TODAY AT ISPOR

Our overview of:

the plenaries and insights emerging from the global market access landscape

ISPOR Europe 2023 Presenter

Remap

PLENARY SESSION

EUROPEAN HEALTH DATA SPACE – RWE PUT TO WORK FOR PUBLIC HEALTH

INTRODUCTION

In this keynote panel, a number of panellists providing perspectives from both national level decision-making and the industry discuss the challenges and opportunities faced with the upcoming EU HTA. Interesting points are made on readiness for the EU HTA, and although a number of challenges exist that must be addressed for successful launch in 2025, the panellists also provide positive opinions on how the scheme may be implemented by member states, likening the implementation of the EU HTA to the uptake of the EMA in the 90s.

THE DISCUSSION

The discussion commenced with the query of EHDS replacing existing health databases. Andrzej Rys, Principal Scientific Advisor at the European Commission, outlined the three developmental stages: **organizing data gathering**, **defining best practices and the legal framework**, and **establishing a system for cross-European data sharing**. Markus Kalliola, Project Director at the Finnish innovation fund Sitra, emphasized the importance of determining how EHDS data would be processed post-research.

The subsequent discussion revolved around EHDS beneficiaries and access. Dr. Petra Wilson, Managing Director at Health Connect Partners, highlighted the universal benefit for patients, foreseeing enhanced efficiency in healthcare delivery. Panel members affirmed that EHDS would facilitate more efficient care delivery and foster potential for public health research. Trine Pilgaard, Director of Market Access at Pfizer, emphasized EHDS contributing to better decisions and streamlined healthcare.

Addressing EHDS access, the consensus was to involve as many users as possible while maintaining stringent protocols. Key stakeholders include HTA agencies, research centres, hospitals, and doctors, with an emphasis on preventing misuse such as advertising or raising insurance premiums.

Patient privacy emerged as a key challenge, with concerns about the opt-in/opt-out mechanism. While legal processes are being debated, the panel expressed hope that robust procedures could minimize the need for individual patient opt-ins. In the concluding segment, panel members highlighted opportunities and challenges. Patient privacy and logistical hurdles in building a network for data sharing were identified as challenges. However, the potential to broaden RWE data access for informed decision-making by healthcare providers was seen as a significant opportunity. Patrice Verpillat emphasized the broader perspective on disease states provided by a pan-European database, while Petra Wilson viewed EHDS as an opportunity to advance global acceptance of data usage.

THE KEY TAKEAWAYS

1. The quality of patient care can greatly benefit from the EHDS through both better decision-making by healthcare providers, or government bodies, and improved access to RWE for research and development.

2. The EHDS provides a fantastic opportunity for pan European data usage but there is still concern that patient acceptance and privacy will provide a significant challenge to its implementation.

3. The logistics of EHDS will also require significant attention before implementing the program, requiring pan European cooperation and robust processes for who may have access to the database.

4. Whilst there is considerable ambition for broader cooperation on data usage the question remains; **what are the motivating factors that may persuade key players to take part in the program and how it will benefit them?**

EDUCATIONAL SYMPOSIA

EUHTA IMPACT ON INNOVATIONS: EXPECTATIONS AND CHALLENGES OF EUHTA FOR GERMANY

INTRODUCTION

The recently introduced EU HTA Regulation marks a significant development as it establishes, for the first time, a standardized approach to the benefit assessment of novel therapies across Europe. This regulation specifically governs a collaborative clinical assessment of new medicinal products on a European scale. The initiation of this process is slated for January 2025, encompassing various products, notably advanced therapy medicinal products (ATMPs) and oncology medicinal products, including orphan drugs. The details and specifics of this framework are set to be further clarified and defined. This session brought together several German stakeholders to discuss the expectations and challenges of EUHTA in Germany.

THE DISCUSSION

Eva Dietrich, founder and head of the institute for evidence-based positioning in the healthcare sector, opened the discussion and made several points from the perspective of the AMNOG process:

- EUHTA is unlikely to have an impact on access to innovative medicine in Germany, largely due patients already having very good access through the AMNOG process.
- The German government believes the AMNOG process should continue regardless of EUHTA, at least in the short term, as it is necessary to maintain the equal treatment of companies and drugs over time.
- The G-BA has stressed that the introduction of EUHTA will not delay patient access to innovative medicines in Germany, however, concern from companies and stakeholders remain.

- In conclusion, Eva posed the question of whether EUHTA will be relevant for the G-BA and IQWiG and answered by stating “not from the AMNOG perspective”.

This was followed by a talk from Lutz Herbarth, head of the medical compliance team at the health insurer KKH, who discussed the EUHTA from the perspective of the German Statutory Health insurance association (GKV-SV). He pointed out that the GKV-SV have expressed concerns over the EUHTA procedure and how this will impact the endpoints used in trials, however, health insurers believe that EUHTA will have minimal impact on the on the operation of their businesses.

The final speaker was Julia Rumsch, head of the Brussels office for the Federal Association of the Pharmaceutical Industry (BPI) and focused on the current plan for the implementation of EUHTA. Concerns were raised that details on the timelines for EUHTA processes and how the legislation will be implemented are still lacking, although there was acknowledgment that more information is due to be released in Q4 2023 or Q1 2024. In addition, Julia mirrored the sentiments of Eva Dietrich’s talk earlier on the issues of EUHTA hampering the rapid access of patients to innovative medicines in Germany.

Panellists, when probed on the impacts of EUHTA regulations not aligning with the AMNOG process, conceded that the implementation of new legislation will be a stepwise process that is likely to require Germany adopt its procedures. However, it was also pointed out that in the long term there may be further additions to EUHTA regulations such as acceptance of patient reported outcomes.

THE KEY TAKEAWAY

There is concern among some stakeholders in Germany that EUHTA will interrupt the AMNOG process thereby slowing patient access to innovative medicines, however, over time EUHTA may evolve and reduce these potential issues. Whilst from a health insurers perspective there is expected to be minimal impact from the new legislation.

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

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