EU HTA Regulation: All set for 2025?

Partner with IQVIA to be optimally prepared for the new market access pathway in Europe

The implementation of the new European Health Technology Assessment (EU HTA) regulation represents a fundamental turning point for health technology developers (HTDs), HTA bodies, payers, and patients.

Starting in 2025, the HTA clinical assessment of new cancer drugs and Advanced Therapy Medicinal Products (ATMPs) will be conducted centrally. These Joint Clinical Assessments (JCAs) are aiming to streamline HTA efforts across EU Member States and ultimately accelerating patient access to innovative medicines. By 2030, the new HTA process will be rolled out for all drugs, vaccines, in-vitro diagnostics and high-risk medical devices.

What this means for you

Although this new era holds significant promise for all stakeholders, HTDs will need to adjust their current market access strategies and launch preparations to align with the evolving environment. This will ensure they maximize the benefits of the new HTA process.

While several guidance documents on the EU HTA process and assessment methodology have been published, uncertainty remains around their implementation. HTDs need to accommodate these uncertainties in their evidence and tactical planning, not just for assets eligible for the EU JCA in 2025, but also for their pipeline products, to ensure future EU HTA success.

How the new EU HTA process will impact the way health technology developers prepare for market access

PLANNING	EVIDENCE	ANALYSES	AFFILIATES	LAUNCH
Complex JCA dossier will need to be prepared **in parallel to EMA dossier** Alignment needed on **regulatory strategy, including label** **Resource intensive** process with **tight timelines**	Increase in **evidence requirements** for some markets **Patient-reported outcomes** likely to become more prominent Timely preparation for **JSC** needed, if eligible	Impact on **evidence needs** expected to be **exponential** Many **post-hoc analyses** and **indirect treatment comparisons** required	Local teams will need to be engaged to anticipate components of the **PICO** and to align on EU JCA/HTA strategy More **concise 'delta' local dossier** development required	New process may impact **launch timelines** and sequencing Earlier launch may impact **international reference pricing** and parallel trade

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Abbreviations: EU: European Union; HTA: Health Technology Assessment; HTD: Health Technology Developer; JCA: Joint Clinical Assessment; JSC: Joint Scientific Consultation; PICO: Population, Intervention, Comparator, Outcome.

How IQVIA can help you

With hands-on experience in the development of European HTA dossiers (500+ in the last five years, >100 in Germany alone), IQVIA can be the right partner for you to successfully work through the uncertainties of the new process.

Our dedicated EU HTA Solutions team can support you with robust preparation for EU HTA through end-to-end services, ranging from global strategy development and evidence generation, including JCA statistical analysis plan development and analysis, to dossier development and local execution. As recognized thought leaders in EU HTA, we understand that you need a holistic and cross-functional approach to ensure that you and your organization are ready in time — at a global, regional and local level.

Our offering connects IQVIA's broad European network of >1,800 local "on-the-ground" market experts, our proprietary data sources and tools, and our unique combination of expertise ranging from HEOR, evidence synthesis and market access to clinical and technical expertise and organizational redesign, to create an effective solution tailored to your needs. Our centralized management ensures efficient and integrated delivery while building a close partnership on your EU HTA journey.

IQVIA's offering connects in-depth local HTA expertise, strategic thinking and technical expertise.

IQVIA's EU HTA Solutions team provides end-to-end support

Define asset- and portfolio -specific EU HTA strategies

- Assess the impact of JCA on your current and future portfolio
- Assess eligibility for JSC and risks/ benefits, support application and strategic planning
- Conduct tailored PICO simulations, consolidation and prioritisation to anticipate JCA scope and define overall JCA strategy
- Develop JCA evidence generation strategy with actionable planning and implementation steps based on gap analysis mapping your evidence package against expected JCA evidence requirements

Implement EU HTA strategies successfully

- Develop briefing book, prepare for advice meeting and make strategic recommendations on how to optimise pivotal trial based on the advice
- Execute all aspects of evidence generation strategy including: GVDs and objection handling, SLRs, ITCs, external comparator studies, database studies and post-hoc analyses
- Provide end-to-end JCA support, from strategy development to JCA dossier development, and post-submission support
- Support local P&R activities, including global model development and adaption, dossier development and pricing negotiation

Optimize and adapt processes

- Adapt your access strategy framework to account for the impact of the EU HTA regulation
- Establish new internal ways of working to optimise new JCA/JSC processes
- Conduct peer benchmarking to assess JCA/JSC readiness
- Develop bespoke training materials for a range of internal stakeholders on JCA/JSC
- Support with regular internal communications on the latest internal and external JCA/JSC developments
- Provide PMO support for internal initiatives

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We are ready for 2025 — are you?

Reach out to the IQVIA EU HTA Solutions team to discuss your needs at: EUHTASolutions@iqvia.com

Scan the QR code to check out IQVIA's latest publications on EU HTA.

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