WORLD EPA CONGRESS

2023 SUMMARY

Amsterdam, Netherlands

21-23 March 2023

Remap

CONTENTS

World Evidence, Pricing & Access Congress 2023

Remap Consulting joined over 1,200 other delegates from pharma, biotech and Payers/HTA's, in attending Europe's largest congress in evidence, pricing and market access, in Amsterdam, Netherlands from 21st - 23rd March 2023.

The conference featured 300 speakers, 100 sponsors and exhibitors and 6 tracks covering market access, rare diseases, HTA and the most burning industry discussions.

Day 1 of the World EPA Congress kicked off with the opening plenary sessions, including a welcome from conference chair Ana Plata (Global Pricing Head, AstraZeneca).

Our report summarises some of the plenary sessions and parallel tracks that took place during the conference.

Plenary Sessions Overview

The wizardry of market archetypes to uplift your access strategy in the EU

One of the first speakers at the World Evidence, Pricing and Market Access Congress 2023 was Alberto Briones of Lifescience Dynamics. His plenary session discussed the use of archetyping in the process of market access strategy building.

Key discussion points:

- Developing market access strategies across Europe can be challenging
    - Defining the launch preparation and brand protection strategies should be informed by integrating the market and therapy area dynamics. However, this iterative process remains complex and time-consuming.
- This process can be streamlined by archetyping market dynamics
    - Although sometimes viewed as an oversimplification, if applied correctly, archetyping allows market and area dynamics to drive targeted strategy development and the hypotheses can be efficiently tested to facilitate the decision-making processes
- A case study on biosimilars (Bx) in Europe demonstrates how the archetyping approach can be applied and validated
    - There are multiple factors driving biosimilar use and uptake. Mapping the Bx use drivers across countries allows framing the market archetypes. Those can be used to build strategies that are archetype specific before refining them to a country-specific level.
    - To execute and operationalise archetypes, after developing the preliminary archetypes they need to be validated and pressure-tested. Gaining payers' perspective on key drivers used for archetyping to validate the methodology is crucial to assure its relevance.

- Archetyping can be especially useful when developing a strategy for smaller or emerging markets

    - Smaller, emerging markets are often at risk of being deprioritised during decision-making. Archetyping allows for the initial validation in multiple markets at once, saving resources and time that would be needed to do exhausting payer research in each of them.

To conclude, the use of archetyping still holds an important place in developing access strategies in the complicated environment of EU markets. If well-designed and thoroughly validated, it can streamline this process and facilitate decision-making.

Exploring the use of Access Operating Models: a "new" model for industry?

During a panel discussion led by Sandro Cesaro (AstraZeneca), Christoph Glaetzer (Janssen of Johnson & Johnson), Alexander Bastian (A.M. Pharma) and Sally Chung (GSK) shared their thoughts on the use of access operating models.

Key discussion points:

- Panellists reflected on the advance of the importance of Access, which in recent years has become the front and centre topic for the pharmaceutical industry.

- Access objectives are now shared across multiple functions, and patient access commitments are often included in companies' mission statements.

- The starting point for the debate was the two publications, "Access in the New World" (PharmEx, Jan 2021) and "A Cross-Functional Formula: Operationalizing the Broader Role of Access" (PharmEx, Aug 2022).

- Panellists discussed the four key concepts proposed by the authors on how to operationalise the broader role of access through the access function. Those consisted of:

    - Earlier focus: The heightened focus on Access in early asset decision-making, exemplified by MA being represented in early development decision-making committees.
    - Shared objectives: Provide enterprise leadership and shared access objectives between functions, e.g. through access objectives being included in executive incentives for key functions.
    - Top of mind: Market Access maturing into key function at the extended leadership teams level such as establishing a "Chief Access Officer"
    - Drive operationalisation: Global strategies developed in close collaboration with key countries by for e.g. practising proactive access roll-out plans and training

- Debaters agreed with the proposed model, adding that all four concepts interconnect, such as progress in one aspect can facilitate the development in others.

In conclusion, as payers and stakeholders develop and mature their approach to Market Access, companies need to operationalize the broader role of access through the access function. It is an effort that comes from transformations on different levels, and interdepartmental cooperation is vital.

Considerations to reduce disparities between RWE evidence and trial evidence during conditional reimbursement negotiations

Sangeeta Budhia (VP, Pricing & Market Access, Parexel) spoke about the importance of RWE during HTA negotiations.

- Treatments are entering the market with less robust evidence and data due to high unmet need in some diseases. The evidence may be associated with high uncertainty , therefore increasing long-term risk to payers. Payers may accept products with the condition that further data is collected , this includes collection of RWE

- RWE provides understanding of the safety and efficacy of the new therapy in the real world using sources such as: EHRs and claims data, registry data, patient generated data, mobile devices/wearables data. RWE bridges gaps between what is seen in RCTs and its implementation in the real world

- HTA organization's willingness to accept RWE varies based on circumstance (indication, type of RWE etc) e.g. payers value RWE data especially where evidence base is less robust e.g. in rare diseases

- Use of RWE will add a level of complexity as we move towards common HTA/Joint Clinical Assessment. How will an EU body make decisions using RWE data for 27 different countries?

- Manufacturers should:
  - Look at their evidence generation plans, understand where uncertainty is and whether RWE is the most appropriate to address those gaps
  - Seek early scientific advice in order to address questions about evidence generation plans including RWE strategy
  - Develop structured plans for RWE activities as part of evidence generation plan

In conclusion, use of RWE can strengthen the product value across different stakeholders and at different stages of the product lifecycle and manufactures should be aware that successful RWE implementation requires recognition of the value of RWE and utilisation of a strategic RWE approach.

Solving the global healthcare inequity gap

On Day 2, Jayasree Iyer, CEO of Access to Medicine Foundation, delivered a presentation titled "Solving the Global Healthcare Inequity Gap." She stressed the need for early consideration of access and the requirement for different interventions to ensure that treatments function effectively in specific markets.

Iyer highlighted several opportunities for the industry, such as comprehensive access planning for late-stage R&D products and improving the quality of access plans.

Additionally, she discussed the implementation of equitable pricing strategies, the registration of products in more countries, and the use of nonexclusive voluntary licensing.

Iyer cited Novartis as an example, outlining their access strategy for Kisqali® (ribociclib), a treatment for breast cancer. In South Africa, Novartis used a novel combination to increase access, making it available at a 20% reduced rate compared to the private sector price on a buy-out basis, while also offering financial assistance via access to an innovative care foundation covering up to 25% of the co-pay.

Bold Access Models for Accelerating Global Health Equity

Led by Amy Israel, the session discussed the importance of planning and building access models in order to drive equitable access.

- Equity recognizes that each person has different circumstances and allocates the exact resources and opportunities needed to reach an equal outcome

- Medicines are not getting to as many people as they should. A recent study showed that only 50% of WHO Essential Medicines List medicines are available in low-and-lower-middle income countries (LLMIC). Over 10mln people died of cancer in 2020 and 70% of these deaths occurred in LLMIC

- An example of access model for accelerating global health equality is the Access to Oncology Medicines (ATOM) coalition. It is an innovative partnership of nearly 40m partners taking collective action to improve access and capacity to use essential life-saving cancer medicines and diagnostics in LLMIC. ATOM focuses on:

    - Improving the capacity to receive and use cancer medicines in targeted LLMICs
    - Making more WHO EML generic and biosimilar cancer medicines available over time
    - Securing an increasing number of patented medicines and new medicines in the pipeline from biopharma

How can we design a model for cancer care that is truly equitable?

You need to start shaping a favourable environment for product launch while it is early in the pipeline. Think about the 5 'S' to create optimal healthcare delivery and equitable access:

- Staff – global shortage of healthcare workers, limited specialized know-how to E.G. pathology readings
- Stuff – imaging, reagents for testing

- Space – chemotherapy safe rooms, beds in hospitals
- Systems – referral mechanisms from community to primary to tertiary centres
- Social support - family paid leave, grief support

In conclusion, manufacturers should think about their access models and ask themselves what will their contribution be on the journey to drive equitable access. This will pave the way for developing health justice in deprived regions.

Unlocking the power of social listening: a critical role in early value assessments

The objective of the plenary session led by James Wright of Valid Insight was to discuss the potential of social listening in early value assessment.

- Early clinical development involves many choices between products and indications. Assessing the relative value of those can pose a significant challenge and requires identifying the unmet need and determining the optimal positioning, differentiation and evidence needed.

- There is often a discrepancy between clinicians' and patients' views on the unmet need and therefore the patient needs have to be carefully considered in the decision-making process.

- The increasing role of social media in the patients' journey makes it a promising source of information on patient perspective. For example, research on how patients with colorectal cancer use social media platforms to support each other led to the discovery that the majority of raised questions were discussing the diagnosis and CT scans, highlighting the lack of education on that topic available for them at their through their healthcare providers.

- As with other techniques of insight collection, there are several challenges associated with the process, such as the volume and quality of available data, language and cultural barriers, privacy concerns and algorithm bias

To conclude, social listening is a very data-rich source of patients' views on their conditions. The analysis techniques are still emerging and there are many challenges to be tackled, but if used carefully social listening can be a useful tool to facilitate understanding of the patient perspective in early value assessment.

National implementation of the HTA regulation: example and feedback from the French National Authority for Health

On Day 3, Fabienne Bartoli (Director-General, French National Authority for Health), discussed “National implementation of the HTA regulation: example and feedback from the French National Authority for Health”. She described the three core missions of the French National Authority for Health (HAS), which are:

- Assessing and appraising
- Providing recommendations
- Measuring and improving

As previously mentioned by other speakers, the European HTA regulation on joint clinical assessment will be enforced in January 2025, and the preparatory work for this is already underway at HAS. The regulation's objective is to reduce the burden on national HTA authorities and industry, promote business predictability within the EU, and guarantee the EU HTA collaboration's long-term sustainability.

The European HTA community displays a high level of willingness to collaborate, as demonstrated by the EUnetHTA21 consortium reaching a key milestone. However, there are still challenges that need to be addressed such as scalability, coordinating with other national activities (e.g. early access), and improving timelines. Bartoli outlined the next steps at HAS, which include adopting an internal workplan focused on capacity building, optimizing processes, and spreading the principles of European cooperation. Additionally, interactions with key stakeholders will be planned to guide them through the procedural changes, and maintaining connections with other HTA bodies will be important.

Market Access & Pricing parallel track

During his presentation titled "Planning for Reimbursement of Rare Disease Therapies," Simon Shohet, Vice President of International Market Access at Amicus Therapeutics, addressed the issue of reimbursement for rare disease treatments. One significant challenge he discussed was the removal of previous privileges afforded to orphan drugs by HTA bodies, which has created significant hurdles in obtaining the necessary evidence. Shohet pointed out that study endpoints in rare diseases are often disputed, with European HTA bodies holding differing opinions. He illustrated this point by referencing the 6-minute walk test. Shohet also emphasized the importance of well-conducted payer research, which can provide valuable insights into evidence requirements and variations between HTA bodies.

During the conference, Giovanny Leon (Global Price Affordability & Early Access Executive Director, Novartis AG) presented on “Developing a customer-centric price perspective”. Leon drew attention to the challenges that patients face on their healthcare journey, with particular emphasis on the difficulties posed by prescription costs. Patients' out-of-pocket expenses can vary due to factors such as the country and healthcare provider, which can hinder both treatment initiation and adherence. Leon pointed out that the final pharmacy price includes not only the ex-factory price of the product, but also additional costs such as manufacturer and pharmacy mark-up, and taxes. Higher co-payments are associated with lower uptake of prescriptions by patients, and Leon called for a shift in pricing mindset, highlighting the World Health Organization's guidelines on country pharmaceutical pricing policies.

Evidence parallel track

During the Evidence session, Pall Jonsson, Programme Director for Data at the National Institute for Health & Care Excellence (NICE), delivered a presentation titled "Developing and Implementing an Approach to Using Real-World Evidence (RWE) in Health Technology Assessment." He highlighted the importance of being a part of a healthcare system that continuously learns from data. To achieve this, he outlined several critical requirements, including access to data, expertise in evaluating the quality of RWE, the implementation of best practices and methodologies, the robust incorporation of RWE into decision-making, data and research partnerships, and the ongoing assessment of the impact of NICE guidance. However, there are significant challenges in achieving these goals, with trust in the reliability of the data being a crucial factor.

HTA parallel track

On Day 2, there was an afternoon session on HTA was chaired by Ramiro E Gilardino (Global HTA & Access Policy Leader, MSD), who introduced Andrew Olaye (Head of EMEA Market Access, Orchard Therapeutics Ltd) to speak on “Lessons learned from joint HTA processes”. Olaye discussed both FINOSE (an HTA collaboration network between Fimea [Finland], NoMA [Norway] and TLV [Sweden]) and BENELUXA (involving Belgium, the Netherlands, Luxembourg, Austria and Ireland). Talking through the key learnings and recommendations, he highlighted that despite relying on a joint HTA report, country reimbursement recommendations and decisions might be different, so this must be taken into account.

Remap Consulting Presentation

Dr. Graham Foxon, Managing Director and Founder of Remap Consulting, presented at the World EPA Congress on the topic of "EU HTA: Will it facilitate or hinder patient access to new medicines?"

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

- What is the EU HTA and why is it important?
- Feedback from manufacturers on EU HTA
- Will it help or hinder EU patient access?

Following the talk, Graham summarised the key takeaways for manufacturers and market access teams in regards to EUNetHTA implementation:

- Joint Clinical Assessment (JCA) is a non-binding clinical assessment that will be utilised as part of national pricing and reimbursement decision making processes (to varying degrees)
- Markets will have the ability to perform additional clinical analysis (e.g. patient groups, comparators or health outcomes) and economic analysis on top of JCA
- Manufacturers will need to design clinical trials that capture comparators, endpoints and patient populations most relevant to the European-wide market
- Manufacturers should be prepared to increase market access activities earlier within the product launch process

If you would like to know more – please attend our next EU HTA webinar on 26th April 2023, 16:00PM 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.

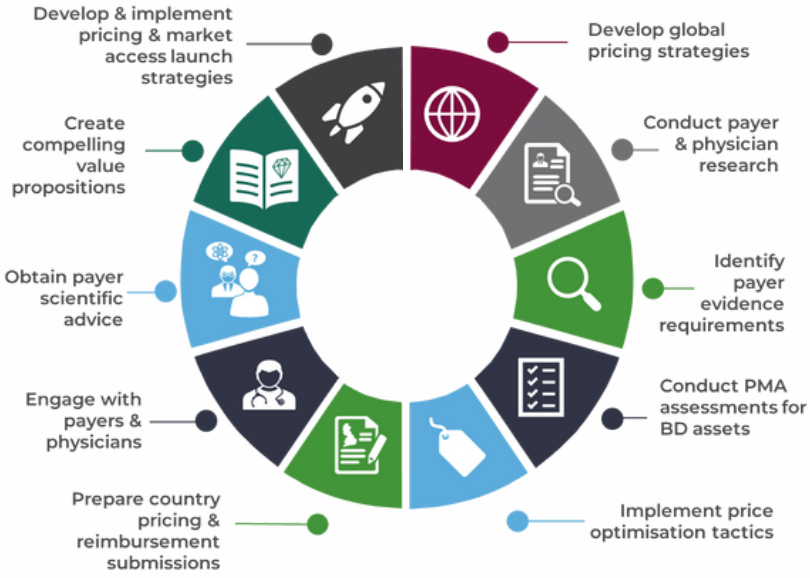
Launch Strategy & Implementation

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:



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We hope you've found this report informative.

If you'd like to share anything from your World EPA Congress experience or hear how we can support you in getting your product to market, email Paul and Graham, managing directors, today at: contact@remapconsulting.com.

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