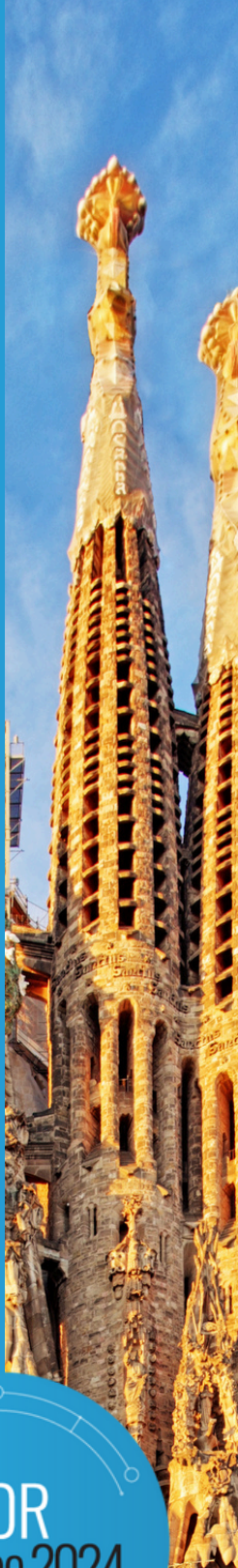
TODAY AT ISPOR



Our overview of the keynote address and plenary from Monday 18th November 2024

ISPOR Europe 2024 Presenter

Remap

Keynote 100a: Translating from EU to Africa to Empower Patient Involvement and Access to Healthcare

SPEAKERS: Mimi Choon-Quinones and Rob Abbott

INTRODUCTION

Healthcare systems in Africa face a pivotal moment. The continent's growing population presents both challenges and opportunities for innovation in patient involvement and healthcare delivery. In her keynote address, Mimi Choon-Quinones, an advocate with over three decades of experience, shared her vision for translating lessons from the EU's Beating Cancer Plan to empower patient access and involvement across Africa.

AFRICA IS AT A HEALTHCARE CROSSROADS

Africa accounts for significant global health losses, including 227 million years of healthy life annually, translating to $800 billion in lost productivity. Many African health systems rely heavily on NGOs, volunteers, and non-state actors to bridge resource gaps. Choon-Quinones' NGO, recently chosen by the Pan African Parliament as a key partner, is working to create a comprehensive healthcare strategy to address these disparities over the next decade.

Using health economics and outcomes research (HEOR), the organisation aims to tackle systemic inequities while fostering innovation. The cornerstone of this effort is codifying strategies for better access, based on adaptable lessons from Europe.

KEY ELEMENTS FOR BUILDING RESILIENT SYSTEMS

Choon-Quinones emphasised three critical elements for transforming African healthcare:

Addressing workforce shortages: Initiatives like upcoming workshops at the World Economic Forum will focus on critical healthcare metrics, such as minimal residual disease assessments in cancer treatment.

These programmes aim to bridge the gap between advanced medical techniques and practical implementation across diverse healthcare environments.

Generating evidence: Reliable data empowers patient-centric policies and healthcare delivery. African countries are leveraging national electronic medical record repositories, like those in Ghana, to provide robust evidence frameworks that inform cost-effectiveness modelling and budget impact analysis.

Forging partnerships: Collaborative efforts are essential for sustainable growth. Choon-Quinones shared inspirational examples of partnerships from her personal journey, including her father's pioneering health equity projects in New York. Similar collaborations with the Pan-African Parliament aim to align Africa's cancer care strategies with the EU's Beating Cancer Plan.

LESSONS FROM EUROPE: ADAPTABILITY AND COLLABORATION

A significant takeaway from the keynote was the adaptability of EU initiatives to African contexts. For example, the EU's Beating Cancer Plan offers a roadmap for integrating evidence-based decision-making and stakeholder collaboration into a unified strategy. However, Choon-Quinones cautioned against simply replicating models, stressing the need for context-specific adaptations that respect Africa's unique healthcare landscapes.

By engaging policymakers, clinicians, and patient advocacy groups, Africa can accelerate access to equitable and effective care. These efforts also highlight the role global stakeholders, including HEOR experts, play in fostering knowledge exchange and collaboration.

THE 3 KEY TAKEAWAYS

1. Lessons from the EU can inform African healthcare policies, but strategies must be tailored to local contexts for maximum impact
2. Reliable data generation and sharing are fundamental to advancing patient access and decision-making
3. Collaborations between governments, NGOs, and international stakeholders are essential for sustainable health systems

Plenary 100b: The evidence-price conundrum - what is the way forward for patient access?

SPEAKERS: Rob Abbott, Mimi Choon-Quinones, Yannis Natsis, Richard Bergstrom, Valerie Paris, Pedro Facon, Birgitte Klindt Poulsen

INTRODUCTION

In April this year, the European Parliament adopted its position on the Commission's proposal to reform the core EU pharmaceutical legislation. As the complex trialogue negotiations between the Commission, Parliament and Council continue, great change is underway in the US, with a new administration taking shape. Back here in Europe, everyone is ready for the EU HTA regulation that will come into force from January 2025. All these changes, taken together, have led to a focus on the critical role of evidence and evidence quality in pharmaceutical price and reimbursement negotiations.

THE TIME FOR INTERVENTION IS NOW

Rob mentioned that Martin Luther King Jr. coined the phrase "the fierce urgency of now." emphasising that timeliness is important and recognising when application and impact are as significant, if not more so, than discovery. This initiated the panel discussion led by Yannis, titled "The Evidence-Price Conundrum: What Is the Way Forward for Patient Access?"

QUALITY OF EVIDENCE AND IMPACT ON PAYER DECISION MAKING

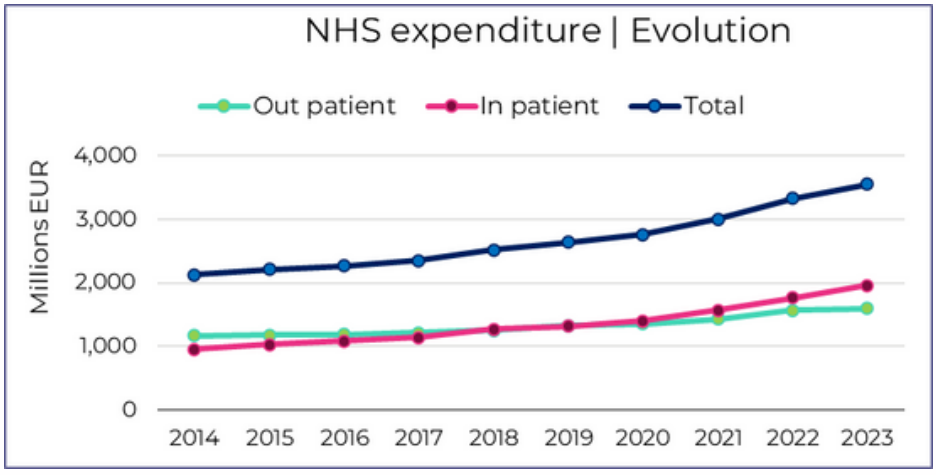
Birgitte started the discussion by highlighting that sparse data sets challenge payers, impacting the health economy through misplaced investments, withheld treatments, and potential patient harm.

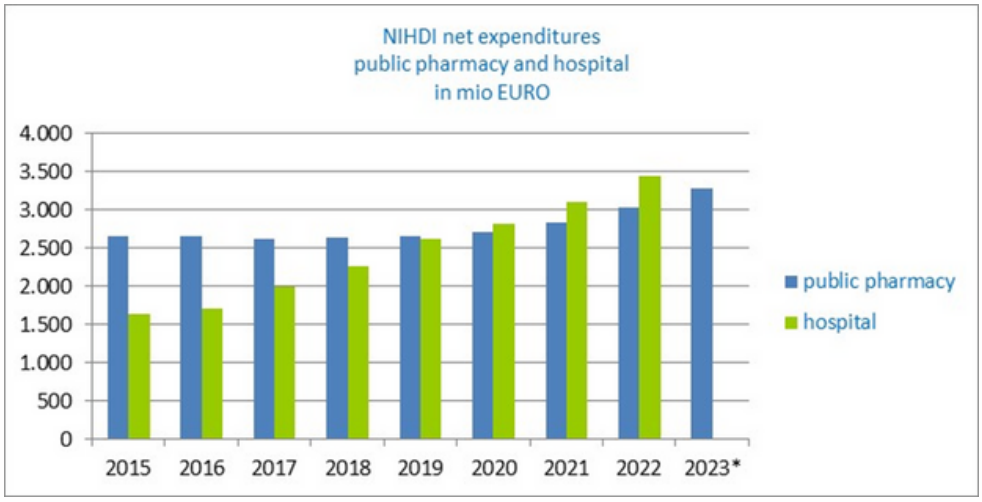
Pedro observed that national budget constraints are real and cannot be ignored. Every decision has consequences. Insufficient evidence makes it difficult for payers to evaluate the value of a drug.

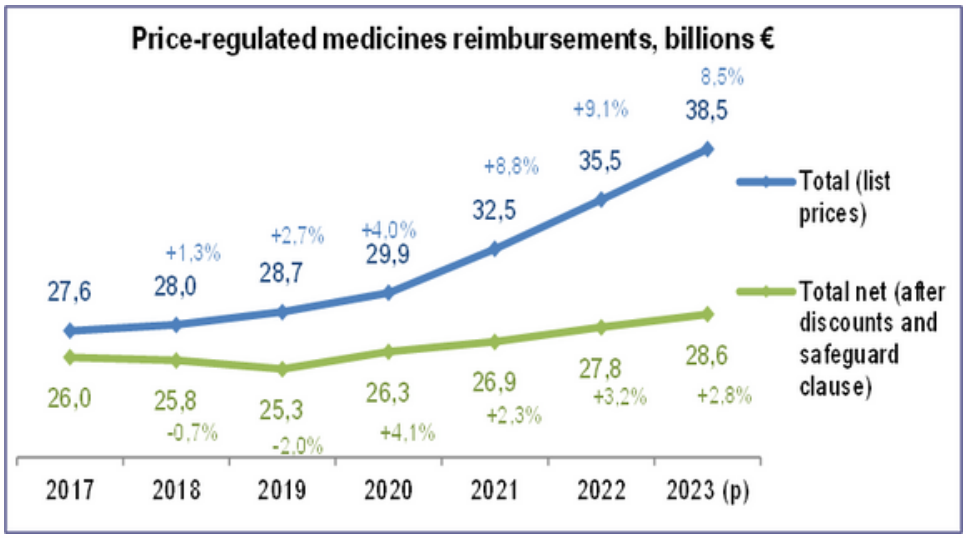
Richard reminded the audience that several key drug reimbursement decisions in the past have been based on incomplete evidence packages. The approval of statins and Hepatitis C drugs by reimbursement agencies in the past are classic examples of payer approval despite limited evidence. He noted that it is often impossible to have complete and mature evidence ready for HTA discussions. Richard stressed that this is particularly challenging in oncology. Birgitte disagreed with Richard, noting that between 2009 and 2022, nearly 15% of accelerated FDA approvals were withdrawn due to failed confirmatory trials. Pedro noted that while managed entry agreements (MEAs) were created to address uncertain evidence, 54% of refunds are now due to poor research questions and weak study designs. MEAs effectively contain costs but fail to manage uncertain evidence. Efforts are being made to improve early-stage research design in MEA contracting. There is also potential for better coordination between regulators and payers.

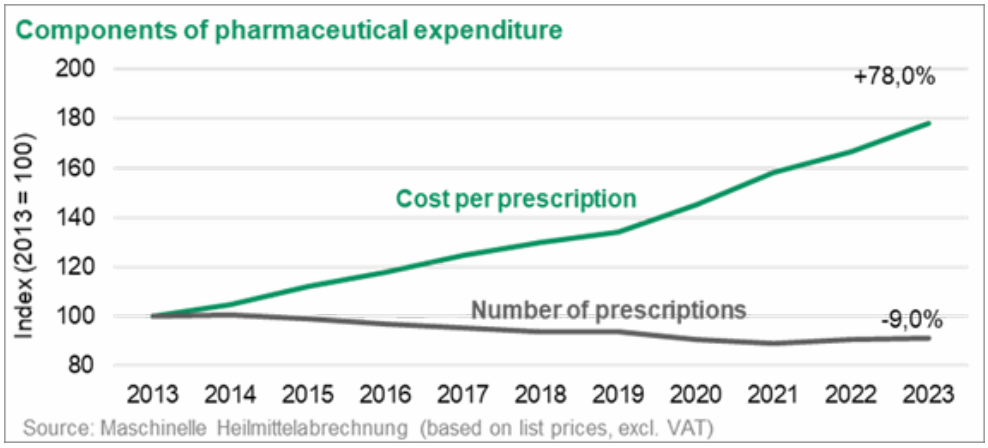
THE TIME FOR INTERVENTION IS NOW

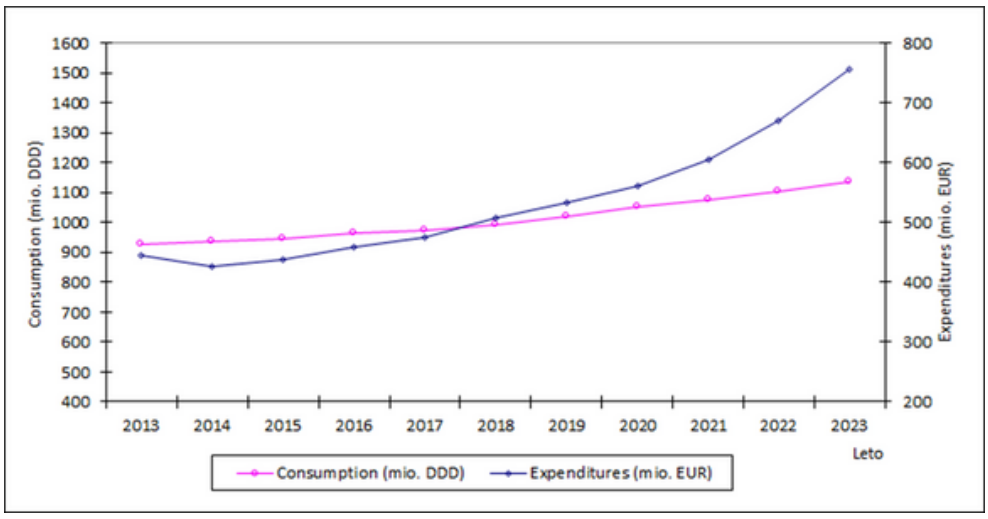
Yannis began by drawing attention to the recent 204 report from the ESIP.











Valerie observed a trend towards increasing expenditure on orphan and oncology drugs and mentioned the recent rise in medication shortages across the EU. She noted that countries often do not pay enough for generics. While product-level rebates are increasing, outcome-based rebates remain limited. She also mentioned the claw-back mechanism, where expenditure caps bring more transparency. However, simple discounts on high prices pose a challenge for HTAs in setting the right price.

Richard agreed with Valerie regarding clawbacks, stating that simple discounts do not increase prices. He noted that monitoring outcomes in Belgium has been difficult, although tracking performance may improve over time. Budget constraints are a significant issue, with 50% discounts being common. According to an IQVIA report on US discounts (post-IRA), the average discount rate is 30%, with insulin at 80%. In the EU, orphan drug list prices are often unreliable, with less than 50% of orphan drugs coming to Europe from the US, presenting a key challenge.

Richard also highlighted that less than 50% of biologics nearing the end of their exclusivity period have biosimilars in development. Previously, the NHS had 10 to 15-year-long price agreements. Payers need to combine HTA with effective negotiation.

Yannis noted that high drug prices remain a systemic issue. Pedro shared his observations from Belgium, where the medicines sector, which constituted 70% of health expenditure, was reasonably successful in pricing and reimbursement decision-making. He pointed out that reference pricing and confidential contracts present significant challenges for payers. Pedro expressed concern about the industry's praise for the Belgian government's negotiating capabilities, suggesting that joint negotiations could be a viable solution.

Yannis noted that payer positions on confidential agreements remained unclear. Pedro maintained that as long as reference pricing persists, confidentiality will be inevitable. Joint price negotiations may be able to address this issue. Birgitte commented on transparency related to pricing, specifically citing the case of Denmark, where the AMGROS has successfully negotiated several deals. She stressed that it was not enough for payers to solely focus on high rebates but there must also be consideration for associated expenses such as complex healthcare costs for monitoring and delivering advanced therapies.

Richard recommended improving alignment between joint HTA/regulatory advice and price negotiation processes. He emphasised the importance of regulatory sandboxing to convene larger groups of experts to ensure comprehensive planning and a broader understanding within the payer community about evidence generation throughout the lifecycle.

He noted that, while regulators are familiar with this concept, public health experts lack readiness. There must be an understanding that evidence generation is a continuous process.

Valerie emphasised the need for horizon scanning to anticipate upcoming decisions and changes in the treatment landscape and advocated for improvements in current managed entry agreements (MEAs). Pedro and Birgitte again stressed the importance of joint collaboration, asserting that evidence must form the basis of decisions.

The discussion concluded with an observation that the high prices of certain medicines and the insufficient evidence supporting new market entries present significant issues requiring immediate attention and solutions.

THE 5 KEY TAKEAWAYS

1. Continuous evidence generation requires early advice from regulatory agencies or HTA bodies
2. Joint negotiations can align HTA and regulatory advice, enhancing transparency in price negotiations
3. Clearly define acceptable Real-World Evidence (RWE) and specify post-HTA approval evidence-generation activities
4. Clarify feasible RWE before and after approval. Address research design weaknesses early in MEA contracting
5. CMAs from EMA should set deadlines for confirmatory trials to share data with HTA organisations

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

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