TODAY AT ISPOR

Our overview of:

the plenaries and insights emerging from the global market access landscape

ISPOR Europe 2023 Presenter

Remap

PLENARY SESSION

THE CALM BEFORE THE STORM? DELIVERING THE NEW REALITY FOR EU HTA

INTRODUCTION

Embarking on a journey that spans over 16 years of planning, the European Union's vision for collaborative Health Technology Assessment (HTA) is now on the verge of becoming a new standard. With the adoption of the EU HTA Regulation in January 2022, a paradigm shift awaits stakeholders, slated to take effect from January 2025. At the heart of this transformative regulation are Joint Clinical Assessments (JCAs), which will soon guide the evaluation of cutting-edge technologies.

In just over 12 months, the inaugural technologies mandated by this regulation will navigate their paths through a JCA. Health Technology Developers and other stakeholders are proactively preparing for these initial assessments.

The plenary discussion delved into the mutual expectations among stakeholders and explored collaborative strategies to overcome anticipated challenges, ensuring a seamless adoption of the new Regulation. Perspectives from the European Commission, EU HTA entities, innovators, Member States, and, notably, the patient community were shared, highlighting the multifaceted nature of this pivotal transformation.

THE DISCUSSION

The session commenced with Adrian Griffin, VP of HTA and market access at Johnson & Johnson, highlighting the inescapable significance of the impending changes in HTA that could reshape the way stakeholders operate.

Greg Rossi, SVP and Head of Oncology Europe and Canada at AstraZeneca, set the scene by revealing that European patients, on average, face an additional two-year delay in accessing innovative medicines compared to their U.S. counterparts.

The initial discussion centered around the goal of transforming HTA in Europe, with Jose Valverde from the European Commission emphasizing EUHTA's primary objective: to expedite patient access to medicines within the EU. Roisin Adams, Head at HTA Strategy National Centre for Pharmacoeconomics, stressed the collaborative spirit among member states, advocating for equitable access and opportunities across the entire bloc.
From the industry viewpoint, Greg Rossi viewed it as an excellent avenue for delivering innovative therapies, making Europe not only more accessible to patients but also more attractive for research and development. However, concerns were raised about the potential impact on member states' pricing and reimbursement negotiations.

Bettina Ryll, founder of the Melanoma Patient Network Europe, highlighted the unequal distribution of recent treatment innovations across Europe. Jose Valverde outlined the commission's actions, emphasizing the six acts tasked by the regulations, with a central focus on the Joint Clinical Assessment (JCA). The next steps involve private and public consultations before EUHTA comes into force in 2025.

Preparation for the upcoming changes involves strategic planning and horizon scanning for agencies like the National Centre for Pharmacoeconomics in Ireland. On the industry side, there's a strong focus on education, particularly regarding PICOs, and discussions about cross-departmental teams and internal process adaptations.

The subsequent discussion addressed preparations for EUHTA, with Roisin Adams noting differences based on country archetypes. Greg Rossi stressed the importance of dialogue with countries to understand their system rewiring for faster access but expressed concerns about potential duplications of work.

Throughout the discussion, a recurring theme emphasized the need to revise incentives offered to companies, considering potential negative impacts on access. Additionally, concerns were raised about the misalignment between the Pharma Legislation Proposal and EUHTA, posing potential challenges to HTA timelines.

Audience questions revolved around resource implications, with industry and local HTA agencies expressing concerns. The industry fears increased resource requirements, especially with numerous PICOs per product. The commission acknowledges potential challenges but believes the long-term benefits will outweigh short-term concerns.

In closing statements, Bettina Ryll acknowledged potential short-term access challenges but stressed the necessity of changes for long-term equitable access. Roisin Adams and Greg Rossi believed the changes would resolve ongoing access issues, making decision-making clearer and more aligned across the EU. Jose Valverde expressed a desire for increased transparency, mutual trust, and collaboration, concluding with the exciting announcement that the first JCAs will commence in 14 months.

THE KEY TAKEAWAYS

1. The EUHTA heralds a promising opportunity to address significant access challenges, including the **equitable distribution of innovative medicines, advancing evidence generation**, and **expediting timelines for product access.**

2. In the coming months, crucial details about the implementation of Joint Clinical Assessments (JCA) will be unveiled. This presents a pivotal moment for the industry to contribute insights before the EUHTA takes effect in 2025.

3. Proactive measures are already underway in both industry and local HTA agencies, involving a strategic overhaul of internal structures, comprehensive educational initiatives, collaborative discussions with partners, and strategic planning exercises like horizon scanning.

4. Despite these positive strides, persistent concerns linger. There's **apprehension that the EUHTA may not deliver immediate acceleration of access**, coupled with fears that countries might be reluctant to relinquish local processes. Furthermore, there's a prevailing worry that the resources required for successful market access by industry could experience an unwarranted surge.

We always welcome your thoughts and opinions on the topics raised at ISPOR.

If you'd like to share anything from your Copenhagen experience or hear how we can support you in getting your product to market, email our leadership team today at contact@remapconsulting.com or reach out personally by clicking their email below.

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