WORLD EPA CONGRESS

2024 SUMMARY

Amsterdam, Netherlands

12-13 March 2024

Remap

CONTENTS

World Evidence, Pricing & Access Congress 2024

The World Evidence, Pricing, and Access (EPA) Congress stands as Europe's premier event in market access, pricing, and evidence, hosting over 300 speakers, 8 tracks, and drawing over 1500 attendees from pharmaceuticals, biotech, and Payers/HTA's.

In its 2024 edition, the congress extends to a two-day event, introducing the Health Economics & Outcomes Research track and a dedicated poster area to bolster academic participation and deepen discussions. Core topics such as Market Access and Pricing, Rare Diseases, HTA/Payer, and Evidence will be enriched with insights into reimbursement trends, payment models, affordability, and HEOR advancements.

The congress proudly collaborates with prominent solution providers including Remap Consulting, a Platinum sponsor, offering an integrated approach to pricing and market access, and sharing thought leadership with key stakeholders in the pharmaceutical and biotech industries.

Keynote Sessions Overview

Changing landscapes around market access and pricing: Global Perspectives

During Tuesday's keynote presentation by a Vivian Mendonca, Senior Vice President and Global Head of Value, Evidence and External Affairs at Menarini Group, crucial challenges and opportunities in market access and pricing for innovative medicines were discussed, with a special focus on evolving landscapes in biomarker complexity within oncology and strategies to combat global health threats in healthcare.

The presentation highlighted four key challenges faced in pricing innovative treatments:

1. Balancing 'fair' innovation rewards with cost-effectiveness considerations.
2. Adapting pricing strategies amidst intense competition and evolving market dynamics.
3. Addressing uneven funding distribution and changing governmental priorities.
4. Managing the shortening of exclusivity periods.

In the realm of rare diseases and interventions combating antimicrobial resistance, a lack of harmonisation in reimbursement pathways across different markets emerged as a significant barrier to patient access. Furthermore, current investment levels were deemed insufficient to drive necessary innovation and product launches in these critical areas where effective treatments are urgently needed to mitigate patient suffering.

Biomarkers also emerged as a pivotal area experiencing rapid development. However, there exists a substantial lack of awareness and understanding regarding the potential value biomarkers offer, leading to access challenges. Biomarker testing, particularly in oncology and cardiovascular diseases, is gaining importance. Yet, significant regulatory and reimbursement variations across markets complicate matters.

To improve patient access to biomarker testing, it is imperative to develop cost-effective testing methods and demonstrate the long-term cost savings associated with biomarker utilization, thereby showcasing their value to healthcare systems. Collaboration and partnerships are necessary to educate stakeholders and promote access to biomarker testing, with patient advocacy groups playing a crucial role in this endeavour.

In conclusion, effective coordination among internal value teams, early engagement with key stakeholders, and proactive involvement in shaping supportive policies are key strategies to maximize pricing and access opportunities for innovative treatments. This proactive approach is essential in navigating the evolving landscapes of market access and pricing while ensuring patient needs are met with timely and affordable access to life-saving innovations.

The key takeaway from the presentation on market access and pricing challenges for innovative medicines is the critical need for stakeholders to align innovation rewards with cost-effectiveness considerations. Balancing the fair rewards for innovation with the affordability and accessibility of treatments is paramount in ensuring sustainable access to life-saving therapies for patients worldwide.

Optimising market access and pricing - leveraging integrated evidence to demonstrate value

In the ever-evolving landscape of healthcare and reimbursement, stakeholders such as policy makers, payers, and manufacturers face the imperative to navigate towards value-based care over volume-based models. Economic pressures in the healthcare marketplace necessitate a shift towards more cost-effective delivery of healthcare services, placing increasing strain on payers to optimise their spending. While traditional pill-based models persist, there is a growing consensus across the healthcare spectrum about the need to align drug prices with their actual value.

One promising solution gaining traction is the adoption of value-based contracts (VBCs), which come in several types:

Outcome-based contracts	These contracts link costs or discounts to specific patient outcomes.
Conditional treatment continuation	This involves tying continued coverage of treatment to meeting short-term treatment goals, often accompanied by a free trial period for the medication.
Indication-based pricing	Under this contract, the net price of a medicine varies depending on different indications, as agreed upon between the parties.
Expenditure cap	These agreements set a limit on the cost of medicine per patient, negotiated to a certain threshold.

The advantages of VBCs are multifaceted:

Improved patient access:	By tying costs to outcomes, VBCs incentivise efficient use of resources, potentially widening patient access.
Reduced medical costs	Aligning payment with successful outcomes can lead to overall cost savings.

Dealing with uncertainty	VBCs allow for constructive management of uncertainties regarding a drug's safety and effectiveness, especially at launch.
Alignment of price and value	They directly address the challenge of pricing drugs based on their true value, promoting fairness and sustainability in healthcare spending.
Early access	Patients may gain access to medications during the evidence-gathering phase, fostering innovation and patient-centered care.
Reduced risk	Payers mitigate financial exposure by linking payments to predefined outcomes.

Several challenges hinder widespread adoption of VBCs:

- Data availability: Insufficient data to measure value accurately remains a significant hurdle.
- Administrative complexities: Implementing VBCs requires streamlined processes and agreement on outcome measures.
- Definition of value: Stakeholders often have differing definitions of value, complicating contract negotiations.

Real-world evidence (RWE) plays a pivotal role in enabling VBCs, yet fragmented healthcare data often leads to measuring what is convenient rather than what truly matters. Early engagement with stakeholders and strategic partnerships are crucial for developing tailored VBCs that align with everyone's goals. Key factors in selecting outcome measures include credibility, relevance, practicality in data collection, comparability across settings, and adherence to legal and compliance standards.

While RWE presents challenges such as data timeliness and participation rates, it remains foundational in driving informed decision-making within VBC frameworks.

The Key Takeaways

1. VBCs encourage collaboration among payers, providers, patient organisations, and biopharma entities.

2. VBCs hold the promise of containing healthcare costs while enhancing patient outcomes and access.

3. Selecting the right outcome measures and utilising accurate data are fundamental to the success of VBCs.

In conclusion, the shift towards value-based contracts represents a pivotal moment in healthcare, demanding collaboration, data-driven decision-making, and a shared commitment to delivering value across the healthcare continuum.

Rare Disease Track Overview

Patient access in rare diseases: addressing challenges throughout the pathway

Investment in rare diseases is a topic marked by shifting priorities and complex dynamics. While there is a growing inclination towards equitable distribution of funds between rare and common diseases, the reality often sees a tilt towards financing common diseases when costs escalate. This shift is influenced by challenging negotiations on pricing between payers and the pharmaceutical industry, where payers seek optimal value for their investment. Thus, it is crucial to consider factors such as disease severity and life-threatening nature alongside other considerations.

The Discussion

Currently, among EU nations, Germany, Italy, and France lead in orphan drug approvals by the EMA, with an average of 84% success. Germany notably stands out with a swift average time of 89 days between approval and patient access, followed by Denmark at 243 days. However, this success also highlights a significant challenge associated with orphan drugs that demands immediate attention.

Looking forward, there is optimism surrounding an upcoming reform set for parliamentary debate in May 2024. This reform aims to foster innovation and improve access to medicines, particularly addressing high unmet medical needs in the rare disease space.

Several data challenges exist along with potential solutions:

- Study design issues, such as insufficient randomised trials, could be addressed by leveraging more real-world evidence.
- Lack of defined clinical measures or validated endpoints might be mitigated by using surrogate endpoints.
- Absence of comparative data due to heterogeneous practices and lack of existing treatments could be addressed through indirect treatment comparisons.

Accurately capturing the patient journey accurately is another critical yet neglected aspect in the rare disease domain. Patient perspectives are vital for empowering and improving their quality of life, especially in scenarios where a 10-day waiting period for drug access is deemed too lengthy. Some rare diseases exhibit daily progression, leading to irreversible damage by the time the 10-day mark is reached.

Collaboration among stakeholders is essential to integrate patient advocacy at an earlier stage. While clinicians require education, a deeper comprehension of patient challenges is crucial identifying the appropriate clinician for diagnosis and subsequently referring them to the right specialist.

The Key Takeaway

1. Supporting orphan drugs incurs higher costs compared to drugs for common diseases, leading to challenges in attracting investments due to perceived lower returns on investment.

2. Across the European Union, a significant number of member states require over 400 days for patients to gain access to their orphan drugs. This indicates that market access for rare diseases lags considerably behind that of common diseases.

3. Resolving data challenges, such as study design issues and lack of comparative data, has the potential to accelerate patient access to orphan drugs, benefiting both patients and stakeholders.

While early access programs assist vulnerable patients and generate real-world evidence, they also pose challenges by potentially extending access times for non-participating patients. Balancing these factors is crucial for devising effective solutions that benefit all stakeholders.

Digital Transformation Track Overview

Improving Access to Digital Therapeutics in Europe

Digital Therapeutics (DTx) offer evidence-based therapeutic interventions through software programs aimed at preventing, managing, alleviating, or treating diseases. They have transformative potential for patients, empowering them with at-home treatment options, fostering engagement, and enabling holistic management. Healthcare providers (HCPs) benefit from improved or alternative therapeutic options and enhanced data sharing with patients. From a healthcare system perspective, DTx target unmet needs, reduce overall burdens, and integrate generated data seamlessly.

The Discussion

Despite their immense potential, DTx adoption in Europe remains limited. Only Belgium, Germany, and the UK have established national value assessment frameworks, with reimbursement pathways currently operational only in Belgium and Germany. Germany stands out for pioneering clear pricing and reimbursement frameworks for Digital Health Applications (DiGA).

Four primary barriers hinder DTx market access:

1. Lack of harmonisation in regulatory requirements across EU Member States, leading to varied interpretations and a lack of precedent for risk classification.
2. Challenges in evidence requirements and the absence of standardized value assessment processes for DTx across most countries.
3. Absence of a standardized access pathway, complicating market entry strategies.
4. Insufficient funding for DTx, coupled with low awareness and recognition of their potential value, further hampering uptake.

The Key Takeaway

1. Value assessment processes for DTx must be tailored, predictable, and consistent, incorporating a comprehensive evidence portfolio, including real-world data.

2. Payers should adopt flexible approaches allowing provisional access while additional data is collected, facilitating faster market entry.

3. Collaboration among policymakers, healthcare providers, and companies is essential to drive DTx uptake, streamline regulatory processes, and improve overall access for patients.

By addressing these key takeaways, stakeholders can work towards unlocking the full potential of DTx, ensuring they become integral components of modern healthcare systems across Europe.

Empowering patients to collect their outcomes - making value-based healthcare a reality

Why should we empower patients to collect their outcomes? The simple answer is: it leads to better outcomes. However, achieving this requires consensus in the care pathway between patients and providers.

Empowering patients has shown remarkable success in improving outcomes, as seen in the case of prostate cancer where utilising Patient Reported Outcome Measures (PROMs) resulted in enhanced Quality of Life (QoL). Yet, to continually improve outcomes, we must enhance clinical guidelines, optimise costs, and ensure that the entire healthcare ecosystem, from patient access to provider engagement, values and integrates Patient Reported Outcomes (PROs) effectively.

The Discussion

Currently, there are approximately 400 digital health apps, but only a small fraction are integrated with national or local care records. Within the next 5-10 years, it will become standard for these apps to seamlessly integrate with electronic health records, providing a more efficient data collection method.

While some Health Technology Assessment (HTA) bodies consider the patient perspective, future impact will come from leveraging this patient-driven data. Recognising the significance of PROMs, especially in chronic conditions that necessitate a blend of self-care and healthcare, is vital for informed decision-making in healthcare.

Healthcare has also improved significantly through the use of data-collecting devices like wearables. Allowing patients access to their healthcare data, as exemplified by the NHS app, facilitates data sharing among healthcare providers, promoting better patient-centered care. However, integrating patient-reported outcomes into HTA processes remains a challenge.

This transition will require time as we must address concerns about data quality and patient engagement. Studies indicate that patients often disengage from apps over time, highlighting the need for direct patient engagement to sustain outcomes reporting.

Additionally, ensuring the credibility of patient data presented to payers and HTA bodies is crucial, possibly utilising generative AI and machine learning for data analysis.

PROs offer external validity that clinical trials alone cannot provide, offering personalised insights that enrich QoL assessments. Combining clinical data with PROs is essential for achieving optimal patient outcomes.

The Key Takeaway

1. Understanding high-quality data is crucial; currently, only 3% of hospital data is utilised. Patient engagement also suffers when data requirements are overwhelming, leading to discontinuation of outcomes reporting.

2. PROMs are invaluable but require better integration with HTA processes. HTA bodies must recognise the pivotal role of PROs in decision-making.

3. Prioritising patient outcomes before access decisions leads to the most significant successes in healthcare interventions.

By empowering patients and integrating their perspectives into healthcare decision-making processes, we pave the way for more effective and patient-centric healthcare systems globally.

EU HTA - How to ensure stake-holder alignment on a national level to accelerate broad patient access

The recent publication of the first implementing act of the joint EU Health Technology Assessment (HTA) has brought about significant uncertainties among stakeholders. One of the main challenges and surprises has been the substantial volume of data required, raising questions about the actual reduction in workload that was initially anticipated. Additionally, the extremely tight deadlines are a major concern, especially for manufacturers navigating this new landscape.

The discussion

Further acts are expected to be published in the 3rd or 4th quarter of 2024, posing challenges for manufacturers. It appears that Germany and France will bear the brunt of the workload, with assessment processes resembling those seen in AMNOG (the German pharmaceuticals market access system).

Manufacturers express concerns about the lack of collaboration in the EU HTA process and question whether there will be meaningful opportunities for engagement moving forward. Unlike EUnetHTA, which provided clear stakeholder engagement instructions, the joint EU HTA process lacks such clarity.

Small and mid-size companies face difficulties in gathering local clinical data, particularly if they lack a presence in specific localities. Coordinating local adoption is challenging, although these companies may find it easier to restructure to align with EU HTA requirements. Dependence on consultancies for knowledge and assistance in navigating the EU HTA is also noted.

The European market may become less attractive for investment due to the evolving and challenging environment. Questions arise about the timeliness of the JCA (Joint Clinical Assessment) report if manufacturers opt to launch their products in different countries at varying times.

The Key Takeaway

1. **One voice, big impact**
The joint EU HTA creates a unified approach across all 27 member states, offering a streamlined process that can significantly impact manufacturers' ability to create global clinical development plans.

2. **Market access planning**
Manufacturers must consider market access strategies early in their clinical trial planning to align with EU HTA requirements effectively. This strategic approach becomes increasingly crucial with the introduction of the joint EU HTA.

3. **Local affiliates and adaptation**
Establishing and leveraging local affiliates is essential for manufacturers navigating the EU HTA landscape. Focusing on local capabilities can help limit the number of product information and clinical evidence queries (PICOs) encountered during assessments, streamlining the overall process.

NICE Enough? Do NICE decision outcomes impact international HTA decision-making

The influence of decisions made by the National Institute for Health and Care Excellence (NICE) in the United Kingdom on healthcare systems worldwide remains a topic of ongoing investigation. Despite limited direct evidence of NICE decisions impacting other countries, a recent study delved into this complex issue. This study encompassed 12 countries, encompassing both developing and well-established Healthcare Technology Assessment (HTA) systems. Employing a mixed-methods strategy, it utilised quantitative techniques to examine inter-agency links and qualitative methods to uncover potential factors of NICE processes that might resonate with other agencies globally.

The discussion

Three correlations were identified:

- NICE positive decisions correlated with positive outcomes elsewhere
- NICE optimised decisions often related to negative outcomes in other countries
- NICE terminated or negative decisions are often associated with no HTA appraisal in other countries.

There is a suggestion (though not statistically significant) that the level of consensus on decision outcomes between NICE and the relevant HTA agency was greater in Poland, Italy, South Korea, and Sweden.

Considerations:

- Further research on how to increase the efficiency of HTA processes is needed, assessing whether it should come from collaborative efforts, joint assessments and/or adaptation of evidence generated in or for other geographical.
- The transferability of HTA decisions between jurisdictions is limited due to varying parameters like costs, contextual factors and health systems characteristics.

- Decision makers are more likely to look at NICE documentation for more complex appraisals such as innovative therapies or high cost products
- Negative NICE decisions are likely to have more impact internationally compared to positive one's.
- Influence stems from underlying factors, such as the perception of NICE as a methods innovator and the accessibility of NICE's outputs.
- Collaboration between HTA agencies, particularly those using cost-effectiveness analysis, might strengthen NICE's role on the international stage.

The Key Takeaways

1. NICE has some impact on HTA decision making in other countries, but the means and extend vary considerably and are less driven by the outcomes of individual appraisals. In other words, HTA decisions don't necessarily travel but decision-making evidence does.

2. NICE is not part of the new EU HTA regulation including Joint Clinical Assessment. This and other post-Brexit activities could weaken NICE's influence in the EU region. This potential lack of involvement may weaken NICE's ability to shape health policies and practices in the EU, impacting its influence on healthcare decisions and potentially hindering the adoption of its guidelines and recommendations across member states.

3. NICE may have more resources available compared to newer or less developed HTA bodies. Based off the interviews conducted, they found that HTA bodies with fewer resources or less experience might look to NICE's interpretation and critique of company evidence to help their own critique of the submitted evidence.

Market Access Track Overview

Accelerating access to innovative medicines in the UK – key strategic themes for global access leaders

Today's panel discussion on access to innovative medicines in the UK brought together experts representing payer, clinical, company, and health economist perspectives. Delving into the complexities of the UK market, the panel explored challenges and opportunities for launching new medical products effectively.

Opening remarks and market perception:

The panel unanimously acknowledged the UK market's perceived complexity, often deemed a 'painful' landscape for manufacturers developing launch strategies. However, amidst these challenges, there was a shared optimism about the market's potential. The robust data infrastructure and a growing desire for collaboration among stakeholders—companies, payers, healthcare professionals, and patients—were highlighted as key factors offering opportunities for successful product launches.

Payer perspective and policy improvements

Rob Kettel from NHS England provided an optimistic outlook, citing policy improvements that facilitate timely patient access to innovative medicines. Noteworthy advancements include shortened timeframes between NICE assessments and final guidance publication, as well as enhanced capabilities in creating innovative commercial agreements with manufacturers. Initiatives such as the VPAG and Innovative Medicines Fund aim to foster innovation and competition, benefiting both patients and taxpayers.

Health inequity & COVID-19 impact

The panel identified health inequity across UK regions as a significant barrier to uptake, exacerbated by the COVID-19 pandemic.

Christopher Kipps discussed the introduction of secure data environments (SDEs) to streamline national and regional data collection, aiding in identifying access disparities. Strategies leveraging collected data can effectively boost uptake across diverse regions.

Health economic perspective & cost-effectiveness

A focus on cost-effectiveness thresholds and strategies like preventative medicine was emphasised from a health economic standpoint. While cost-effectiveness thresholds vary regionally based on quality-adjusted life years (QALYs), they are applied nationally to ensure efficient resource allocation. Innovative approaches such as vaccines and genomics hold promise in mitigating healthcare inequities.

EU HTA process and accelerating access

The potential impact of the EU Health Technology Assessment (HTA) process on UK access was discussed. Clear frameworks for real-world evidence (RWE) and managed access agreements were identified as accelerators for access in the UK compared to the rest of Europe. However, caution was advised, emphasising the need for robust evidence packages to maintain confidence among stakeholders.

The Key Takeaway

In conclusion, while the UK market poses challenges, initiatives like the VPAG and Innovative Medicines Fund incentivise innovation and collaboration across disease areas. Ongoing education of healthcare professionals and patients is crucial to mitigate healthcare inequities and ensure swift uptake of new therapies.

The panel discussion highlighted the importance of a cohesive approach among stakeholders to navigate complexities and drive positive outcomes in accessing innovative medicines in the UK.

EU healthcare reforms and implications for local market pricing

Delving into the potential ramifications of the proposed revisions to EU pharmaceutical legislation, specifically focusing on the reduction of the data protection timeline, is crucial. Currently, Europe invests a staggering 39 billion EUR in Research and Development (R&D), showcasing a thriving R&D landscape. However, when compared to powerhouses like the US and China, Europe still lags behind.

Manufacturers are expressing concerns about the proposed legislation, viewing it as a possible threat to ongoing R&D efforts in Europe. The reduction of the data protection period from 8 years to 6 years implies that manufacturers will have a shorter timeframe to recoup their investments, which are vital for sustaining further R&D endeavours.

The discussion

The looming question revolves around whether manufacturers will continue to invest in lengthy clinical trials akin to those in cardiology or in complex and expensive trials typical in rare disease research. There's speculation about a potential shift towards developing more intricate products, which are harder to replicate and often come with a higher price tag.

The EU aims to incentivise manufacturers to invest in combating anti-microbial resistance (AMR) by offering an additional year of data protection. This move could potentially stimulate R&D activities in this critical area. However, despite such incentives, access remains a significant hurdle. Introducing access incentives for anti-microbials, akin to orphan drug designation, could pave the way for tailored AMR access pathways within Europe.

Data protection duration guarantees manufacturers a specific timeframe to generate revenue essential for ongoing R&D endeavours. With reduced data protection, the logical response might be to increase drug prices. However, this approach faces challenges in Europe due to a decreased willingness among payers to pay higher prices compared to other regions. Manufacturers are unlikely to raise prices without corresponding reimbursement adjustments.

This situation contrasts with the US, where increased data protection could potentially lead to price hikes.

The Key Takeaways

1. Manufacturers must familiarise themselves extensively with the revised EU pharmaceutical legislation to navigate potential challenges effectively.

2. The looming question remains: will manufacturers sustain their R&D investments in Europe amid these regulatory changes?

3. Furthermore, will the EU introduce additional incentives to bolster anti-microbial research and development?

By addressing these critical points and considering potential solutions, stakeholders can better prepare for the evolving pharmaceutical landscape in Europe.

Three ways artificial intelligence (AI) will impact market access in 2024

Artificial Intelligence (AI) is increasingly revolutionising the pharmaceutical industry especially in clinical development and commercialisation strategies, yet its integration into market access strategies remains a work in progress.

Key uses of AI to support market access were highlighted, including helping to inform price predictions and country sequencing strategy during product launches. The optimal use of AI in market access strategies is dependent on the disease landscape in which the company is launching.

Leveraging natural language models for competitive landscape analysis

In the scenario where the landscape is competitive, natural language models to analyse previous HTA reports of competitor products may be a useful tool to help predict HTA outcomes for a new product. These models can help to inform companies on previous decisions for comparator products and allow direct queries to be answered on payer opinions regarding the trial design, duration, size, endpoints chosen and outcomes. The outputs of these analyses can help to inform the market access strategy to mitigate any potential challenges when launching and to effectively differentiate the value of the new product versus the competitor.

Machine learning models for price prediction in complex scenarios

In scenarios lacking clear comparators, machine learning models trained on extensive pricing and market access datasets become instrumental in price prediction. These models delve into potential price drivers such as disease severity, unmet need, budget impact, and target population characteristics. While offering valuable insights in uncertain areas, it's important to note that the accuracy of data generated by machine learning models from large datasets may be slightly lower compared to the targeted approach typically used in HTA analyses.

AI's strategic role in country sequencing and pricing strategies

Beyond price prediction, discussions revolve around AI's potential in informing country sequencing strategies during product launches. Modelling international reference pricing dynamics allows for optimised country launch sequencing, with adjustments tailored to factors like country-specific reimbursement timelines, commercial demands, and internal launch preparedness. This strategic utilisation of AI not only navigates complex international markets but also maximises market access potential, ensuring efficient and successful product launches across diverse global territories.

In conclusion

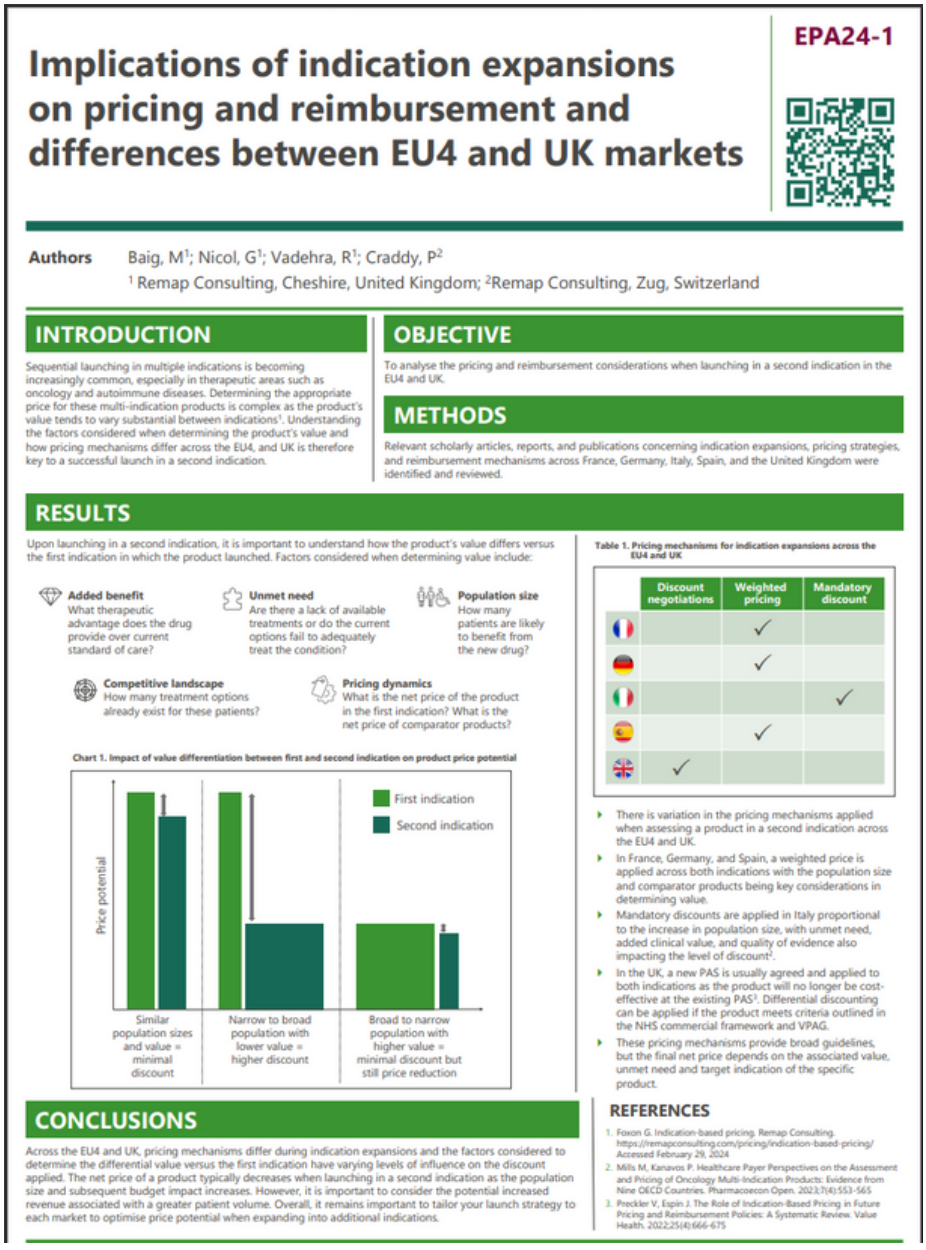
Overall, AI can be an invaluable asset to inform the market access strategy for pharmaceutical companies. However, its value is dependent on the quality of data that are inputted into the relevant models that subsequently determines the accuracy of the insights provided by AI. Market access teams also need to have the data sciences expertise with sufficient market access knowledge to understand how the AI models should be applied to provide relevant outputs.

As companies begin to apply AI, it is important that all stakeholders understand the limitations in the accuracy of the data generated by each model type and continue to use individuals' expertise to sense check the outputs provided and their applicability to specific products. If used appropriately, AI may be a valuable tool for developing market access strategies at a faster rate with a lower burden on team resources.

Remap Consulting Research Poster

We're pleased to have presented a piece of research on indication expansions on pricing and reimbursement at the conference.

If you would like any further information on the plenaries or research presented below, please contact Paul, Graham or Janice at contact@remapconsulting.com



EPA24-1

Implications of indication expansions on pricing and reimbursement and differences between EU4 and UK markets

Authors Baig, M[1]; Nicol, G[1]; Vadehra, R[1]; Craddy, P[2]

[1] Remap Consulting, Cheshire, United Kingdom; [2]Remap Consulting, Zug, Switzerland

INTRODUCTION

Sequential launching in multiple indications is becoming increasingly common, especially in therapeutic areas such as oncology and autoimmune diseases. Determining the appropriate price for these multi-indication products is complex as the product's value tends to vary substantial between indications[1]. Understanding the factors considered when determining the product's value and how pricing mechanisms differ across the EU4, and UK is therefore key to a successful launch in a second indication.

OBJECTIVE

To analyse the pricing and reimbursement considerations when launching in a second indication in the EU4 and UK.

METHODS

Relevant scholarly articles, reports, and publications concerning indication expansions, pricing strategies, and reimbursement mechanisms across France, Germany, Italy, Spain, and the United Kingdom were identified and reviewed.

RESULTS

Upon launching in a second indication, it is important to understand how the product's value differs versus the first indication in which the product launched. Factors considered when determining value include:

- **Added benefit** — What therapeutic advantage does the drug provide over current standard of care?
- **Unmet need** — Are there a lack of available treatments or do the current options fail to adequately treat the condition?
- **Population size** — How many patients are likely to benefit from the new drug?
- **Competitive landscape** — How many treatment options already exist for these patients?
- **Pricing dynamics** — What is the net price of the product in the first indication? What is the net price of comparator products?

Chart 1. Impact of value differentiation between first and second indication on product price potential

Table 1. Pricing mechanisms for indication expansions across the EU4 and UK

	Discount negotiations	Weighted pricing	Mandatory discount
France		✓	
Germany		✓	
Italy			✓
Spain		✓	
UK	✓		

- There is variation in the pricing mechanisms applied when assessing a product in a second indication across the EU4 and UK.
- In France, Germany, and Spain, a weighted price is applied across both indications with the population size and comparator products being key considerations in determining value.
- Mandatory discounts are applied in Italy proportional to the increase in population size, with unmet need, added clinical value, and quality of evidence also impacting the level of discount[2].
- In the UK, a new PAS is usually agreed and applied to both indications as the product will no longer be cost-effective at the existing PAS[3]. Differential discounting can be applied if the product meets criteria outlined in the NHS commercial framework and VPAG.
- These pricing mechanisms provide broad guidelines, but the final net price depends on the associated value, unmet need and target indication of the specific product.

CONCLUSIONS

Across the EU4 and UK, pricing mechanisms differ during indication expansions and the factors considered to determine the differential value versus the first indication have varying levels of influence on the discount applied. The net price of a product typically decreases when launching in a second indication as the population size and subsequent budget impact increases. However, it is important to consider the potential increased revenue associated with a greater patient volume. Overall, it remains important to tailor your launch strategy to each market to optimise price potential when expanding into additional indications.

REFERENCES

1. Foxon G. Indication-based pricing. Remap Consulting. https://remapconsulting.com/pricing/indication-based-pricing/ Accessed February 29, 2024
2. Mills M, Kanavos P. Healthcare Payer Perspectives on the Assessment and Pricing of Oncology Multi-Indication Products: Evidence from Nine OECD Countries. Pharmacoecon Open. 2023;7(4):553-565
3. Preckler V, Espin J. The Role of Indication-Based Pricing in Future Pricing and Reimbursement Policies: A Systematic Review. Value Health. 2022;25(4):666-675

CLICK HERE TO VIEW ONLINE

Remap Consulting Presentation

Dr. Graham Foxon, Managing Director and Founder of Remap Consulting, presented at the World EPA Congress on the topic of "Opportunities for manufacturers arising from EU HTA".

During the talk, Graham covered the following points in this rapidly evolving landscape:

- Determine what manufacturers need to consider when preparing for EU HTA
- To identify what activities manufacturers can action now to ensure EU HTA presents an opportunity rather than a barrier

Following the talk, Graham summarised the key takeaways for manufacturers and market access teams in regards to opportunities arising from EU HTA.

BE

- **Prepared**
  - Understand what is required for the EU HTA
  - Ensure budget and resources are available
- **Organised**
  - Who does what, when and how
  - Communication across functions
  - Which products are affected?
- **Adaptable**
  - Changes to process are likely
  - Consider EU/local HTA challenges
- **Early**
  - Market access for EU HTA needs to start -1 year prior to EMA submission
- **Willing to learn**
  - Learn from others! - internally and externally

If you would like to know more – please attend our next EU HTA webinar on 25th April 2024, 15:00PM CET.

Remap Consulting

Remap Consulting is a specialist pharmaceutical pricing, reimbursement and market access consultancy offering an integrated, evidence-based approach to optimising price and patient access for our client's products.

We work with a broad range of clients, from top 10 pharma through to small start-up organisations on a diverse range of business-critical projects, market access training and product launches.

Our mission is to help solve your pricing & market access challenges to enable improved patient access for your products.

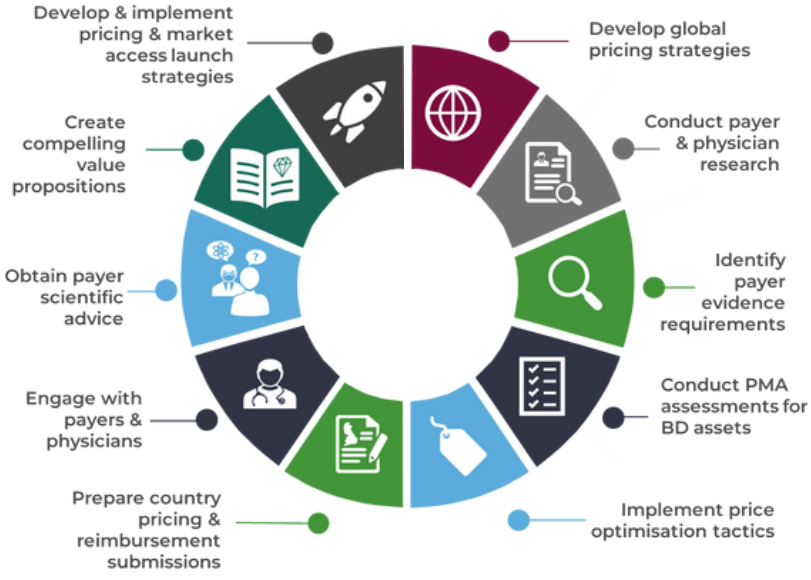
Launch Strategy & Implementation

Price Optimization

Training

Flexible specialist training to upskill your team

- Bespoke training solutions specific to your needs and product pipeline
- Extensive range of off-the-shelf training modules from foundation to advanced market access learning including:



For more information on our services, please visit our website www.remapconsulting.com.

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

If you'd like to share anything from your Amsterdam 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.

Paul Craddy
MANAGING DIRECTOR
& FOUNDER

PAUL@REMAPCONSULTING.COM
+44 7957 028493

Graham Foxon
MANAGING DIRECTOR
& FOUNDER

GRAHAM@REMAPCONSULTING.COM
+44 7415 946778

Janice Haigh
PRACTICE LEAD

JANICE@REMAPCONSULTING.COM
+44 7399 817285

