint; avoid unvalidated surrogates	Highlight clinically meaningful differences; surrogates acceptable if widely recognized	Present clinical and QoL outcomes; emphasize model-relevant endpoints
Effect Presentation & Notes	Provide absolute and relative effects (Δ, RR/HR) with transparent methods; justify any post-hoc analyses; include sensitivity and multiplicity considerations to support credibility	Provide absolute and relative effects (Δ, RR/HR) with transparent methods; justify any post-hoc analyses; include sensitivity and multiplicity considerations (HAS emphasizes scientific transparency)	Use both absolute and relative measures; align with JCA standards	Keep tables simple; clarity and simplicity valued	Use tabular formats with absolute/relative measures; distinguish pre-specified vs exploratory analyses

National HTA methodologies show broad alignment with JCA methodological guidance, particularly regarding comparator relevance, endpoint structuring, and effect reporting. However, notable differences persist in the depth and specificity of requirements. Germany and France demand detailed methodological rigor, while Belgium and Ireland adopt more pragmatic approaches. Despite these variations, convergence is feasible when a PICO relevant across jurisdictions needs to be addressed in the JCA dossier. This shared relevance can facilitate cross-national acceptance of evidence, bridging procedural differences and enhancing the utility of the JCA in national assessments.

Effective JCA dossier development requires early and systematic incorporation of consolidated PICO questions, reflecting both EU-level and Member State-specific priorities. The dossier's structure mandates clear articulation of the medical condition, target population, and care pathways, with the option of strategically highlighting regional differences. Evidence selection and synthesis must address each PICO, with justifications for any gaps or deviations, and provide detailed tabular listings of studies by PICO question, including direct and indirect evidence. Methods for information retrieval, data analysis, and synthesis must adhere to the HTA Coordination Group guidance and key national requirements, with explicit rationale for any methodological adaptations. The results section must present relative effectiveness and safety by PICO, ensuring all relevant comparators and outcomes are addressed as per Member State requirements.

Abbreviations: CHMP: Committee for Medicinal Products for Human Use; **CT**: Commission de la Transparence (French scientific committee of HAS); **EC**: European Commission; **EU**: European Union; **G-BA**: Gemeinsamer Bundesausschuss (Germany); **HAS**: Haute Autorité de Santé (France); **HTA**: Health Technology Assessment; **HTD**: Health Technology Dossier; **JCA**: Joint Clinical Assessment; **MCID**: Minimal Clinically Important Difference; **NCPE**: National Centre for Pharmacoeconomics (Ireland); **PICO**: Population, Intervention, Comparator, Outcome; **PICOS**: Plural of PICO; **RCT**: Randomised Controlled Trial; **RIZIV**: Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (Belgium); **RIZIV/INAMI**: Combined Belgian HTA and insurance bodies; **RR/HR**: Relative Risk / Hazard Ratio; **SMR/ASMR**: Service Médical Rendu / Amélioration du Service Médical Rendu; **ZIN**: Zorginstituut Nederland (Netherlands)

Conclusion

To achieve accelerated patient access, manufacturers must embed Member State and local affiliate PICO input and evidence requirements into the strategic planning and content development of the JCA dossier. This necessitates cross-functional coordination, proactive engagement with HTA bodies, and flexible evidence generation plans that anticipate both EU and national expectations, ensuring the dossier robustly supports diverse European market access pathways. While methodologies can be combined to adequately address PICOs relevant across jurisdictions, prioritizing analytical and methodological needs of key markets is likely an integral part of the process. To realize efficiency gains for companies and authorities and thereby accelerating patient access to innovative medicines, data must be prepared and presented in a way that is directly useable for national procedures. That way, even if the JCA report is delayed, the HTD can directly transfer data into national dossiers. This analysis reflects the status quo as of November 2025, methodological and procedural updates to the JCA process are possible with the review of the HTA Regulation in 2028.

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