Anticipating the top 7 global market access trends for 2024: Cencora's healthcare landscape outlook

As we enter 2024, the global healthcare landscape is experiencing fundamental changes ushered in by major policy shifts and challenging payer decisions. While groundbreaking legislative changes and increasing global pricing pressures may be the clear headliners, there are other changes — state-of-the-art technological and medical innovations, the growth of potentially curative therapies — swirling against a backdrop of uncertainty across different geographies. In the United States, the Inflation Reduction Act will not only accelerate pricing pressures on high-cost, highly utilized products, but it will also lead to downstream patient access impacts. Globally, payers continue to expect that manufacturers demonstrate the value of their products to the healthcare system and patients.

In light of this ever-changing environment, Cencora's market access team offers insights on the top trends that are changing the face of market access. In 2024, all stakeholders will need a clearer understanding of how these dynamic trends will affect patient access to innovative therapies across global markets.

1. Drug pricing pressures

While drug pricing pressures have been a reality for manufacturers for years in most global markets — specifically the European Union (EU) — these pressures are emerging as a new reality for industry within the United States.

Key focus areas for 2024:

- The Inflation Reduction Act (IRA) is ushering in a new era of government price scrutiny, negotiations, and pressures for manufacturers.

- Negotiations in Medicare are likely to have future impact on innovation throughout industry.

- Medicare Part D redesign will cap out-of-pocket costs for patients, but manufacturers and Part D plans must share in the cost burden.

- Higher financial liability for Part D plans is likely to lead to narrower formularies, greater utilization management, higher premiums, and less plan availability in 2025.

Similarly, in Europe, the European Commission published its proposal in April 2023 to reform the EU's pharmaceutical legislation.

- A key objective of this legislation is to reduce drug prices by enabling earlier market entries of biosimilar products and facilitating exchanges of best practices on pricing and reimbursement between member states.[1]

2. Complete EU market access footprint

Significant legislative changes in Europe loom on the horizon over the next few years. While the most prominent is the EU Health Technology Assessment Regulation (HTAR), the European Commission has proposed a pharmaceutical package revising general EU pharmaceutical legislation

and making medications more accessible and affordable. Individual member states are also crafting other healthcare reforms.

Key focus areas for 2024:

• In Spain, a Royal Decree aims to revamp HTA regulation by introducing changes to governance bodies' structures and processes, in addition to implementing health economic assessments inspired by the UK's National Institute for Health and Care Excellence (NICE) approach.[2]

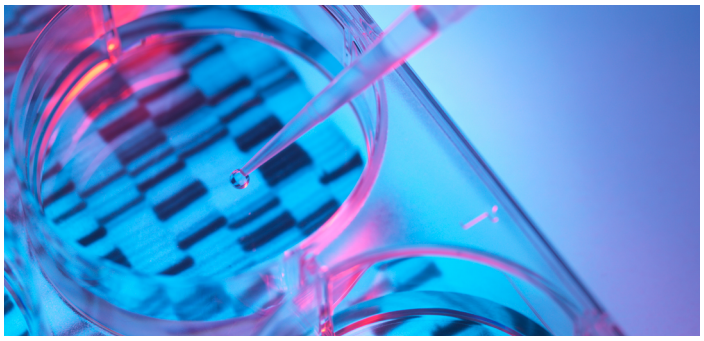
• In Italy, there have been significant reforms to the Italian Medicines Agency (AIFA), including merging the Technical and Scientific Committee (CTS) and the Pricing and Reimbursement Committee (CPR) into a single entity called the Scientific and Economic Commission for Medicines (CSE). This unified body will have the responsibility for conducting scientific assessments as well as making pricing and reimbursement decisions.[3]

• The objective for both is to ensure equal access to innovative medicines and new medical devices within individual countries and across the EU, specifically the following:

  – Reducing bureaucracy and redundancy across member states.

  – Speeding up access to innovative medicines.

  – Easing patient affordability challenges with greater price transparency, innovative payment schemes, population health models, and outcomes-based agreements.



3. Innovative and curative therapies

With cell and gene therapies (CGT) and other potentially curative therapies making significant advances in recent years, stakeholders have greater access to post-market data to review, evaluate, and support decision-making.

Key focus areas for 2024:

The CGT landscape is shifting from rare/ultra-rare indications to more common conditions.

• Manufacturers in the CGT space must consider the extensive ways in which this shift will impact global healthcare systems, patient access, long-term data collection, manufacturing capacity, and payer, provider, and patient education.

• Given the growth of CGTs, the US Food and Drug Administration (FDA) is ramping up its reviewer resources to support Biologics License Applications (BLAs), necessitating enhanced market access strategies focused on breaking down access barriers and attaining appropriate reimbursement.

• In the EU, advanced therapeutic medicinal products (ATMPs) will be submitted through the Joint Clinical Assessment (JCA) from 12 January 2025.

4. Role of real-world evidence in access

While pharmaceutical and biotechnology companies have traditionally relied on clinical trials for drug development, real-world evidence (RWE) is becoming a more important source of information. RWE includes data from insurance claims, electronic health records, patient registries, and beyond. By assessing how drugs, biologics, devices, and other products work in a real-world setting, companies and regulators gain insight into their impact on a far larger and more diverse population than in clinical trial settings.

Key focus areas for 2024:

• Stakeholders are increasingly recognizing the value of RWE to inform regulatory decision-making, optimize healthcare delivery, and enhance patient outcomes.

• As an example, the FDA does accept RWE to support decision-making in some cases. In 2018, the FDA established a framework to evaluate the potential use of RWE to support expanded indications of approved products.[4]

• Equally, access to outcomes-focused RWE will enable payers to better determine the value of the product. The utilization of RWE in decision-making will continue to expand as data sources expand and improve and as new methodologies for leveraging RWE are introduced.

5. Value-based healthcare

The combination of macro trends (e.g., prevention, cost of care, and social and demographic shifts) and micro trends (e.g., new modes of action, increased focus on rare diseases, and personalized care) is driving to the need to improve and reshape patient pathways beyond traditional drug delivery. Value contracts based on outcomes are complex and challenging to govern, as many factors beyond pharmaceutical intervention affect medical and patient outcomes. The process of defining the right outcome parameters, making these transparent, validating them, and compensating for

patient variation, is difficult. The exception is for those conditions where pharmaceutical intervention is the predominant therapeutic step, such as with curative CGTs or hematology.

Key focus areas for 2024:

• Value-based partnerships are expected to:
Gain prominence, mainly between manufacturers, hospitals, and often payers.

• Focus on integrating and improving care and increasing transparency of care, rather than on specific outcomes measurement (which is seen as a lagging indicator).

• Increase in importance amid a greater focus on new personalized medicine, rare disease, and curative therapies, all of which potentially impact the patient profiling process, care delivery path, supply chain, reimbursement decisions, and/or financing methods needed.

6. Drug-device combination products

The global market for drug-device combination products is growing rapidly. Micro-/nanotechnology and developments in electronic engineering and bioinformatics have resulted in state-of-the-art innovations in disease diagnosis and treatments. Flexible sensors, wearable electronics, 3D-printed implantable modules, and real-time monitoring are overtaking traditional drug delivery systems and biosensors. While these combination products do enable more personalized, patient-centered care, payers may struggle to evaluate the value proposition of both the drug and device components.

Key focus areas for 2024:

• Developing and providing evidence of improved patient outcomes and cost-effectiveness of the drug-device combination.

• Building convincing cases via collecting and utilizing real-world data to address payer concerns for gaining market access.

• Collaborate (pharmaceutical and medical-device manufacturers) to bridge the knowledge gap between these sectors in order to develop comprehensive market access strategies.

7. Artificial intelligence accelerating market access

Artificial intelligence (AI) is expected to radically transform every aspect of the healthcare industry, including the life sciences sector. AI promises enormous potential in streamlining and optimizing the complex process of gaining approval for new therapies.

Key focus areas for 2024:

• By leveraging AI technologies, biopharma companies can analyze vast amounts of data more efficiently, identify key insights, and make data-driven decisions to support their market access strategies.

• Importantly, AI could revolutionize forecasting and pricing strategies by analyzing RWE, patient outcomes, and health economic data, enabling biopharma companies to demonstrate the value of their products during a HTA and negotiate favorable reimbursement agreements with payers.

Keep your finger on the pulse

2024 promises to be another exciting year for industry. At Cencora, we stand ready to help answer your key business questions and help you meet your objectives. Over the coming months, our seasoned experts will continue to explore these fast-evolving trends and assess the impact on the way stakeholders across the healthcare system innovate, interact, and support decision-making.

1 European Commission. Reform of the EU pharmaceutical legislation. Accessed December 19, 2023.

2 PharmaTech.com. Changes Afoot in Pharmaceutical Laws and Regulations in Spain. Accessed December 13, 2023.

3 NAVLIN DAILY. Italian State-Regions Conference Approves AIFA Reform. Accessed December 13, 2023.

4 U.S. Food & Drug Administration, Real-World Evidence. Accessed December 19, 2023.

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