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# MARKET ACCESS

## Balancing benefit and value against health care sustainability

Federal Market Access: Implementing A Cross-Functional Strategy To Optimize Outcomes

Rebate Reform: Big Changes Are Looming For The US Drug Market

Market Access Knowhow Keeps Strategic Medtechs Ahead Of The Game

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# Room At The Top? The Case For A Chief Value Officer

What is the value of a drug? Asking different stakeholders may elicit different replies. Yet one trend is clear, the focus on "value" across the health care sector is becoming ever sharper. Price and value, for example, increasingly shape public debate, particularly where the two are perceived as discordant or unequal.

Consequently, over the past twenty years, stakeholders have increasingly pressured the health care industry to rationalize pricing decisions. For pharmaceutical companies, this is manifested in multiple points of scrutiny around the mandate and effectiveness of the pricing and market access functions, and has arguably led to a degree of strategic inertia or hesitancy in some organizations.

From the US to Europe and beyond, the introduction of health care reforms designed specifically to define the value of new therapies clearly poses challenges for pharmaceutical companies. Yet, as this analysis argues, companies need to engage more actively, tapping into the unique insights that come from years of clinical trials, research, and strategy, to uncover and articulate the real value of their therapies to stakeholders. This necessitates coherent stewardship of price and access challenges, underpinned by three pillars of value: value creation, value communication, and value governance. And to manage this effectively, it may be time to knock on the door of a new C-suite hire – a Chief Value Officer (CVO).

## HEALTHCARE REFORMS AND INCREASED SCRUTINY

Growing scrutiny by governments, payers, and clinicians has translated into numerous health reforms and initiatives relating to value, price, and access in many countries.

In the US over recent years, institutions such as the American Society of Clinical Oncology (ASCO), Memorial Sloan Kettering (MSK), National Comprehensive Cancer Network (NCCN), and more broadly the Institute for Clinical and Economic Review (ICER) have proposed methodologies that define and evaluate the value for new therapies (*see Exhibit 1*). Since expanding its remit to include evaluation of drugs in 2014, ICER has been involved in price and access discussions at the policy and product level. ICER supported a 2015 announcement by Express Scripts to consider indication-specific pricing, and is now working with the Veterans Administration's pharmacy benefit services office on drug choices and payments, which gives ICER an institutional advisory role at one of the world's largest publicly-funded formulary management system. On the product front, high profile examples of public scrutiny impacting pricing include a Memorial Sloan-Kettering Cancer Center (MSKCC) rejection of *Zaltrap* (aflibercept) in 2012, which resulted in Sanofi halving the price.

Moreover, specific federal government policies, such as The Medicare Prescription Drug Price Negotiation Act of 2017, require the negotiation of covered drug prices on behalf of Medicare beneficiaries. And generally, the Trump administration has questioned the ethics of price increases by large pharmaceutical companies in the US, especially where the same products are sold elsewhere in the world for much less.

Lessons can be learned regarding wide-scale government reform from abroad. In the UK, the establishment of the National Institute for Clinical Excellence and Health (NICE) effectively led to a sea-change in the way treatments and drugs were assessed and purchased. Likewise, the AMNOG process in Germany had major implications for the organization and operation of the health care system, introducing new levels of scrutiny and technical standards that limit industry influence over reimbursement decisions. Elsewhere in Europe, recent notable developments have included a coalition between the Benelux countries, Ireland, and Austria to leverage a larger patient population in industry price negotiations. Further afield, Japan is accelerating the pace of generic product listing along with a pilot scheme that embraces cost effectiveness analysis as part of its economic evaluation model; and in Canada, decisions once the responsibility of the provinces are now being centralized with plans for a federally administered universal drugs pricing regime and an expanded role for the Patented Medicines Price Review Board (PMPRB).

## ARTICULATING AND MANAGING AN ENHANCED VALUE MODEL

The case for a Chief Value Officer is embedded in the need for companies to better articulate the merits of a business model that delivers innovation to patients and other stakeholders. While functions associated with value, price, and access have become more sophisticated in large pharmaceutical companies, many still suffer gaps in organizational structure and capabilities. Changing this requires a coherent and strategic approach to developing methodologies, refining structures, and training employees capable of delivering the key constituents of an enhanced value model; namely, these three pillars of value creation, value communication and value governance: 1) Value creation identifies and captures the appropriate evidence during early-stage drug development and clinical trials, and supports this with retrospective data and real world evidence capable of strengthening the value proposition. 2) Value communication seeks to optimize stakeholder perceptions of a company's societal contributions and the usefulness of its products. It requires companies to respond strategically to the ongoing policy debate around pricing and access, with particular emphasis on cultivating a wider range of external stakeholders. 3) Value governance addresses organizational alignment – how best to build and then incorporate value-related components or functions into the day-to-day activities of not just commercial portfolio managers and asset teams but other key functions like medical and public affairs, aligning this within an overarching market access strategy. It also poses the question, who

Exhibit 1

**Frameworks And Tools For Assessing The Value Of Cancer Drugs**

| ORGANIZATION | FRAMEWORK | STATED OBJECTIVES |
|---|---|---|
| American Society Of Clinical Oncology | ASCO Oncology Value Framework | Assess the value of new cancer therapies based on clinical benefit, side effects, and improvements in patient symptoms or quality of life in the context of cost |
| Memorial Sloan Kettering Cancer Center | Drug Pricing Lab/Drug Abacus | Focus on the development of rational approaches to drug pricing and health insurance coverage that sustain innovation while ensuring affordability |
| National Comprehensive Network | NCCN Evidence Blocks | Help health care providers and patients make informed choices when selecting systemic therapies based upon measures related to treatment, supporting data, and cost |
| Institute For Clinical And Economic Review | ICER Value Assessment Framework | Inform decisions aimed at achieving sustainable access to high-value care for all patients via "long-term value for money" and "short-term affordability" |

SOURCES: American Society of Clinical Oncology; Drug Pricing Lab (Memorial Sloan Kettering Cancer Center); National Comprehensive Cancer Network; Institute for Clinical And Economic Review

is leading the charge?

As shown in *Exhibit 2*, the complex relationship between these three areas obliges companies to revisit functions associated with value, price, and access. Of course, most organizations will already be engaging on such issues, albeit in a less prescribed and structured way. This latter point is critical, however, as this is not an exercise in defining "value" on an ad hoc basis (neither is it about attempting to define value in absolute terms, as the concept will always be nuanced and contextual), but of optimizing the ability of companies, and the industry more generally, to embrace a coherent outward-looking approach that delivers compelling messages.

Exploring each of these value functions in more detail will highlight the knowledge required to establish, lead and manage an enhanced value model.

## VALUE CREATION

Value creation operates in a complex and highly nuanced environment that reflects differences in approaches between countries. Indeed, systems tend to be unique, with decision makers in each country employing specific methodologies to determine value, price, and access. The US, for example, is a competitive market with free pricing at launch followed by negotiations with commercial and government payers for preferred or parity access. This contrasts with the UK and Sweden, where positive guidance based on cost effectiveness analysis is required to gain access to patients. Different again are the hybrid systems, such as Canada and Belgium, wherein products deemed not to be cost effective require negotiation with payers to establish terms. Other markets have an assessment of clinical value and price negotiations, which can be separate processes (France and Germany) or combined (Italy).

Consequently, enterprises need a sophisticated appreciation of different markets and systems in order to generate sufficient evidence to procure access consistently, in the markets where it counts. Without this, country affiliates face substantial challenges. Organizations will need to draw on such knowledge to inform protocol development, and balance the risk and limitations associated with financial or outcomes-based agreements (market entry agreements and value-based contracting). It is also important that companies take a global perspective on their pricing and reimbursement exposures.

Effective value creation requires an end-to-end approach, wherein goals and activities span the entire product life-cycle, from the preclinical phase through to launch and life-cycle management.

Integrating value creation into the early stages of the R&D continuum is key to understanding markets and creating product value. Subsequently, that value can be extracted to inform pricing and articulate the meaningfulness of the therapy to a stakeholder which, in turn, secures patient access in the most efficient manner. Moreover, an efficient value creation model will help to protect the value of a product after launch, ensuring capable product life-cycle and franchise management and facilitating price renegotiations or product expansions if required in future. Conversely, a weak understanding of the market, coupled with a poor evidence generation plan will result in an inadequate value proposition and ongoing challenges associated with access and price.

This need for knowledge and effective articulation of value is particularly acute with new technologies, such as gene and cell therapies, where the value chain is especially complex. As the use of big data technologies and artificial intelligence increases, so too will the need to understand the value of therapeutics at both a personalized and broad population level. And while there is still much progress to be made on real world evidence being used on the access front, the use and ownership of data more broadly represents an ongoing challenge and an opportunity for the industry: whereas, in the past, data was owned by the industry, it is now shared among multiple owners. Lack of data interoperability remains a barrier to deploy data as a value measurement tool.

## VALUE COMMUNICATION

Turning to value communication, it's prudent to assess this not in a narrow way as it relates only to the therapeutic value of specific products, but in a broader context that addresses value to the industry and society as a whole. This serves as a catalyst for tailored and targeted messaging for key constituencies, such as:

- **Therapeutics** – A compelling value proposition relates to the clinical, safety,

humanistic and economic benefits of novel therapies, addressing patients, physicians and other stakeholders involved in the value chain.

- **Industry And Society** – A well crafted narrative of contributions to the health care community, the economy and society at-large with respect to inline products, pipeline and broader aspects of industrial policy (R&D investment, patent development and life-cycle).
- **Stakeholder Engagement** – Proactive engagement to facilitate discussion about evidence requirements and innovative approaches to defining value. It will also address issues around uncertainty (e.g. by way of financial or outcomes-based agreements).
- **Public Communication** – Clear value justification and policies/principles shaped to address scrutiny related to therapy and corporate practices.

What stands out is the need to consider the unique priorities of each stakeholder. These often vary according to the therapeutic area, setting of care and geography. Take hospital products, for example, with access being determined both by hospital administrators and pharmacists. The priorities here are not mutually exclusive.

For payers, concerns about clinical and/or cost uncertainties are obviously top of mind, and with treatment and purchasing decisions impacting already tight budgets, there is an inevitable desire to offset costs where possible. Naturally, patients want therapies that treat their conditions effectively and provide a reasonable quality of life without breaking the bank. Likewise, the general public is concerned to see a balance between the price and value of a treatment. Economic, societal, and even political factors are, thus, entwined in the collective public mind, as is the reputation of the pharmaceutical industry and high-profile companies.

## VALUE GOVERNANCE

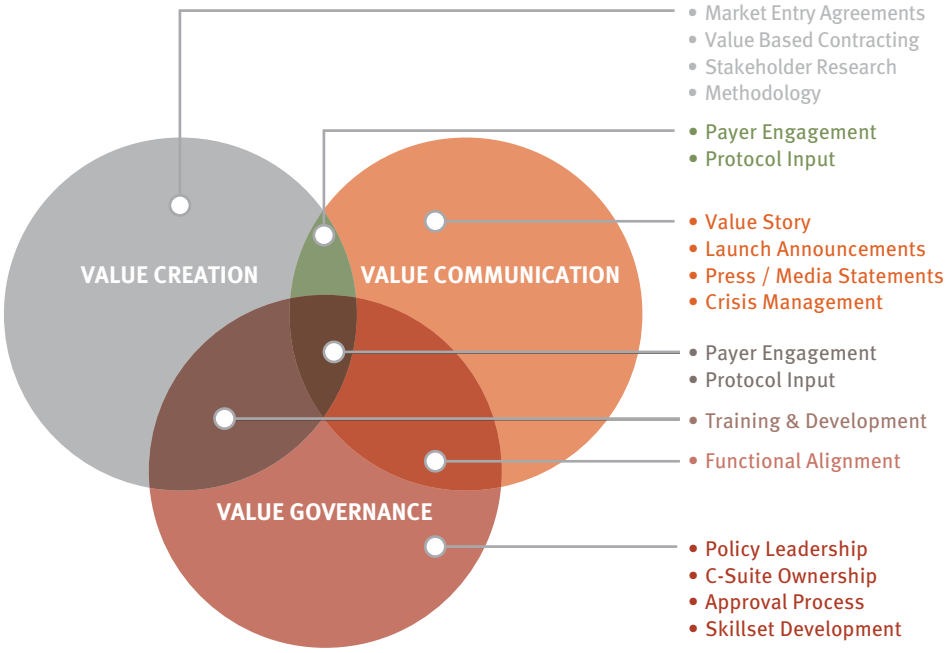
While policy making, approval processes and skill development are key tenets of value governance, effective leadership is required to drive these areas and optimize organizational benefits. Over the last few decades, functions associated with value, price, and access have taken a more prominent role in large pharmaceutical organizations, not least in response to increasing payer sophistication and the market entry of novel, expensive therapies. Access functions reporting into a head of Market Access, Value & Access or Patient Impact and Health are now commonplace. However, heads of these groups do not always come from an access background and they often report into a commercial function.

Many companies still have significant gaps in operational and organizational skills and capabilities. Training and development, up-skilling programs and functional alignment are often weak in access functions, and the concomitant absence of clear career paths is costly both in terms of employee motivation and organizational competence. Companies that invest more in the governance of personnel development are likely to manage the turnover in human capital, achieve greater organic growth and be best placed to manage the ever increasing payer demands associated with price, value, and access.

Critically, governance is also about taking the lead in developing a vision on value, price and access. It necessitates the defining of principles (particularly those relating to reimbursement policy), establishing a reputation as the partner of choice, and ensuring that these attributes translate into policy and execution, permeating through organizational culture and day-to-day activities of line managers.

Exhibit 2

**Complexity Associated With Value Creation, Communication And Governance With Clear Industry Leadership**




## HEADING TO THE C-SUITE?

Although companies have undoubtedly become more savvy and sophisticated in matters associated with access, value and price, there is still much to do. The case for a Chief Value Officer is compelling because it will provide much needed leadership at the C-suite level. Without this, the necessary momentum for change and the ability of organizations to focus on value creation, communication and governance may falter, undermining the ability of companies to uncover and articulate the real value of their contributions. Progress is essential because the alternative is becoming an outsider as health systems evolve in the coming era of demographic transition and mounting deficit pressures. Status quo thinking could lead to cessation of that essential license to operate.

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