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Pricing and reimbursement

Historic global shifts in drug pricing and pharmaceutical reimbursement policies are colliding with intensifying competition to boost market access in the race to produce innovative therapies. Life sciences companies are responding to these commercial pressures through dynamic pricing techniques in which prices fluctuate based on real-time data such as customer demand; robust data analysis of market data to identify trends related to reimbursement and coverage decisions; and portfolio management approaches that account for a growing number of specialized treatments for a range of ailments.[1]

In the US, life sciences leaders are developing new commercial strategies to address the pricing impact from the 2022 Inflation Reduction Act (IRA), which includes provisions aimed at lowering out-of-pocket costs for patients. These maneuvers are arising as pharmacy benefits managers anticipate a surge of biosimilar drugs that are expected to hit the market, offering an opportunity to lower drug prices through 2024 and beyond.[2]

At the same time, pharmaceutical companies worldwide are reconfiguring their commercial teams to better understand niche diseases such as genetic disorders through hyper-targeting of patient populations. These developments are reshaping tactics in the life science sector as companies reposition pricing in an increasingly competitive landscape.

Across non-US markets there's also a recognition of the increasing pressure on pricing and equitable access to treatments. The Access to Medicines Foundation, a non-profit that monitors the pharma sector's progress in addressing access to health care in more than 100 low- and middle-income countries, is tracking increased global awareness and demand for addressing inequities in health care, such as a need for greater regulatory harmonization in Sub-Saharan Africa.

> ***"There's definitely more awareness among different stakeholders on the issues of global inequity," Jayasree K. Iyer, CEO of the Access to Medicines Foundation. "Products are available, but they're not available for people who really need them in resource-limited settings. So, awareness has definitely crept into the industry, investors, and governments to better demand leadership from companies."[3]***

Confronting pricing uncertainties

One of the most significant pricing changes came under the IRA in the United States, which for the first time empowers Medicare, the US national health insurance program, to negotiate drug prices and compels drug makers to pay inflationary rebates. The number of drugs it can negotiate is limited, but the impact could be outsized as the IRA allows Medicare to negotiate prices of some of the most expensive drugs. The IRA will also cap Medicare patients' out-of-pocket expenses to about US$2,000 a year. It's the most consequential legislation addressing drug costs since the passage of the Medicare Modernization Act in 2003, which established the original drug benefit.[5]

The IRA, as written, will cap Medicare Part D out-of-pocket drug costs for beneficiaries at US$2,000 by 2025. Life sciences companies can negotiate drug prices through the end of the decade, but the law will have specific implications for high-cost medications. Drug makers will need to assess the financial impact, conduct negotiations with the US Centers for Medicare and Medicaid Services (CMS), and adjust agreements with customers. According to the current changes, the law empowers Medicare to negotiate prices for 10 drugs in 2026, which may increase to 60 by 2029.

We anticipate the sector will consider arguing that the government acted beyond its statutory authority. Another: Claiming that the IRA runs afoul of the US Constitution's Eighth Amendment, which protects against excessive fines. One provision in the IRA allows the government to levy an excise tax of up to 95% on drug companies that don't comply with price negotiations.[6]

For now, the sector is confronting lower prescription costs for Medicare patients as drug pricing provisions take effect in 2023.[7] Among the drugs that could be affected are the anticoagulant Eliquis, manufactured by Bristol-Myers Squibb and Pfizer; Eli Lilly's diabetes medicines Trulicity and Jardiance; and the cancer medicine Imbruvica from AbbVie and Johnson & Johnson.[8] In 2020, Medicare spending on these four medicines totaled US$18.6 billion across more than 3.7 million beneficiaries.[9]

Drugs without a single source and competing products that are approved and marketed will not be eligible for negotiation. Small-molecule and biologic drugs derived from living sources are exempt from negotiation until they have been on the market for nine years and 13 years, respectively, which could limit the law's incremental impact on drug sales.[10] These drugs will be excluded from negotiation until generics and biosimilars are available.

> ***Richard Saynor, CEO of Sandoz, the Swiss pharmaceutical company said, "True innovation is about giving people access to high quality generics and biosimilar-originated products in a fair and transparent way."***[11]

Promoting flexible pricing approaches

As a result of the IRA drug pricing provisions, Medicare may broaden its acceptance of value-based pricing, which some health providers already offer. For instance, Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other providers that deliver coordinated high-quality care to Medicare patients. These organizations treat almost 20% of Medicare Advantage and about one-third of traditional Medicare patients.[12]

Adopting similar pricing for prescription drugs, however, would require an independent assessment of clinical value that would determine payment, rather than current models that define payment by the manufacturer's list price.[13,14]

Many companies have called the IRA reforms an attack on innovation. AstraZeneca CEO Pascal Soriot warned that the negotiation requirements could inhibit patent protections under which pharmaceutical companies can recoup drug development investments over a decade. Soriot has also called the law an "imposition of price" rather than a negotiation.[15] Eli Lilly attributed its decision to stop development of a US$40 million cancer drug to the IRA.[16]

Despite these concerns, companies such as the Swiss pharmaceutical firm Novartis have said they will continue to invest in the US, the world's biggest pharmaceutical market.[17]

Tailoring pricing and reimbursement to regional markets

Creating policies on drug pricing and reimbursement depends on factors such as health records, competition, and profit margins.[18,19] For instance, a study of almost 60 Dutch health care decision makers found they were less likely to reimburse products with higher margins, with 61% of respondents saying profit margins should play a role in reimbursement decision making.[20]

To more accurately assess health care costs and benefits, markets such as the European Union (EU), the UK, and Australia use health technology assessment (HTAs). The tools provide recommendations on medicines and other health technologies that can be financed or reimbursed by members. HTAs consider a drug's initial price, target population, and clinical effectiveness in determining its value.[21]

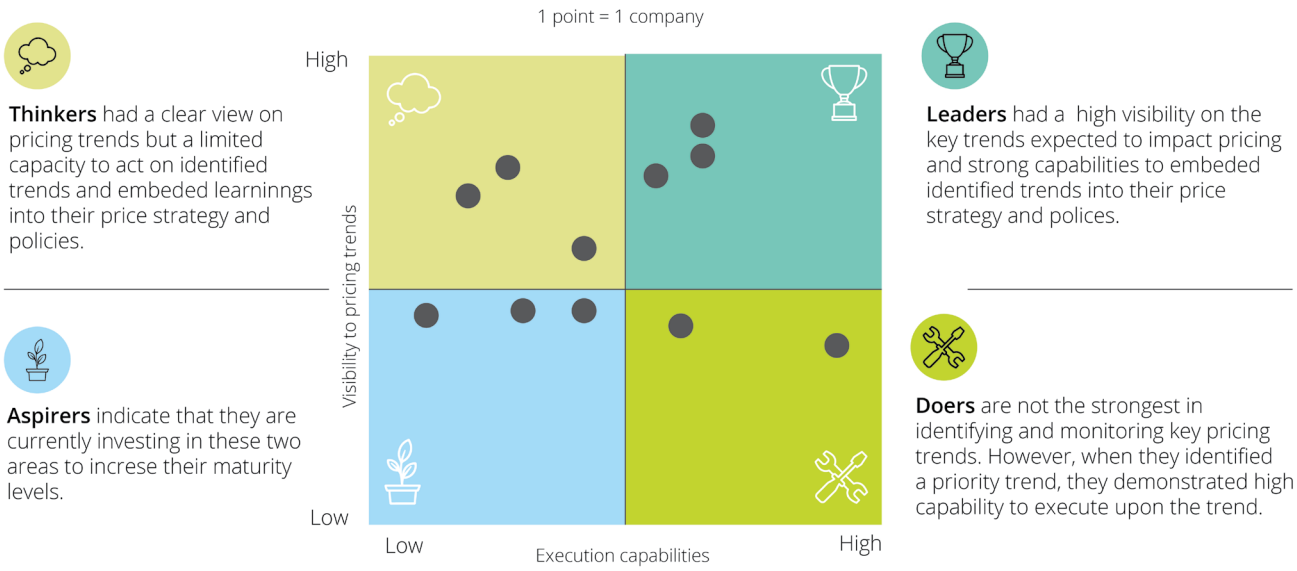
Beginning in 2025, the EU will require that pharmaceutical manufacturers align their clinical development programs with HTA requirements to improve clinical value, pricing, and reimbursement.[22]

In the nearer term, the European Commission is actively discussing plans to bring medicines to patients underserved parts of the EU by trimming two years from exclusivity agreements. The EU legislation would allow pharma companies to earn back one or both years of the protection if they agree to launch the medicine in all areas of the political bloc – with significant implications for price negotiations for companies that wish to delay the entry of generic competitors to the market.[23]

To prepare for these new pricing rules, life sciences companies are incorporating pricing and market access decisions more consistently and earlier in the product development process (Figure 1). The US Food and Drug Administration (FDA) offers guidance to manufacturers for communicating economic information before receiving marketing approval.[24] The process creates more comprehensive planning and budgeting for new therapies.

Figure 1. Pharma perspectives study on visibility into pricing trends and execution capabilities.

Four archetypes emerged from the study:



Source: Deloitte analysis

One measure for addressing shifts in drug pricing involves balancing a country's ability to pay with the individual needs of patients. Some pharmaceutical companies are using data analytics to predict local market responses to specific products. For instance, the biopharmaceutical company Amgen, working with local health systems, is using digital capabilities and advanced customer data and analytics to predict customer responses. This approach has also allowed the company to establish access closer to regulatory approval.[25]

AstraZeneca relies on tailored payment models, such as Tiered Pricing, which is based on Gross National Income. The company has also prioritized value-based agreements to align cost with economic prosperity, clinical benefits, and other predetermined conditions. AstraZeneca also considers factors including national budgets, health economics data, and gross domestic product (GDP) when considering a government's ability to pay.[26]

> ***"These agreements allow us to make sure that you know the right medicine is being given to the right patient at the right time in the right setting," according to Ana Plata, Global Pricing Head, BioPharmaceuticals, AstraZeneca. "It's becoming much more common to discuss the impact our medicines are having on health care systems and make sure that patients indeed have timely access to those medicines we're providing."***[27]

In China, health care reforms are improving access to quality drugs, and life sciences companies are aligning their reimbursement strategies to gain access to the National Reimbursement Drug List (NRDL). The NRDL, which went into effect in January 2022, includes more than 2,800 drugs - more than 1,400 of which are Western-made and the rest from Chinese patents. The average negotiated price decrease across all drugs is 61.7%.[28]

China prioritizes domestically produced drugs for the NRDL, but it's more likely to add foreign manufacturers of rare disease treatments to the list because of a lack of homegrown alternatives.[29] Multinational companies such as Pfizer, AstraZeneca, and Biogen recently reduced drug prices by more than 50% to secure a place on the NRDL. Despite the reduced prices, companies can take advantage of a large population to offset the lower margins. Through this strategy, AstraZeneca expects that new treatments will contribute to about 60% of its China revenue by 2024.[30]

Marketing specialized, next generation therapies

The comparatively high cost for treating diseases that affect a small population, is one of the key pricing challenges for this group of medicines. Consider that the average annual cost of orphan treatments, designated in the US as a drug to treat, prevent, or diagnose a disease affecting fewer than 200,000 people.[31] That figure was US$32,000 per patient, with 39% costing more than US$100,000 annually, according to a 2022 literature review and interviews with health plans and pharmaceutical manufacturers.[32] As a result, the growth in specialized, next generation therapies requires its own type of commercialization strategy for pricing and reimbursement.

For instance, commercial teams must be conversant in niche disease areas to engage the right stakeholders. Some are bringing in health economics and outcomes research (HEOR) professionals to support commercial teams by combining commercial and pricing strategies with clinical knowledge.[33] Novartis and Takeda, the Japanese pharmaceutical company, are hiring third-party HEOR professionals, while other companies are upskilling their existing sales teams or tapping external HEOR consultants.[34]

In 2021, the European Commission launched an open public consultation to consider revising legislation on pediatric medicines as well as treatments for rare diseases. The move came after a prior evaluation showed that while regulations had spurred research and development, there continued to be shortcomings in areas of unmet need, as well as a lack of accessibility to treatments for all EU patients.[35]

Pursuing specialty and curative therapies often requires companies to spend a disproportionate amount time on a comparatively smaller patient population. Yet payment models often depend on delivering that outcome over 10 to 15 years. Therefore, some companies either accept payment later or give rebates if the patient enters remission or dies. This makes it difficult for companies to know how much they may have earned at any given time.

For example, if a company spends US$500,000 a year for 50 years on hemophilia factor therapy, compared with a US$3 million gene therapy that cures once, the two approaches require vastly different business models for investing in curative treatments with upfront payments, as opposed to long-term chronic treatments.

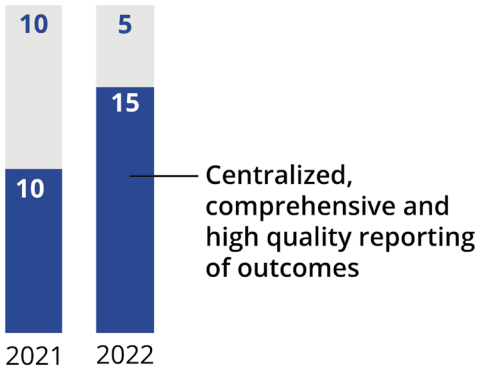
The rise in transformative therapies not only changes the modality from treatment to cure but also fundamentally changes the dynamics around pricing, requiring creative commercialization strategies as new treatments take center stage.

Managing implications of pricing trends and transparency

To increase drug access, life sciences companies' have potential legal hurdles and reputational risks. In the decade since Vermont became the first US state to pass a drug price transparency law, more than 20 other states have put price taken similar action, adopting provisions for price increase notification, price reporting, or budget controls. Pharmaceutical companies must keep up with a patchwork of rules or risk substantial fines: Nevada issued more than US$17 million in penalties against non-compliant companies in 2019, while California fined companies more than US$28 million for reporting violations the same year.[36]

In its annual review of equitable access and pricing transparency, The Access to Medicines Foundation asserts that in a future pandemic, the governments should work with companies to create procurement agreements that are transparent with equitable pricing and global access. The foundation's Access to Medicine Index also stresses the importance of sharing knowledge to reduce disparities in access to medicine (Figure 2).[37]

Figure 2. More companies are increasing transparency about their access-to-medicine activities



Source: 2022 Access to Medicine Index.

> ***"We see a lot of debate in the global context around R&D, cost, and transparency, and we're really only at the foothills when I think of value-based pricing," says Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry. "We're only now starting to see the technology starting to come through in terms of data capture and access in health care systems to fuel genuinely value-based approaches. There's an exciting future there."[38]***

Pricing and reimbursement consideration for executives

- How are we integrating pricing and access trends into our early clinical development decisions and data strategies?
- How can we communicate pricing updates while highlighting real-world evidence?
- How can we assure rapid access to market data to quickly identify trends related to coverage decisions?
- How can we ensure pricing transparency and more effectively manage our reputational risks in regard to pricing?

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Pharma market access and launch strategies

Inflation's impact on health care

Acknowledgements

We would like to thank the following individuals for their contributions to this chapter: Anne Phelps, Hanno Ronte, Brian Corvino, and Brad Maruca.

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