Transforming Health Technology Assessments in Europe: A New Era for Market Access

The way health technology assessments (HTAs) are conducted in Europe is undergoing a significant transformation. Starting next year, all new advanced therapeutic products and oncology drugs will be subject to a mandatory, EU-wide joint clinical assessment (JCA). By 2030, this will extend to orphan drugs, class IIb or III medical devices, and class D in vitro diagnostic devices.

This shift aims to enhance access to new products by streamlining the nation-specific approach currently in place for post-regulatory approval adoption. The EU HTA regulation represents one of the most substantial overhauls in decades. Organizations that proactively address the associated challenges can benefit substantially in the long run.

Understanding the New HTA Regulation

The European Medicines Agency (EMA) evaluates a product's efficacy and safety, whereas an HTA examines broader factors, including clinical effectiveness, cost, and overall impact. While the EMA considers whether a product could be adopted, HTAs evaluate if it should be adopted.

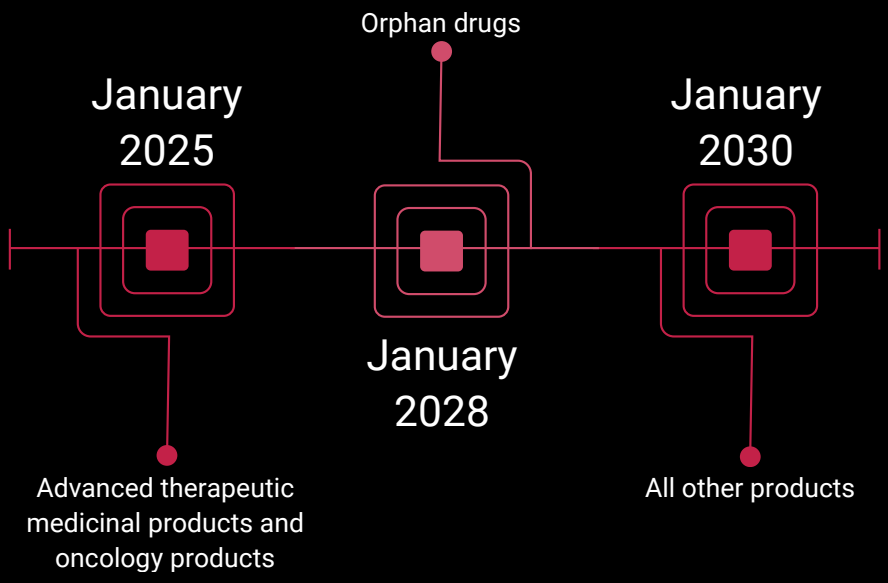
Currently, HTAs are conducted independently by each EU member state following EMA assessment and regulatory approval. This fragmented approach can lead to inconsistencies, delays, and redundant costs and efforts across nations.

The Regulation on Health Technology Assessment (HTAR), established in 2021 by the European Network for Health Technology Assessment (EUnetHTA), seeks to unify this process with a new, EU-wide strategy. Joint Scientific Consultations (JSC) will facilitate collaboration between EMA, EU HTAs, and industry stakeholders on various aspects of assessment (PICO: Population, Intervention, Comparators, Outcomes). Each member state will contribute to this process, resulting in an EU-wide JCA.

While countries can still pursue their own HTA pathways, JCAs will serve as a valuable foundation for expediting adoption.

Timeline for Implementation

The regulation will be implemented in phases:



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Opportunities and Challenges

The new approach presents significant advantages for medicine and device developers. A unified JCA can lead to quicker market access across the EU, reducing administrative burdens and duplicated efforts. The involvement of national stakeholder groups in developing PICOs ensures that the needs and preferences of target countries and patient groups are considered, providing valuable insights for future product development.

However, this transition poses several challenges. A completed JCA is required within six months of EMA approval, but gathering all the necessary PICOs can take up to three months, leaving limited time for developers to respond. Additionally, supporting multiple PICOs simultaneously may necessitate providing extensive evidence on various endpoints, subgroup analyses, sensitivity analyses, and indirect treatment comparisons.

Managing the Transition

To navigate these challenges and seize the opportunities, pharmaceutical companies and prospective market authorization holders (pMAHs) must prepare thoroughly. Although the initial changes will take effect in January 2025, early adaptation of internal processes is crucial. This includes developing new standard operating procedures (SOPs), reallocating resources, and training teams.

Companies should also anticipate the likely content of PICOs to streamline response times once the regulation is enforced. Leveraging existing data on products and patient needs can help predict potential questions and plan accordingly.

Since it is impossible to foresee all PICO requests, teams must be adept at using their data to answer unexpected questions swiftly. Organizations lacking robust in-house data science capabilities might consider partnering with data-specialist contract research organizations (CROs) to access relevant insights efficiently.

Staying Ahead

Ultimately, JCAs will become mandatory for all products, compelling pharmaceutical companies and pMAHs to adapt. However, embracing the new EU HTA framework is more than just a regulatory requirement. It offers a path to streamlined market access, deeper understanding of patient populations, and the ability to address unmet medical needs in future developments.

Key Takeaways:

1. **Unified Assessments:** The EU HTA regulation introduces a mandatory, EU-wide joint clinical assessment (JCA) starting in January 2025.
2. **Streamlined Market Access:** A single JCA process aims to expedite market access across the EU, reducing administrative burdens and costs.
3. **Stakeholder Insights:** National stakeholder groups' involvement in developing PICOs ensures that patient and clinician needs are considered.
4. **Preparation is Key:** Early adaptation of internal processes, SOPs, and team training is crucial for a smooth transition.
5. **Anticipate and Adapt:** Companies should leverage existing data to anticipate PICO content and be prepared to answer unforeseen questions swiftly.
6. **Collaborate for Success:** Partnering with data-specialist CROs can help organizations access necessary insights quickly and

By preparing now, pharmaceutical companies can navigate the transition effectively and position themselves for long-term success in the evolving European healthcare landscape.

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