Getting drug pricing right

The pharmaceutical sector has faced growing criticism in recent years for the high price of its medicinal products. In the face of strong regulatory, sociopolitical and competitive market forces, getting pricing "right" is challenging but essential for the success of the industry, companies, stockholders and patients

Questionable pricing strategies in recent years have caught the attention of the media, governments and the public. For example, Mylan's EpiPen price increased by more than 600% in several years.[1] And the price of the drug Daraprim (pyrimethamine), commonly used for patients with AIDS and certain cancers, rose from $213.50 to $750 per tablet following the acquisition of the product by Turing Pharmaceuticals.[2] One year later, the price of the latter dropped to $350 per tablet.[3] Similarly, cycloserine, a drug for the treatment of multidrug-resistant tuberculosis, saw its price rise from $500 to $10,800 per 30 tablets following its acquisition by Rodelis Therapeutics.[3] There are several other examples of companies that have dramatically hiked their prices following the acquisition of existing drug products.

These drugs are long-established generic products. The annual increase in treatment for some patients rose to hundreds of thousands of

dollars.[3] Outcries came not only from patients, but doctors who feared that they would need to prescribe alternative, less-effective therapies. The companies implementing these pricing strategies clearly exploited an existing and flawed system.[1]

They also created a strong backlash against the pharmaceutical industry, with extensive negative discussions and heightened levels of scrutiny on social media. Innovator companies developing novel medicines must develop effective pricing strategies in the face of this harsh rhetoric and political posturing, which can be quite challenging, given that novel therapies represent new standards of care with no existing products to help with value determinations.

Perception of arbitrariness

These unreasonable price hikes, and prices for new biologic drugs that can run into the tens of thousands of dollars per year, contribute to the perception by many consumers, advocacy groups and politicians that drug pricing is arbitrary and only driven by the pursuit of profits. For ethical drug manufacturers, the truth is quite different. Establishing drug pricing strategies is a complex process that is influenced by numerous, often dynamic factors. It has become even more complicated by the growing need to justify and defend the valuation process to a broad range of special-interest stakeholders with little or no understanding of the issues involved.

Drug development and manufacturing is a risky, costly and lengthy process. Advanced technologies and highly trained scientists are required to understand diseases and discover potential new compounds that effectively target them. Specialised equipment and facilities run by skilled operators are required to develop and implement effective manufacturing processes. The vast majority of drugs that progress to the clinical trial stage ultimately fail to become approved, marketed therapies. Taking into account the costs of all of these failures and the direct R&D and manufacturing costs for a specific new therapy, the cost to develop a commercial drug product is estimated to be in the billions of dollars.[4] Once a drug is launched, often significant additional monies are spent on further clinical studies, safety monitoring efforts and regulatory activities.[1] Pricing strategies are designed to recoup these costs and allow for some level of profitability.

Learning from other sectors

Just as the pharmaceutical industry has turned to other sectors for ideas about new manufacturing solutions to address the need for increased productivity and efficiency, it may gain insights into effective pricing strategies by considering the approaches adopted in other industries managing complex and lengthy product development cycles.

Pricing professionals in the commercial and industrial businesses operating in these sectors generally receive extensive internal training regarding their firms' institutionalised pricing processes, which are specifically designed to best serve the precise interests of each company. Assistance can also be found from organisations such as the Professional Pricing Society, which offers ongoing educational, information sharing and networking opportunities to support the continuous improvement of pricing models.

> "Perhaps one of the greatest lessons that can be learned from studying pricing strategies in other industries is the recognition that there are many pricing models and no one-size-fits-all process

Effective pricing strikes a balance between supply and demand; priced too high, demand falls and vice versa. In the pharmaceutical industry, for instance, studies by the Institutes of Medicine have shown that if the point-of-purchase price is too high, people tend not to fill their prescriptions and never take the medicines they've been prescribed.

In the oil and gas industry, which is a cyclic market, oil and gas retailers command higher margins when demand outpaces supply and lower margins (often negative) when supply exceeds demand. These companies maximise pricing (margins) during the good times so they can cover the downturns in demand and sales during the bad times. The cash and profit generated from high-margin sales and upcycle demand is often invested in exploration, acquisition and production expansion — which eventually leads to increased supply and lower prices/margins.

In turn, gasoline retailers must deal with constantly changing micro and macro supply-and-demand signals, which leads to a highly efficient pricing system. Indeed, gas stations located on the higher-traffic side of the street may be able to have slightly higher prices because of the value they offer in convenience, which may not be obvious to the public. This industry also receives similar scrutiny and scorn to that experienced by the pharmaceutical industry when the price of gasoline is perceived to go above historic norms.

Value-based pricing

One question that pharmaceutical pricing professionals must answer is whether to use cost-plus or value-based pricing. With the cost-plus approach, companies determine prices based on the costs associated with producing their products. Value-based models, by contrast, take into consideration the perceived value of a product to the customer, which can be difficult to determine.

Despite the fact that value-based pricing is generally thought of as a more effective method, simpler cost-plus pricing calculations are often used by default by many organisations … leading to numerous problems, according to Invento's Balaji Viswanathan (VP Products).[5] There are two key concerns with cost-plus pricing: often, money can be left on the table while, at the same time, customers are left unsatisfied.

The cost-plus pricing model has been mandated by some governments in the past in an attempt to control the ability of the pharmaceutical industry to set prices. Under these types of regulations, companies are typically permitted to charge just enough to cover production costs and make a "fair return" on the sale of their drug products. The intentions may be to not only prevent excess profits, but to ensure access to medications by all facets of the population.

The trend today, however, is to move away from cost-plus pricing models and towards value-based pricing regimes in the pharmaceutical industry. This move has been happening in the UK and

Germany, for instance. In the US, value-based pricing was first introduced with the adoption of the Affordable Care Act. The intention was to set prices based on a common understanding of the cost and performance balance between buyers and sellers to better serve each party's interests.

Acknowledging customer needs in pharma

That need to understand cost and performance on both sides — that is, the need to acknowledge the needs and perspectives of customers as the starting point for any pricing/strategy development discussion — is the key to successful value-based pricing and is very different from the traditional cost-plus pricing approach. In the pharmaceutical industry, rather than ask: "What do I need to charge to cover my costs and make a decent return?" the question to answer is: "Given the market's perception of my product portfolio's value, which of those products can we profitably produce?"

A switch to value-based pricing won't make the pricing of pharmaceuticals any easier. The complexities of establishing value can be daunting and costly. Efforts must start with data from the earliest development phases through clinical trial results and also include post-approval studies. Value-based pricing as a strategy is particularly difficult to implement for first-in-class therapies and products that intend to establish a new standard of care. For these drugs, there are no existing products to act as comparators. In these cases, ethical considerations become important. For instance, pricing a drug at the level the market can bear may prevent lower-income patients from gaining access to life-saving medicines.

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Increasing pricing efficiencies

In addition to implementing novel manufacturing strategies designed to increase efficiency and productivity, thereby bringing down the cost and time needed to develop and commercialise new drugs, the pharmaceutical industry is also looking to other avenues that provide efficiency gains. Generic drugs and biosimilars are one such avenue. Indeed, generic drugs account for a significant portion of small-molecule drug sales today, and as increasing numbers of biosimilars receive approvals, they too will have an impact on pricing in the biopharmaceutical segment of the market.

Generics are in fact a great example of efficient drug pricing in close-competition environments. When patent exclusivity is lost and generics are introduced to the market, innovator companies refocus their business models on efficient pricing. To that end, they manage production and supply chain costs more diligently. Outsourcing to contract development and manufacturing organisations (CDMOs) with lower cost structures is common at this stage, allowing for increased supply chain flexibility combined with reduced costs.

The importance of optimised pricing

In the end, pricing optimisation is needed to ensure healthy bottom lines, regardless of the industry sector. In general, pricing optimisation can lead to improvements of 1–2% and can also be achieved quickly compared with other corporate-wide improvements, such as training and internal process development efforts. It can also be done without the disruptions or heavy capital expenditures associated with cost and productivity investments. In addition, pricing optimisation often carries a greater return on investment.

In the pharmaceutical industry, pricing optimisation has the potential to benefit all members of the value chain, including suppliers, manufacturers and patients. The focus of pharmaceutical companies is on the discovery, development and commercialisation of medicines that can improve quality of life and extend lifetimes. Drug pricing policies should reflect, demonstrate and communicate the value of those therapies and their performance to all stakeholders.

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