Remap

Reflecting on the Pricing and Market Access trends that shaped 2024

Trend 2: The road ahead for EU HTA

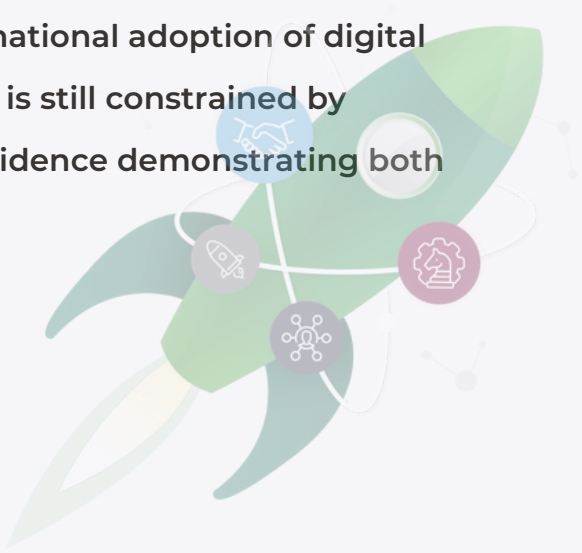
At the end of 2023, we identified five key trends that we expected to shape the Pricing and Market Access landscape throughout 2024. As the year draws to a close, we've revisited our predictions and compiled a summary of how these trends unfolded!

2024 predicted trends:

Trend 1: Enhanced patient access to digital therapeutics on a global scale

As predicted, there has been positive progress in implementing national pricing and reimbursement frameworks for digital therapeutics in the UK, Germany and France. According to BfArM (German Federal Institute for Drugs and Medical Devices), 219 applications for DiGA were made by April 2024, resulting in 56 positive decisions1. According to a report by the most prominent German statutory health insurance provider, Techniker Krankenkasse2, the most prescribed DiGAs have been in mental health, diabetes and obesity management and orthopedic related complaints (knee and back pain). This report also noted that the average remuneration level of EUR 221 for DIGAs was around 60% lower than the average manufacturer price of EUR 552. In the UK, NICE's EVA (Early Value Assessment for Medtech) published six final guidances ranging from depression to back pain, recommending two remote monitoring tools for people diagnosed with heart failure. NICE also opened a consultation on a new process, incorporating both EVA and MTEP for assessing digital therapeutics. The PECAN scheme in France promised early access to digital health therapeutics through a dedicated fast-track route. However, initial feedback from manufacturers has been lukewarm, with one of the first applicants receiving a negative opinion from the HAS (Haute Autorité de Santé) with no opportunities for appeal or additional data submissions.

In conclusion, while there is increasing interest in the national adoption of digital therapeutics across the EU, widespread patient access is still constrained by reimbursement challenges, and the need for strong evidence demonstrating both clinical efficacy and healthcare cost offsets.



Trend 2: The road ahead for EU HTA

The EU HTA regulation has dominated the news, with its official implementation date set for January 2025. Much groundwork for the Joint Clinical Assessment (JCA) and Joint Scientific Consultation (JSC) regulatory frameworks has been laid out, with the European Commission releasing four (out of six) implementing acts (IA).

Key aspects include:

- IA1: Joint clinical assessment for medicine products
- IA2: Cooperation by exchange of information with the EMA
- IA3: Conflicts of interest management
- IA4: Joint scientific consultations for medicinal products

The two remaining IAs relate to medicial devices and will be published in 2025.

According to the recently published work plan for the EU HTA co-ordination group for 2025,

- 17 JCAs are planned in 2025 for cancer therapeutics and 8 for ATMPs
- 5-7 JSC for medicinal products and 1-3 for medical devices
- Requests for JSC can be made between 3rd Feb-3rd Mar and 2nd-30th Jun

The 2025 work plan invited sharp criticism from the pharmaceutical industry with a joint statement from EUCOPE (European Confederation of Pharmaceutical Entrepreneurs) and the Alliance for Regenerative Medicine, EFPIA (European Federation of Pharmaceutical Industries and Associations), EuropaBio (European Association for Bioindustries) and Vaccines Europe noting that 5-7 JSCs would be grossly insufficient and urgent solutions were needed to increase JSC capacity.

In addition to these immediate concerns, several uncertainties remain, particularly regarding how national systems integrate EU HTA outcomes into local pricing and reimbursement processes. Countries like Italy and Spain have been slow to adapt, while others (such as Germany) have resisted ceding control over the HTA process to a centralized EU body.

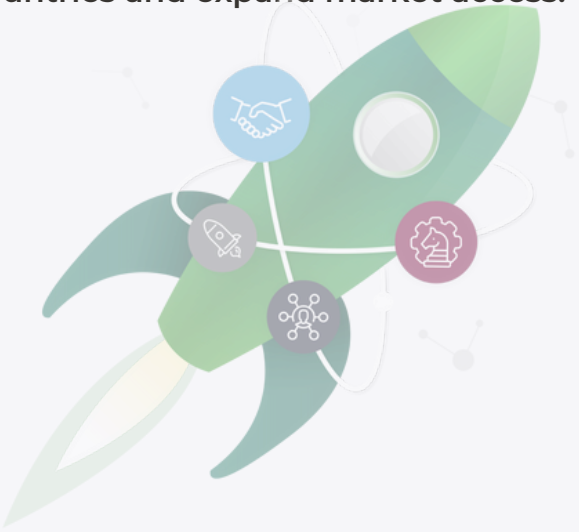
As predicted, there's uncertainty over how manufacturers will navigate multiple PICO (Population, Intervention, Comparison, Outcome) frameworks, and it's unclear whether the European Commission will address the potential challenges of multiple assessments for a single product. As we move into 2025, EU HTA will likely face initial teething problems as countries adjust. Still, the overall trend of increasing EU-wide coordination on HTA will likely gain momentum, albeit slower than initially anticipated, requiring companies to adapt their processes to incorporate the needs of both JCA and JSC into their working practices.

Trend 3: Navigating demand, ethical access and future challenges of obesity

Our predictions about the rising demand and access challenges for novel obesity treatments have been largely accurate. The demand for GLP-1 agonists like semaglutide and tirzepatide has continued to soar, especially with their expansion into weight management for obesity. Novo Nordisk's semaglutide and Eli Lilly's tirzepatide have witnessed significant uptake in 2024. As expected, demand has exceeded supply in several regions, creating challenges for healthcare systems to manage access. The ethical questions surrounding access, particularly with such expensive treatments, have become more pressing. These drugs are seen as promising for managing obesity. Still, they come with high costs that raise issues around insurance coverage, accessibility, and whether they will be prioritized over other health interventions. A clear example of this was NHS England’s announcement that it will up to take 12 years for all patients to be offered Eli Lilly’s tirzepatide under the NHS!

Given the increasing pressure on healthcare systems to balance cost and equity, we see ongoing debates over prioritizing such treatments. As these drugs undergo further trials for expanded indications (such as heart disease), concerns about their long-term affordability and ethical access are intensifying.

In summary, this trend is worth watching closely through 2025 as manufacturers like Eli Lilly and Novo Nordisk launch these treatments in other markets such as China and may consider flexible pricing options to convince more countries and expand market access.



Trend 4: Does value drive price?

Earlier this year, we predicted a shift in focus from value to price. Our predictions were confirmed as increasing focus on cost-containment and price reduction across the EU has been a recurring theme in 2024. The economic aftershocks of the COVID-19 pandemic and the Ukraine conflict have made healthcare costs a significant concern in many countries. The impact of these events has shifted priorities, with many countries focusing more on controlling healthcare expenditure than on the value or clinical effectiveness of treatments. We've seen significant moves toward increasing discounts and clawbacks in markets like the UK and Germany. The push for generics and biosimilars is also gaining ground, further shifting the conversation towards price control. A recent review of pharmaceutical expenditure across the EU revealed that despite cost-containment measures, net expenditure on pharmaceuticals continued to rise with increases in drug prices not necessarily leading to a corresponding increase in patient access9.

As budget constraints continue to shape policy discussions, there is growing pressure on the pharmaceutical industry to innovate around pricing schemes. This brings back focus on the vital role of robust value propositions and early engagement with payers in clarifying evidence-generation plans.

Trend 5: US and Medicare price negotiations

We had anticipated that implementing the Inflation Reduction Act (IRA) in the US would lead to increased uncertainty about drug prices, cost savings, and downstream consequences for research and development plans and funding of innovative treatments. We also noted the increasing litigation from pharmaceutical manufacturers challenging the IRA price-setting processes. Our predictions were proved correct, and the analyses and discussions on the short and long-term consequences of the IRA continue into 2025, with several legislative bills aimed at correcting discrepancies with the IRA legislation noted in 2024. During the recent Q3 earnings calls, comments from across the industry were largely united in noting the negative impact on innovation. Another issue that has come to light is the IRA's requirement for Medicare to negotiate a maximum fair price for selected small-molecule drugs nine years after their FDA approval compared to thirteen years post-approval for selected biologics. This discrepancy between these time frames has led to questions about the relative value of small-molecule drugs versus biologics and has invited criticism from the industry. Several researchers have since analyzed clinical and cost data for FDA approvals and found that biologics and small molecules deliver similar health gains on average. Despite these criticisms, there has also been a widespread acknowledgment of the overall impact of the IRA price negotiations in limiting out-of-pocket costs to no more than USD 2,000 per year for all Medicare beneficiaries.

Conclusion

In conclusion, our annual predictions have proved to be relatively accurate this year. National budgetary pressures and the continuing uncertainty in the pharmaceutical industry on the value and impact of IRA price negotiations in the US are expected to continue into 2025. The impending implementation of EU HTA has led to a renewed emphasis on early launch planning and joint scientific advice processes. We look forward to continuing this exploration of pricing and market access trends as in the new year, we will share with you our forecast of key trends for 2025!