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 NEW PHARMA LEGISLATION PROPOSAL: THE GOOD, THE BAD OR THE ...

INTRODUCTION

After extensive negotiations and recent stakeholder consultations, the European Commission has unveiled a r**evised proposal for the EU pharmaceutical legislation**. The objective is to establish a future-proof regulatory framework with four core pillars identified back in 2020:

- Ensuring access to affordable medicines for patients, addressing unmet medical needs, such as in the areas of antimicrobial resistance and rare diseases.
- Supporting competitiveness, innovation, and sustainability of the EU's pharmaceutical industry, fostering the development of high-quality, safe, effective, and environmentally friendly medicines.
- Enhancing crisis preparedness and response mechanisms, ensuring diversified and secure supply chains, and addressing medicines shortages.
- Ensuring a robust EU voice globally by promoting high standards of quality, efficacy, and safety.

This panel session critically examines whether these initial intentions are adequately reflected in the latest proposal.

THE DISCUSSION

The panel delved into several crucial topics during the session, shedding light on the complexities and challenges within the pharmaceutical landscape.

Medicinal Prices and Evidence Requirements

The discussion kicked off with an exploration of the contradictory trends in medicinal prices, especially for innovative medicines, alongside a diminishing emphasis on evidence requirements. Johan Pontèn from the Medicines Evaluation Committee highlighted the lack of effectiveness evidence, leading to payer ambiguity about the value of these medicines. He emphasized the need for streamlining the pathways for new products to address these challenges. Yannis Natsis, from the European Social Insurance Platform, connected this trend to the post-COVID-19 mindset, where speed trumps evidence, resulting in the current conundrum of low evidence and high prices.

Affordability vs Sustainability

The second focal point revolved around the delicate balance between affordability and sustainability. Gloria Ghequiere, advisor to the Belgian deputy prime minister, noted progress in thinking about medicine shortages but underscored the persistent issue of stakeholders paying significant amounts for innovations while generic prices remain low. Panelists expressed concerns about the proposal lacking measures to address rising prices, despite welcoming initiatives for increased competition through a simplified regulatory framework.

Designations of Unmet Medical Need

The final segment tackled the designations of unmet medical need and high unmet medical need. Panelists, echoing the sentiment of moderator Dr. Anja Schiel, discussed the risk of every new medical product receiving a special designation. Denis Lacomb, CEO of the EORCT, proposed a shift towards evaluating overall public health needs rather than broad designations of unmet need at the patient level. Panelists collectively urged the next set of European Commissioners to define a new strategy on unmet need.

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.

THE KEY TAKEAWAYS

1. Stakeholders are concerned by the contradictory trends of increasing medicinal prices and the erosion of the evidence requirements for new products.

2. The legislation lacks clarity, with the stakeholders involved being concerned about the unmet medical need designation and the incentives that have been put forward not having the desired effect.

3. There is a lack of alignment between the Pharma Legislation Proposal and EUHTA, where there could potentially be increased pressure on HTA timelines going forward.

4. Overall, there is a **sense of hesitancy among stakeholders** with the title of this talk going unanswered: The Good, the Bad or the ... **What?**

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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