



CORPORATE FINANCE

AUGUST INSIGHTS PAPER: LAB TO LIFE

Bringing Breakthrough Medicines to Market

Market overview



Technological advancement and AI are accelerating drug discovery and development timelines and disrupting traditional pricing reimbursement schemes



Trending consolidation is being driven by demand from pharmaceutical and medical device companies for Market Access capabilities to provide end-to-end solutions within the broader commercialisation offering



Increasing complexity of novel therapeutics and shifts towards personalised medicine require specialised Market Access services to navigate an increasingly complex route to market



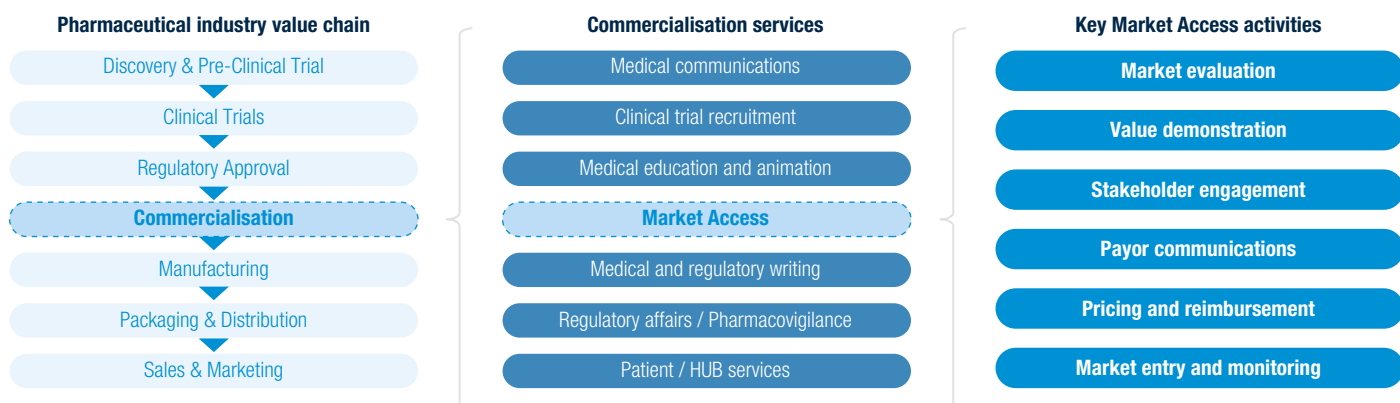
With a favourable policy environment, expanding data infrastructure and a collaborative approach between stakeholders, the UK has positioned itself as a highly attractive market for innovation

Market access – a complex and crucial factor in the pharmaceutical industry value chain



Market Access within the pharmaceutical industry is a broad concept capturing the process to ensure medicines and medical technologies are available to clinicians, and therefore accessible to patients at the right time and price. Securing appropriate payor coverage for products and developing each drug's pricing, contracting, reimbursement and fulfilment strategies is the responsibility of the Market Access team. In the context of pharmaceuticals in the UK, Market Access is the process of getting a drug listed on the NHS' approved drug list to be

eligible for reimbursement by the appropriate regional and/or local governing healthcare body or insurance companies. It requires the appropriate communication of a product's value, supported by health and economic benefit evidence. Proper functioning Market Access services help provide the population with new medicines at an equitable price that is reasonable in the context of limited public budgets, while incentivising pharmaceutical companies to continue developing new therapies.



Source: Association of the British Pharmaceutical Industry (June 2024), CIL commercialisation Services Market Analysis report (March 2024)

Core Market Access steps for a successful new product launch



Market evaluation – path of funding determination

Detailed analysis of the competitive landscape, regulatory environment, and stakeholder is needed to develop a plan to facilitate the product's successful market entry.

Value demonstration – clinical, societal and economic value

Developing clinical, social and economic value models to understand the overall value and support stakeholder communications and pricing and reimbursement negotiations.

Stakeholder communication and engagement – understanding and communicating the patient benefit

Engaging with key stakeholders (including patients, patient advocacy groups, and healthcare professionals) in order to communicate the value and gain support for new treatments, as well as understanding the target market.

Payor communications / marketing – gaining payor support

Communicating with payors (insurance companies and/or public health agencies) the value proposition and stakeholder support, helping future pricing and reimbursement negotiations.

Pricing and reimbursement rate negotiations

Negotiating a price that reflects the drug's clinical, societal and economic value, with consideration for the ability of the healthcare system to fund public use.

Market entry – strategy execution, monitoring and adaptation

Launching into the market and facilitating patient access based on the market analysis and launch strategy once regulatory approval is obtained. Includes timely monitoring of results and adapting the strategy as needed.

The rising use and importance of Market Access services



Market Access is becoming increasingly complex and more pharmaceutical companies are looking to outsource commercialisation services to specialised providers. Key themes contributing to this trend include:

Rising number of complex, niche and specialised therapies targeting smaller patient populations presents broader challenges:

Technological advancement continues to improve the range of diseases that can be treated. A growing number of complex therapeutics has resulted in an increasing volume of drugs coming to market, as well as an increasing need for Market Access services to communicate the value of the drug to the market and provide patients access to necessary drugs at fair prices. Negotiating pricing and reimbursement for medicines that target smaller populations is more difficult, increasing the need for Market Access services to successfully commercialise new drugs.

Constrained public budgets resulting in more competition for less resources:

With concerns in the UK and globally around soaring debt to GDP ratios, austerity measures threaten resources available and increase competition for drugs coming to market. This means pricing and reimbursement negotiations may only become more difficult, resulting in further reliance on Market Access services to communicate the clinical, economic and societal benefits of the drug to be approved for reimbursement.

Integration of AI throughout the drug commercialisation pathway:

Generative AI has the potential to accelerate the drug development pathway through identification of new drugs, speeding up of drug development and clinical trials, and

automating more of the approval process. AI is also expected to be integrated into the pricing and reimbursement models, providing more accurate and timely data analysis.

Pricing pressures and global shift to value-based pricing:

A dynamic political environment globally and a general shift towards value-based pricing is increasing the need to demonstrate the total value proposition of the product through improved clinical, economic, and societal outcomes. This requires more time, resources and specialisation to determine and communicate the total value; which is ultimately used for price and reimbursement negotiations.

Expanding number of independent launches from small biopharma companies that lack in-house resources:

Many new drugs are being developed by small biopharma companies and launched independently (without partnering with larger pharma companies). With limited internal resources, Market Access and other outsourced pharma services are needed to support these independent launches.

Increased appetite for outsourced pharma services across the value chain:

Reducing overhead costs and capital investments in infrastructure and personnel has been trending in the pharmaceutical industry to provide a lower fixed cost structure and flexibility to scale operations based on current pipeline and demand levels. There are no signs of this trend slowing down, with international outsourcing also on the rise as companies look to expand outside of their domestic markets.



Despite a turbulent few years in UK politics, the recent General Election offers a more positive outlook for the UK Life Sciences sector



The July 2024 UK General Election brought the Labour party into power through a landslide majority, with a promise of change. The UK economy is estimated to have grown 0.6% in the first half of 2024, the highest of all G7 countries¹. That said, Labour have inherited an economy with over a decade of low economic growth and an alleged £22bn black hole in the public finances.

For the healthcare sector, this is defined by stressed public health services following years of NHS underfunding. The industry needs a clearly defined plan to rebuild the UK's healthcare system, address the persistent inequalities in access to medicine, and unlock the sector's true growth potential.

Both in the run up to and post-election, Labour have expressed their commitment to the life sciences sector. Per the Labour Party Manifesto 2024, the Labour Government intends to invest at least 3% of GDP in R&D in both public and private sectors and increase annual pharmaceutical R&D expenditure by £10bn.² Earlier this year at the Labour Business Conference, the party set out their plan for the life sciences sector – 'A Prescription for Growth' – detailing their core focus areas: rebuilding the NHS and strengthening the industry's foundations.

Some of Labour's key commitments include:

1. Creating a more certain funding environment

Addressing the sector's ongoing challenges with funding uncertainty, Labour aims to implement a more streamlined funding process, with the ultimate aim of attracting long-term investment. This includes setting 10-year budgets for funding bodies and key R&D institutions.

2. Improving the business environment

Providing much needed stability by maintaining or increasing R&D tax credits, as well as retaining the patent box regime, protecting the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCT).

3. Modernising and unblocking the regulatory regime

Cutting the red tape in the drug approval process, Labour plan to build a system of earned trust in place of reporting and audits. In October 2023, Labour declared plans for a new Regulatory Innovation Office (RIO) to address Medicines and Healthcare products Regulatory Agency (MHRA) backlogs. The new RIO expects to hold regulators accountable for driving innovation and minimising delays.

4. Harnessing data for improved patient services and medical research

Currently the UK's vast amounts of health data are fragmented. Labour plan to make better use of the data generated from the NHS, the world's largest integrated healthcare provider. Leveraging the power and scale of the UK's healthcare data will be further supported by a broader strategy on AI to support the development of data-driven systems.

Outlook

The UK life sciences R&D and commercialisation ecosystem has historically faced challenges, and despite being a leading innovator in pharmaceuticals, the UK has been slower to adopt new treatments compared to its European counterparts.³

Post-Brexit, the Government implemented pivotal regulatory and policy changes aimed at cultivating greater investment, research and patient access with the potential for the UK to enhance its status as a global leader for biopharmaceutical innovation.

The UK Government has made significant efforts to reduce the negotiation and reimbursement challenges that pharma companies face for effective access in the UK. New approaches to regulation, Health Technology Assessment (HTA) and reimbursement have established accelerated regulatory pathways, including:

- The Early Access to Medicines Scheme (EAMS) launched in 2014. The MHRA is continually seeking to expedite the regulatory approval pathway, working in collaboration with international agencies such as the FDA and EMA.
- Likewise, the national HTA agency NICE has revised its processes to facilitate access, and the new Voluntary Scheme for Branded Medicine Pricing & Access (VPAG), introduced earlier this year, will substantially grow the NHS spend on innovative drugs and achieve cost savings on older, branded medicines.
- The Government has invested in leveraging the vast amounts of healthcare data generated across the NHS and private healthcare market to support improved patient outcomes.

Whilst the benefits of Labour's proposed objectives may take some years to come to fruition, Labour have certainly demonstrated their commitment to the UK's healthcare system and R&D infrastructure. On top of the progress already made to date, this approach will ensure the UK is an increasingly favourable hub for drug innovation underpinned by a robust data ecosystem, with efficient regulatory pathways to support faster patient access to therapies.

Source: ¹ Office for National Statistics (<https://www.ons.gov.uk/economy/grossdomesticproductgdp>); ²Bloomberg UK (<https://www.bloomberg.com/news/articles/2024-01-30/labour-plan-for-10-billion-investment-in-uk-life-sciences>); ³Association of the British Pharmaceutical Industry (<https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/improving-access-to-medicines-in-the-uk/>)

Selected Precedent Transactions¹



| Date | Target | Acquiror | Deal rationale |
|--------|--|---|---|
| Jun-24 |  Mtech Access  Delta Hat <small>Powered by Petauri</small> |  petauri <small>POWERING HEALTH</small> | The acquisition of two UK assets – Mtech Access and Delta Hat – will bolster Petauri's suite of technical and specialised solutions, on a global scale. |
| May-24 |  AxTalis |  MAP <small>ACCELERATING PATIENT ACCESS</small> | AxTalis, the Belgium-based consultancy firm, marks MAP's first acquisition since investment from Kester Capital in 2023, strengthening the group's European presence. |
| Apr-24 |  CHEORS <small>COMPLETE HEOR SOLUTIONS</small> |  PharmAlliance | The acquisition of CHEORS strengthens PharmAlliance's global footprint, and expands its launch and commercialisation capabilities. |
| Feb-24 |  Cogentia® |  HELIOS <small>MEDICAL COMMUNICATIONS</small> | Helios (backed by NorthEdge) acquired Cogenti, adding HEOR and Market Access to its offering as well as building on their global capabilities. |

Despite a widely consolidated middle-market, Market Access continues to be a sought-after segment of commercialisation services



As complexity and volume of novel therapeutics increases, Market Access services in the drug commercialisation pathway are becoming more critical for successful launches. Companies that can provide specialised knowledge across various regions and therapy areas at scale provide a more attractive offering to pharmaceutical companies.

Pharma commercialisation providers are increasingly looking to develop a full-service, end-to-end service offering. Existing platforms lacking Market Access solutions are looking to acquire those capabilities, while platforms with existing Market Access capabilities look to bolster their offering by acquiring companies with niche, specialised skillssets and specific geography regulatory knowledge.

The past half-decade has seen rapid consolidation in the Market Access sector, with strategics and Private Equity (PE) picking up assets within Market Access looking to build full-service commercialisation platforms, as well as adding to their global client base and regional footprint. For example, May 2021 saw Fishawack's acquisition of PRMA Consulting, a Market Access and HEOR consultancy. Similarly, in September 2022, HMP Global acquired Proximity Health, a California-based consultancy focused on providing Market Access insights in the Oncology space.

There have also been several PE platforms making multiple roll-ups to strengthen their offering: Lumanity completed six bolt-ons in the Market Access and Med Affairs sector between 2020 and 2022 alone. Similarly, Fingerpaint Group also completed its second bolt-on of MYND in 2023, following the acquisition of 1798 in 2020.

With a surge in M&A activity over the last half-decade, Market Access continues to be one of the most in-demand subsegments of pharma commercialisation, with the scarcity of smaller providers making it even more valuable.

Pharma commercialisation more broadly continues to represent an attractive investment opportunity, underpinned by strong pharmaceutical market fundamentals, as touched on in our June Insights Paper. This is reflected in the generally strong valuations in the market, often generating double-digit EV/ EBITDA multiples. For Market Access more specifically, businesses can achieve higher valuations due its increasingly specialised and in-demand services.

Given the largely consolidated landscape across the mid-market, strategics and PE-backed platforms are now increasingly looking for specialist capabilities within Market Access. For example, RWE (Real World Evidence) and tech-enabled tools to further strengthen their offering, as well as acquiring for regional expertise in Market Access strategy and relationships. 2024 has already seen a number of deals to this extent, including PharmAlliance's acquisition of CHEORS, a provider of RWE and Health Economics Outcomes and Research (HEOR) and Market Access services, in April this year.

Overall, demand for Market Access companies is expected to remain high as Pharma Commercialisation platforms look to either acquire Market Access capabilities, or expand their current offering with additional headcount, functional services, and/or geographic presence.

Source: ¹MergerMarket, A&M Analysis



Sector outlook



An increasingly complex drug commercialisation environment along with trending outsourcing of pharma services provides a positive outlook for growth in outsourced Market Access services providers. As more complex and niche medicines come to market, all competing for limited public funding, going to market with a well-crafted market access strategy will continue in its importance in ensuring drug launches are successful. This is all before considering the disruptive impact of AI throughout the entire drug commercialisation pathway.

A Labour Government has brought optimism to the Life Sciences industry, promising funding stability for continued R&D and a commitment to strengthening underlying infrastructure, including the development of data-driven systems. The increased digitisation of the healthcare industry will enable deeper insights and analytics to feed into Market Access strategy. Furthermore,

Labour's focus on rebuilding the NHS will support patient access to medicines and products, relieving pricing and reimbursement negotiation challenges currently faced by Pharma companies.

Labour's commitment to the Health and Life Sciences industry, alongside strong market fundamentals, sets an opportunistic environment for investors. Pharmaceutical services continue to attract significant attention from both strategics and PE-backed platforms, with the demand for such businesses reflected in the higher valuation multiples being achieved.

Despite a recent period of heavy consolidation across the middle-market, Market Access continues to be a sought-after area of commercialisation expertise. Specialist capabilities, therapeutic expertise and local know-how are key consolidation trends looking forward, with commercialisation providers aiming to strengthen and expand their current Market Access offering.

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