SSI Strategy Webinar

EU HTA Regulation: What's changing & why it matters

Webinar Hosts:
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The new EU Health Technology Assessment (HTA) Regulation aims to harmonize and facilitate HTA evaluations across EU member states by introducing a mandatory joint clinical assessment (JCA) at the EU level, supported by an optional joint scientific consultation (JSC) process. The Regulation represents a significant shift, particularly in terms of timing and evidence requirements for pharmaceutical companies. Early strategic thinking, optimized study designs, and timely readiness will be crucial to navigate this changing landscape successfully.

In this webinar, Dr Chantal van Gils, VP of Evidence and Value at SSI Strategy, and Dr Sigrid Klaar, Medical Advisor & NDA Advisory Board Member, share insights into the new EU HTA Regulation and its implications for the biotech and drug development sectors.

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A Fragmented Landscape

Health technology assessment (HTA) evaluates the value of health interventions to inform pricing, reimbursement, and access decisions within healthcare systems. While marketing authorization assesses the absolute benefit-risk balance, HTA considers the relative effectiveness, safety, and often cost-effectiveness compared to existing therapies. Historically, HTA processes have varied across the 27 EU member states, prompting efforts towards greater harmonization.

The multiplicity of national HTA systems in the EU poses challenges for pharmaceutical companies, including differing methodologies, evidence requirements, and timelines. This complexity increases development costs, delays patient access, and hampers the EU's competitiveness in a global market. A more unified HTA process can address these issues while reducing duplication of efforts.

Towards a Unified Approach

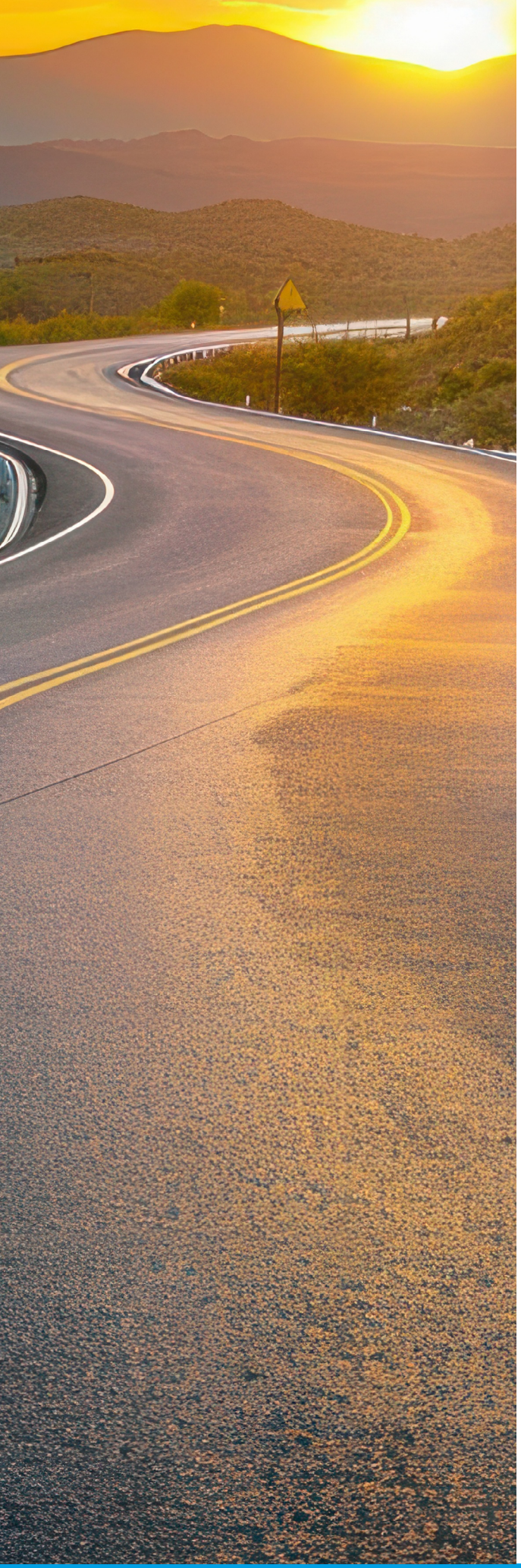
Following extensive discussions, the EU adopted the HTA Regulation in 2021, driven partly by industry requests for a more harmonized approach. The Regulation introduces a mandatory joint clinical assessment at the EU level, focusing on relative effectiveness and safety. This assessment will run in parallel with the marketing authorization process by the European Medicines Agency (EMA).

The new HTA Regulation outlines the following key activities:

1. Joint Clinical Assessment (JCA): A mandatory EU-level evaluation of a health technology's relative effectiveness and safety compared to appropriate relevant comparator(s). The required assessment scope will be presented to the company by the HTA assessors and will be defined by the four "PICO" aspects – Population, Intervention, Comparator, and Outcomes.

2. Joint Scientific Consultation (JSC): An optional procedure, akin to EMA scientific advice, allowing developers to discuss clinical study designs and evidence generation plans. It can only be granted when the clinical studies and investigations are still in the planning stage, however, so timing is key.

The JCA will initially apply to new medicines for cancer and advanced therapy medicinal products (ATMPs) from January 2025, extending to orphan drugs in 2028 and all other centrally approved products by 2030.



While the JCA focuses on clinical aspects, national HTA bodies will retain responsibility for economic evaluations, country-specific considerations, and final pricing and reimbursement decisions.

The Road Ahead

The Regulation presents unique challenges for therapies in complex areas like oncology and rare diseases, which often rely on single-arm trials, surrogate endpoints, and indirect treatment comparisons – methodologies not traditionally favored by HTA bodies. Early engagement and proactive planning will be essential for these products.

The HTA Regulation aims to:

- Harmonize clinical evidence requirements across the EU, reducing duplication of efforts for the health technology developers as well as among national HTA bodies

- Accelerate patient access by aligning HTA and marketing authorization timelines

All while maintaining flexible national systems for economic evaluations and access recommendations.

Successful implementation of the HTA Regulation will require significant adaptation from pharmaceutical companies, particularly regarding:

1. Earlier evidence generation planning: Integrated thinking about clinical data needs for both regulatory and HTA purposes, ideally from early clinical development and from the pivotal trial protocol stage, at the very latest.

2. Increased cross-functional collaboration: Closer integration between clinical development, regulatory affairs, health economics and market access teams.

3. Targeted investment in HTA capabilities: Building expertise in areas like indirect treatment comparisons and modeling to meet JCA evidence requirements.

4. Proactive stakeholder engagement: Consulting clinicians, patient groups, and HTA bodies during evidence planning to understand the treatment landscape and unmet needs.

5. Operational readiness: Allocating sufficient resources to simultaneously manage regulatory and JCA activities under tighter timelines.

Companies should initiate HTA regulation readiness assessments, explore the need and optimal timing for JSC, and develop roadmaps tailored to their pipeline priorities and product development phases.

Conclusion

The EU HTA Regulation presents a transformative opportunity to improve consistency and efficiency in assessing the value of new health technologies. However, successful implementation will require pharmaceutical companies to strategically adapt their evidence generation, resourcing, and cross-functional processes. Early planning and investment in building HTA capabilities will be crucial to navigate this transition and ensure continued patient access to innovative therapies across the EU market.

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About the hosts

Dr Chantal van Gils

Chantal is Vice President of Evidence and Value at SSI Strategy. She is a seasoned specialist in real-world research, epidemiology, and health economics. She brings extensive knowledge and a wealth of professional experience in harnessing population-specific analyses and quantitative methods to inform both interventional and observational clinical studies including pragmatic trials, natural history of diseases, registry-based data, patient-related outcome reports or multi-dimensional molecular medicine data.

Dr Sigrid Klaar

Sigrid is Medical Advisor & NDA Advisory Board Member. She is a former senior regulatory assessor and HTA agency medical advisor. MD, PhD, Specialist in Oncology. With HTA experience from the Swedish Dental and Pharmaceutical Benefits Agency (TLV), including national reimbursement applications as well as EUnetHTA and FINOSE joint clinical assessments. Deeply involved in the EU HTA regulation before and after its adoption, including under EUnetHTA 21. Extensive experience from oncology drug approvals of all drug types in the EMA centralised procedure, scientific advice at the Swedish Medical Products Agency, and drafting guidelines for industry in the EMA Oncology Working Party. Sigrid applies her knowledge to successfully support companies on the clinical and HTA aspects of drug development.

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