OVERCOMING PHARMA'S **VALUE AND ACCESS CHALLENGES**

Novasecta

The pharmaceutical industry is becoming crowded with innovative, expensive medicines as healthcare budgets continue to tighten. It is increasingly challenging for pharma companies to demonstrate the value of new medicines and negotiate a price that rewards investment in innovation. Meanwhile, payers are struggling to reimburse new medicines at the prices proposed by pharma companies and are evolving value assessment approaches and pricing policies to manage this. Payers and Health Technology Assessment Agencies (HTAAs) are also increasingly collaborating on a global scale to leverage shared information and adopt a unified approach to assessing the value of new medicines.

Pharma companies must proactively navigate these challenges to overcome access barriers and deliver value for patients. Embedding operational excellence in Value and Access is critical to achieving this.

Demonstrating Value

The traditional value measures of efficacy and safety are no longer sufficient for pharma companies to convince payers to reimburse new medicines at a price and position in the treatment paradigm that optimises access and supports commercial success. Payers and HTAAs are raising the bar by relying on a growing range of value measures to guide reimbursement decisions, and pharma companies need to be prepared to respond.

The UK's NICE published updated HTA guidelines in 2022 that place greater emphasis on Real World Evidence (RWE) and Patient Reported Outcomes (PROs) and established an 'HTA Innovation Lab' to develop new assessment methods. ICER, one of the more prominent HTAAs influencing decision-making by US payers, considers a wide range of value measures in its assessment framework from budget impact to the effect of delivery mechanisms on patient adherence.

IMPERATIVES FOR PHARMA COMPANIES

- **Promote an open and ongoing dialogue with payers and HTAAs** to understand and shape the evolving value assessment landscape, ensure the patient voice is reflected in assessment models, and co-create new evidence requirements and measures
- **Build externally-wired Value and Access teams** that can communicate the value of the function and the needs of the external landscape, to ensure Value and Access has early involvement in decision-making, and clinical trials and endpoints are designed to meet payer requirements
- **Create compelling value stories** in the form of comprehensive and well-structured evidence packages that incorporate a variety of data (e.g., RWE, PROs) from a range of sources (e.g., patient registries, wearable technology) to meet evolving payer requirements and strengthen value demonstration

Obtaining a Price that Rewards Innovation

Payers are under growing pressure to control drug prices as their budgets struggle to absorb the costs associated with ageing populations and the rising number of expensive therapies, and governments are updating drug pricing legislation to manage this. Meanwhile, pharma companies need to recoup the rising costs of development, often from smaller patient populations (e.g., for rare diseases).

The Inflation Reduction Act (IRA) will enable the US government to negotiate the price of the highest-spend Medicare drugs from 2026. Similarly, the German GKV Financial Stabilisation Act includes legislation that halves the period of free pricing following a new drug's launch and increases the mandatory rebate pharma companies must pay to insurers.

IMPERATIVES FOR PHARMA COMPANIES

- **Establish a continuous feedback loop with payers,** collaborating closely to co-create new pricing and payment solutions and continuous evaluation approaches that satisfy both sides of the table
- **Leverage comparator and analogous drug data** including direct and indirect costs to form a convincing economic argument, reinforce price points, and shift the payer mindset to a longer-term view
- **Embrace innovative payment models** such as value-based agreements to share risk with payers and ensure the requisite endpoints are pre-emptively included in clinical trial designs

Negotiating with Unified Payers and HTAAs

Payers and HTAAs increasingly view international collaboration as an opportunity to share information, streamline processes, promote comparable access to medicines across countries, and ultimately support their negotiating position on a global scale. Pharma companies need to help payers and HTAAs understand the implications of their decisions, particularly considering this increasingly unified approach.

The UK's NICE recently launched an initiative with the Canadian and US HTAAs, CADTH and ICER, to create a more consistent and transparent approach to storing and analysing confidential clinical data. With a similar objective, a joint EU HTA procedure will be launched by EUnetHTA in 2025 following the passing of the European Commission's HTA regulation in 2021.

IMPERATIVES FOR PHARMA COMPANIES

- **Optimise cross-functional collaboration** between Value and Access and other key externally facing functions such as Government Affairs, Public Affairs, Medical Affairs and Regulatory Affairs, to involve the right internal stakeholders at the right time and enable an effective and aligned 'one-company' interaction with the external stakeholder ecosystem
- **Coordinate efforts between affiliates** to take advantage of global access and pricing opportunities and share insights, lessons learned, and best practices
- **Maintain close relationships with external stakeholders** including payers, HTAAs, policy makers, and regulators to stay informed of access challenges and opportunities, and help shape the access landscape and legislation

IN CONCLUSION

Pharma companies need to navigate challenges associated with complex value assessments, stricter price control, and increasing collaboration between payers and HTAAs. To overcome these challenges, pharma companies must convince payers of products' compelling clinical and economic value, proactively shape the pricing and reimbursement environment in collaboration with external stakeholders, and adopt a global perspective to ensure patients can get timely access to innovative medicines at a fair price.

Novasecta supports pharmaceutical leaders to embed operational excellence in their organisation. For Value and Access, this is a critical outcome to maximise the effectiveness of the function in overcoming the challenge of delivering value for patients.