Understanding today's drug pricing environment

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In a healthcare world that experiences a plethora of high-cost new therapies coming to market in parallel with price increases for existing speciality drugs, pharmaceutical companies are having to move away from traditional pricing models that are largely based on demand and what the market will bear. At the same time, they face an evolving access environment where reimbursement decisions are taken in different ways, on different criteria and with input from a much wider group of stakeholders. A central theme in this is value. European assessment authorities evaluate new drugs by assessing improvements in efficacy and safety in relation to price differentials, as a basis for granting access or not. Their aim is to achieve what they believe to be a fair price for the product by setting a price ceiling, negotiating a discount on the list price or entering into a risk-sharing arrangement whereby cost is limited when drugs do not work as promised.

In the United States, payers adopt a combination of rebate schemes and utilisation management techniques, such as pre-authorisation of patients and step edits, and these are all on the increase. Data from IMS Health suggests that average rebates to payers on drug prices nearly doubled between 2007 and 2014[1]. However, as prices for specialty drugs continue to rise, others have suggested that higher prices are purely implemented to feed the rebates that are now the norm.

Emergence of value-based pricing

All of these pricing structures are routes to reaching an agreement

between company and payer that delivers adequate return to both parties. But now we are seeing the emergence of value-based pricing, where the price is determined as a function of measurable 'value' brought by the product to relevant stakeholders. Health systems or payers may impose a price on the manufacturers or manufacturers may adopt a more overtly reasonable approach to price setting, but in both cases, price is determined according to some empirical measure of value in the eyes of the people that matter. Value-based pricing is more transparent, but is still designed to maximise returns as measured by revenues or profits. As such, it can still result in a similar price paid to that negotiated through rebates or risk sharing, but the increased transparency helps to short-cut what can become a lengthy negotiation process. Value-based pricing is inherently focused on the impact the product is going to have rather than starting with a purely demand-based unit price.

Pricing new drugs requires company and payer to reach agreements that deliver adequate return to both parties

But herein lies a challenge: how do you measure value? Is it just about improvements in patient outcomes based on efficacy and reduced safety risks, as a function of price? Or does it also include wider societal benefits, such as returning patients to the workplace and reductions in long-term social care costs? By assessing value in terms of benefits accrued throughout the use of the product, marketers can consider pricing variation over time that is consistent with the full value estimate. Here, things become more complicated, since the payers footing the short-term bills may not benefit from the wider societal impacts. The debate around hepatitis C is a good example of this, where new and highly priced therapies introduced in the past few years have effectively brought a cure, thereby potentially reducing long-term care costs. It is no surprise, therefore, that health technology assessment (HTA) bodies have approved these hepatitis C therapies as cost effective, but that does not make them affordable to payers who have to pay for the drugs and will not necessarily benefit from the longer term economic impacts.

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Market understanding

To anticipate and address the inertia they are likely to face, pharmaceutical companies need to look beyond expectations of likely demand, patient outcomes and competitive landscape, and take an analytical approach to understanding each market they are interested in. In parallel, they need to be rigorous about assessing the stakeholder landscape for access to drugs in those markets – how decisions are taken, by whom, on what grounds, who influences whom – all as a basis for orientating market access strategy around external dynamics. This also relates to less easily defined but equally critical factors, such as the reputation of the industry and how this can determine attitudes to companies when they are bringing new drugs to market.

Not only do markets and geographies differ in their handling of drug reimbursement, there is a wide range of stakeholders such as medical societies, advocacy groups and policy makers who have a growing influence on decisions, how they are implemented and to what effect. This is not just about communication with stakeholders: it is also about constructing a market access and pricing strategy to address their priorities and concerns, and thereby deliver value in their terms.

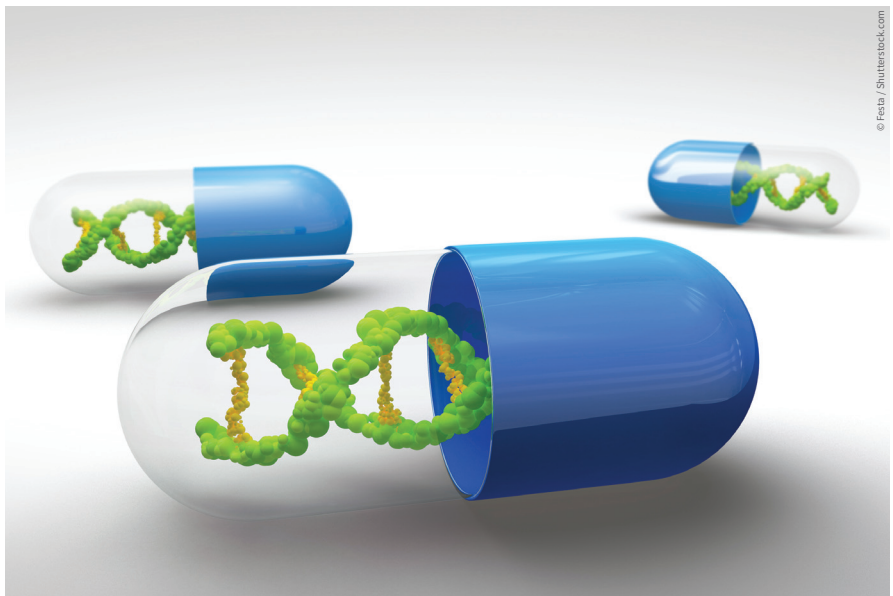
Value-based pricing as delivered by manufacturers is a relatively new concept, where the company effectively does the work of an HTA body to determine a reasonable price for a new drug. But how can companies appropriately select and prioritise value metrics for a therapy, given the varying priorities of decision makers and their influencers? To be effective, value-based pricing must address the needs of the wider group of stakeholders as well as the payers, and go beyond the simple measure of increase in efficacy divided by increase in cost as compared with current standard of care. This means value-based pricing must be based on economic and scientific evidence as well as accommodating inputs from the wider stakeholder community. In this way it will:

- Capture value perceptions from all stakeholders who have an impact on product reimbursement and utilisation, including payers, physicians, patients and pharmacists
- Assess the trade-offs stakeholders make to determine the value of a drug, including clinical, pharmaco-economic and societal impacts
- Allow for the relationship between value and financial incentives, such as rebates or discounts received by prescribers and payers
- Factor in the incremental, often significant, value-added features such as dosing frequency, mode of administration and innovative drug-delivery mechanisms

This approach relies upon recent advances in measuring and modelling how stakeholders make decisions to offer coverage, and to reimburse and utilise pharmaceutical products. Key advantages of the approach are as follows:

- The value of a feature of a product and its competitors can be estimated

- Value estimates are based on key stakeholder priorities and therefore may vary accordingly. For example, oncologists put disproportionately more value on longer overall survival of 40 months compared with overall survival of 12 months
- Value estimates for each stakeholder are obtained independently of price, enabling the use of an estimated value model to develop alternate pricing and market access strategies throughout the life of the product. This can help focus short- and long-term commercial activities to increase stakeholder understanding of, and positively enhance perceptions of, value



Speciality drugs such as gene therapy treatments can command extremely high prices

The method can be used to model the minimum and maximum price a product can command in the market, based on a measurable understanding of its relationship to value and with reference to market expectations.

Buy-in to value needs to start early

Manufacturers need to commit to understanding, engaging and involving a wider group of stakeholders well before a product nears launch. In this way, they can secure the insights and priorities of the people that matter during the product development cycle and in ways that ensure these stakeholders have contributed to and bought into the product profile and what it delivers.

> "It is in companies' best interests to initiate a more professional and sustainable approach to engaging with stakeholders"

Clearly this interaction mainly relates to payers or HTA bodies, but also includes influencers such as professional groups, patients and their representatives, care providers and policy makers, all of whom may have different priorities from the ultimate decision makers.

Multi-faceted external relations is a discipline the industry often finds hard to get right because companies comprise discrete functional groups who are rarely aligned. In addition, stakeholders take a lot of shifting from their position on issues, especially if they feel pressurised by people they see as having a vested interest when it comes to launching a new product. This is why success depends on cultivating long-term relationships rather than short-term communication around key commercial milestones.

This requires leadership and coordination across multi-disciplinary teams, both globally and at an affiliate level, so that stakeholder engagement becomes part of the psyche of the whole team associated with the product.

External focus is vital

Critical to a successful approach to engagement is planning the approach around the most influential stakeholders' interests rather than the company's interests: who are the most influential targets? What are their personal priorities? What will drive them to take action themselves? Who 'owns' the relationships with them? How do stakeholders interact with each other and how likely will they want to engage, if at all? If we consider value as the ultimate driver for success, we need to redefine it in terms of benefit to the stakeholders in relation to their perception of cost, which may be wider than drug price. This value measure might only concern patient outcomes or economic impact, but it could relate to wider societal benefits, operational support for practitioners, political pressures, etc. And all of these need to be conceived in ways that make stakeholders feel comfortable and secure with the position they take, possibly requiring evidence and weight of opinion among their peers to protect them from criticism. This is a far cry from a manufacturer-driven paradigm where price is determined by demand potential.

In conclusion, there is no reason why reimbursement decisions and drug prices cannot be made on an empirical assessment of value, either on an economic level or a wider societal level. And yet, because health systems are so big and so complex, with input from so many stakeholders with different priorities and areas of influence, it is the 'people side' of the problem that presents such a significant challenge to both manufacturers and decision makers. As a result, it is vital to ease the process by committing to building better relationships, better understanding and genuine transparency among all those involved. This is not just a problem for the industry to solve, but it is in companies' best interests to initiate a more professional and sustainable approach to engaging with stakeholders, both for setting price and for subsequent access discussions.

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Reference

1. Bain & Company, 2016. Pharma: The Market Access Dilemma. Credit Suisse Report, IMS Health