**Planning for Change: Adapting to Shifts in the Global Market Access Landscape**

**Lujing Wang, MD, MPH, Senior Practice Executive, Pricing and Market Access Practice**  
**Ryan Richardson, MS, Associate Practice Executive, Pricing and Market Access Practice**

**Introduction**

Aside from R&D, sales and marketing have long been the drivers of commercial success of the pharmaceutical enterprise. Marketing efforts have historically focused primarily on physicians and patients, the underlying engines of demand. However, as the number of expensive therapeutics entering the market grows and the need to contain costs intensifies, a new set of stakeholders—loosely defined as “payers”—is rising in importance.

Many commercial planners now recognize that their organizations face challenges related to the need for successful planning and management of the rising impact of payers, and that payer influence on the industry will likely continue to grow in the coming years. This article discusses the complexities associated with the rise of payer influence and global payer differences, and provides product planners with key considerations for adapting global market access strategies to the new climate.

**The Rise of the Payer**

Undoubtedly, payers have long wielded influence on the pharmaceutical industry. However, several emerging factors have converged to shape the current market access environment for pharmaceuticals: the increasing number of drugs in the competitive landscape, added pressures to control costs, and the growing use of evidence-based medicine (EBM) and health technology assessments (HTA) among payers in making coverage or treatment decisions (Figure 1).

Pharmaceutical companies have long filled their development pipelines with drugs targeting the most lucrative markets. Many drug manufacturers developed “me too” products to seek a piece of the pie of these proven markets rather than seek new territory. As a result of this strategy, some disease categories have become saturated, providing leverage to payers to control costs. With certain indications having multiple options, new market entrants must compete with established standards of care set by payers and physicians. As such, manufacturers are being required to clearly describe drug incremental value to those making reimbursement decisions. Further, major product lines are losing patent protection and generics and biosimilar products have entered many markets, allowing further options for payers.

Healthcare spending has been on the rise for some time, and one of the drivers of the inflated spending has remained the costs associated with increased drug prescriptions. Healthcare costs related to drugs are tied to the average unit cost of the product and the consumption volume. The proliferation of biologics and specialty drugs that carry a high price tag helped fuel the elevated average unit cost. Longer life spans have increased the aging population and led to a swelling of consumption volume as well. The increased costs related to these factors become a major burden on the public and private sectors.

---

**Figure 1 – Factors Leading to Increased Payer Influence**

<table>
<thead>
<tr>
<th>Evolving Competitive Landscape</th>
<th>Growing Financial and Budgetary Pressures</th>
<th>Expansion of Evidence-Based Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated markets in certain disease categories</td>
<td>Escalating costs of healthcare</td>
<td>Greater emphasis on evidence-based medicine</td>
</tr>
<tr>
<td>New market entrants must compete with established standards of care</td>
<td>Increasing budgetary constraints facing payers around the world</td>
<td>Increased ability to track health outcomes</td>
</tr>
<tr>
<td>Increasing generic and/or biosimilar competition</td>
<td>Expanding use of value-based considerations in benefit designs</td>
<td>Expanded mandates for existing health technology assessment (HTA) institutions</td>
</tr>
<tr>
<td></td>
<td>Consolidation of payers</td>
<td>Creation of new HTA institutions</td>
</tr>
</tbody>
</table>

**Changing Nature of Competition**

- Payers more closely and systematically scrutinizing evidence in making market access and pricing decisions
- Product differentiation more closely linked to evidence base
- Growing evidence-based competition
  - *More data is required*  
  - *Trial planning is becoming more strategic*
- Emerging commercial models
  - *Evolving definition of value*  
  - *Growing prevalence of outcome-based access scheme*
Payer systems, influencing a subsequent demand for cost control through reimbursement policies. Further, attempts to reduce costs also resulted in payer consolidation, as seen with managed care organization (MCO) and pharmacy benefit manager (PBM) mergers, the increased role of government in many countries, sickness fund mergers in Germany, and consolidation of social insurance funds in many European markets. This has further concentrated power and enhanced payer ability to restrict drug access.

With several product choices within major disease categories and improved methodology to compare them, a surge in EBM and HTA usage has ensued that is increasingly forming the basis of decision-making for payers. The ability to track health outcomes has increased, thereby allowing a larger emphasis on comparative studies. Established HTA institutions are receiving expanded mandates to advise reimbursement decisions, and new HTA organizations are being created in emerging markets. Different payers employ distinct sets of analyses in making reimbursement decisions, at times leading to divergent conclusions regarding products. Clearly, this diversity has implications for the commercial operations of pharmaceutical companies.

Changing conditions have allowed payers to place increased demands on drug manufacturers to demonstrate the effectiveness of their products in order to justify reimbursement. If the pharmaceutical industry’s principal challenge of the last 10 years has been reinventing the R&D model to address declining productivity, the next 10 years could very well be termed “the rise of the payer.” The increased emphasis on EBM poses a new issue to manufacturers that will require a greater focus on the payer for commercial planning.

Global Payer Variability

While the term “payer” is often used collectively, in reality it describes a diverse range of institutions and stakeholders, including national, regional, and even local institutions that conduct product evaluation and determine the level of product coverage in a health system. Further, several layers of payer decision makers can affect access and reimbursement decisions, including policy makers and influencers, financiers, benefit designers and intermediaries, clinical service providers, as well as patients and caregivers (Figure 2). In markets with a more centralized national health insurance system, a government department or independent advisory institution may be charged with rationalizing pharmaceutical utilization for the public sector system. However, in many cases, multiple institutions, each with their own incentives, review

Figure 2 – Payer Variability and Levels of Decision Makers

- HTA institutions (e.g., NICE)
- Quality assessors (e.g., NCQA, WHO, PAHO)
- Clinical evaluators (e.g., IQWiG, HAS)
- Advocacy/Ethicist politicians/Activists
- Pharma manufacturers

- Employers/Employees
- Governments, including CMS, Ministry of Health, Regional Health Authorities
- Consumers/tax payers

- Sickness funds, primary care trusts (PCT), HMOs, PBMs
- Medicare providers (PDPs, MA-PDs)
- Contracting and tendering bodies
- Distributors/Wholesalers

- Hospitals
- Physicians
- Allied healthcare professionals (e.g., nurses)
- Pharmacies
- Clinics and non-acute facilities

- Employees
- Underinsured
- Elderly/Disabled
- Uninsured
methods, and mandates, may influence different aspects of pricing or market access.

While the full impact of payers has yet to be evaluated empirically, it is clear that it varies greatly by geographic market, payer type, and therapeutic area. Cultural differences allow payers across global markets to employ a wide range of mechanisms to influence physician and even patient preferences. In Spain, payers provide various forms of incentives to motivate and reward more cost-effective prescribing. In contrast, the German payer system is more punitive in nature and relies on financial penalties to influence utilization. In the US, the formulary is the principal tool that commercial payers use to influence demand. Other frequently used mechanisms include step edits or usage restrictions, price caps or reference pricing schemes, or the threat of censure. The effectiveness of these specific tools that payers employ and the criteria that determine how aggressively such tools are applied shape the competitive landscape.

Payer types also vary in their incentives and interest, largely due to differences in their business model, management philosophy, technical sophistication, and data infrastructure. For example, the Veteran’s Administration (VA) system in the US was the first to implement a state of the art electronic medical record system, while the Department of Defense (DoD) was the pioneer in the use of pharmacoeconomic data in their coverage decision making. These institutions prioritized these activities as they are centralized systems that have the responsibility of measuring the long-term health status of a specific and steady population. In comparison, commercial managed care organizations remain more focused on short-term budget impact on a year-to-year basis, as their members frequently switch insurers or employers.

Payer reimbursement can also diverge by therapeutic area. Payers usually devote much of their time and energy on high spending categories, fast-growing drug classes, high unit-cost therapies, as well as classes with a high degree of perceived interchangeability and substitutability. Mode of administration, site of care, and reimbursement mechanisms allow payers to manage utilization in some categories. In contrast, therapeutic areas with highly personalized responses and less room for substitution garner less attention.

Shifting Relevance of Product Attributes

With the growing influence of payers and the push to contain pharmaceutical expenditures, the levers of differentiation—and hence, the very nature of competition—have shifted. This alteration is important to competition in pharmaceutical markets because payers tend to have different preferences and incentives than physicians or patients. Innovation at the molecule level is only relevant to payers if it can be translated into demonstrable value and tangible benefits. These variations can play a pivotal role in the success or failure of products, and understanding the distinctions is thereby increasingly critical to the commercial planning process.

On a product level, competition in pharmaceutical markets occurs across four main product attributes: efficacy, safety, convenience, and price. Medical innovations were historically defined by key opinion leaders and physicians, and claims of differentiation in efficacy, safety, or convenience were often the determinants that led to one product’s success over a competitor. Because physicians and patients in developed markets typically have limited direct exposure to drug costs, price has tended not to be a major differentiator in markets dominated by branded products.

Increasingly, manufacturers are looking at the payer perspective for their early stage compounds. Attributes that may have generated competitive advantages for products in the past, such as improved convenience for patients following a new formulation, may now lead to only minor advantages in markets where payers exert considerable influence. Further, the strength of a particular claim itself may be scrutinized more heavily, which may make product differentiation more difficult.

In general, the rise of the payer has increased the relative importance of price, blunted the impact of convenience advantages, and, in some cases, altered how evidence of clinical safety and efficacy advantages are interpreted. Certain claims of clinical superiority, for example, may be subjected to more rigorous scrutiny or even thrown out due to statistical or clinical insignificance, or based on the robustness of study designs. These shifts in attribute prioritization have led to a need for organizations to become well versed in shifting trends in their global target markets to highlight distinguishing attributes that define the value of a drug to influential payers.

By analysis, there are varying levels of linkage between the value of a particular drug to payers and its price. The US payer system is fragmented, exhibiting pricing pressures and product evaluation that are independent of the payer organization. This leads to consumer-driven pricing that is set based upon how much the market will bear. As such, there is no direct linkage between payer value assessment and price. France exhibits an indirect linkage between price and value, as it assigns an Improvement of Medical Benefit (ASMR) rating that relates clinical assessment with relative clinical value, and negotiates with manufacturers on the price relative to comparator products. The UK uses stringent linkage between price and value, as it sets a threshold of cost-effectiveness measure based upon the cost per quality adjusted life year (QALY), thereby limiting access to some high cost therapies such as oncologics. Many EU countries and Canada use a hybrid system, using internal referencing to determine reimbursement and external price referencing to set price. Some countries, such as Turkey and Greece, use only external price referencing, without an independent assessment of product.

Payer interpretations of value are critical, as they determine reimbursement level and access. Complicating the issue is the fact that the definition of ‘value’ evolves over time and varies by market and system. When payers pay for value, they could find it from varying criteria, including a new MOA, incremental efficacy and safety, the active ingredient, brand perceptions and images, convenience, long-term health outcomes, or population-level health status. The complexities associated with variations in payer systems, coupled with a near constant stream of new health policy initiatives, have made reimbursement planning a challenge that requires a methodical update of the global market access strategy across the company and product lines.

Adapting the Global Market Access Strategy

In the past, developing a global market access strategy has tended to be a largely tactical exercise. Those overseeing global market access relied heavily on their local affiliates to pursue regional and/or local strategies that met the distinct needs of payers in each market. Increasingly, a more strategic approach is needed in developing a global market access plan. The increasing consolidation of payer systems, expansion of payer mandates to regulate
pharmaceutical markets, and the establishment of new HTA institutions has led to a shift in product attribute prioritization and requires pharmaceutical companies to adapt their commercial models in order to remain competitive.

Updating the business model to account for the rise of the payer is no small task, and will require changes at the corporate and at the product level (Figure 3). Specifically, organizations need to establish Market Access as a global function, optimize market access execution through a comprehensive understanding of the global payer market structures and product-level strategies that address payer variabilities, and develop an efficient and effective evidence generation framework that will fulfill the payer needs in targeted countries.

Establishment of a Market Access Function
With its emergence as an area of critical importance to the commercial enterprise, perhaps the most challenging implications for pharmaceutical companies will be how to adapt their organizational structures to the changes in pharmaceutical markets. Market Access has emerged as its own function in many organizations, and many firms have invested in building up capabilities as payer influence has expanded. The integrated Market Access function has grown to encompass a wide range of functional elements that interface the clinical and commercial organizations. Many of the activities in the Market Access function were aligned with other key business functions in the past, evolving from core activities in Marketing, Finance, Sales, and Medical Affairs [Table 1].

To help prepare the organization to fulfill the duties required with the new environment, companies need to expand their core competencies to increase market access skills and knowledge [Table 2].

Many organizations have been expanding resources dedicated to developing market pricing and access strategies, while in the past they have tended to rely to a great extent on external vendors to source this talent. As payers have become more sophisticated in applying EBM to regulate pharmaceutical markets, companies must now also build up internal capabilities to address the increased responsibilities. This involves building up resources trained in EBM tools, including health economics, quantitative epidemiology, and biostatistics.

The increase in capabilities and human capital is a good first step, but truly adapting to the new environment will require companies to rethink and possibly adjust how the functional areas are structured and work together. Infrastructure, platforms, and processes will need to be developed to allow cross-functional dialogue and execution. One challenge that companies face is finding a way to structure a Health Economics and Outcomes Research (HEOR) section that allows contribution of their insights into the decision making processes that maximize value for a brand across various stages of development and lifecycle. As HEOR historically is a highly technical discipline, this can be difficult.

A further challenge in designing the optimal processes for a global market access strategy is determining where to draw the line between the affiliates and the global organization. Affiliates provide essential on-the-ground perspectives on local political climate as well as knowledge of local

---

**Table 1 – Market Access Functional Consolidation**

<table>
<thead>
<tr>
<th>Activities Integrated into Market Access Function</th>
<th>Previous Functional Area Overseeing Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payer Marketing / Payer Market Development</td>
<td>Brand Management / Marketing</td>
</tr>
<tr>
<td>Pricing and Contracting</td>
<td>Finance</td>
</tr>
<tr>
<td>Account Management / Field Operations</td>
<td>Sales</td>
</tr>
<tr>
<td>Health Economics and Outcomes Research</td>
<td>Medical Affairs</td>
</tr>
</tbody>
</table>
institutions and stakeholders. This information positions the affiliates to advise what steps need to be taken to ensure that the most favorable strategies are pursued. However, there are areas where the global Market Access function needs to provide input, including pricing and contracting strategies, reporting, and decisions surrounding significant investments. Investment decisions might include large evidence generation initiatives, stakeholder management software, and whether to prioritize local efforts.

It is the cross-functional nature and the need for a mix of global and local insight that make the organizational design of the Market Access function difficult. Many companies have already secured the resources, but now need to enhance alignment of the resources in order to achieve optimal value.

**Optimizing Market Access Execution**
Optimization of market access execution will require enhancements on both the corporate and product levels. Corporate capabilities must first be developed to acquire a thorough understanding of the payer market structure, allowing the creation of an effective product-level strategy for commercialization.

**Understanding Payer Market Structure**
Understanding the similarities and differences in how payers affect the competitive landscape across markets is critical to successful commercial planning. These similarities and differences can be characterized as “payer market structure” and are an important component in understanding the role that payers have in healthcare decision making. Several key factors should be analyzed to assess payer market structure, including the locus of decision making, incentives and evaluation criteria, methods of assessment, the evaluation process and stakeholder engagement, as well as policy levers and market access mechanisms (Table 3).

Frequently, even pharmaceutical companies that recognize the need to include the regional payer perspective in their commercial planning often fail to take into account the actual way in which payers

---

**Table 2 – Core Competencies Required for the Market Access Function**

<table>
<thead>
<tr>
<th>Core Competencies of Market Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Understand payer evidence needs and liaise with clinical organization to ensure that clinical programs address these needs</td>
</tr>
<tr>
<td>- Identify and prioritize market access barriers in markets around the world</td>
</tr>
<tr>
<td>- Coordinate and manage initiatives to address market access barriers</td>
</tr>
<tr>
<td>- Collaborate with marketing to develop market- and payer-based pricing strategies</td>
</tr>
<tr>
<td>- Collaborate with new product planning to ensure that the payer perspective is taken into account in product planning and forecasting</td>
</tr>
</tbody>
</table>

---

**Table 3 – Criteria for Assessment of Payer Market Structure**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Why Important to Commercial Planners</th>
</tr>
</thead>
</table>
| Locus of Decision Making | - In fragmented markets, such as the US, payers’ decisions continue to be made on an organization basis, rather than by centralized institutions  
- In fragmented markets, where the loci of decision making is more dispersed, a different payer methodology is required that emphasizes quantitative measures  
- In markets with a single payer, a different approach that focuses less on empirical assessments and more on a qualitative assessment of payer preferences and potential outcomes is more relevant |
| Incentives and Evaluation Criteria | - The specific criteria that payers take into account often differ across markets  
- These differences may arise due to differences in payer or national priorities, or simply because of different incentives as a result of health system structure or policy  
- Some payers may attach different levels of importance to different product characteristics – it is important that these differences are factored into any analysis to support product pricing or commercial positioning |
| Methods | - Some payers employ more sophisticated economic or statistical methods in their analyses, such as NICE in the UK  
- Some payers link cost with outcomes, such as cost-effectiveness assessments  
- Primary coverage decisions can be based on safety and efficacy, cost-benefit, or simply cost-minimization |
| Evaluation Process and Stakeholder Engagement | - The length and timing of product reviews can have a great impact on product commercialization strategy |
| Policy Levers and Market Access Mechanisms | - Different payers have different policy making powers. Some have the power to set the price and control access, others mainly make formulary placement decisions |
operate in their unique health system. This lack of understanding causes difficulty in asking the right questions in payer research, making it difficult to find the information needed for strategic guidance or leading to misinterpretations of results. Failure to understand the unique market structure in which payers make decisions can lead to misguided commercial strategies.

Clearly, an awareness of the payer market structure provides companies the ability to take a health systems-specific approach when developing the commercial strategy for a particular market. The unique value criteria of the different payers are most relevant for evaluating the potential impact of a product. In general, payers can be grouped into three broad categories: those that evaluate predominantly clinical attributes, such as efficacy and safety, those that evaluate costs and benefits, and those that focus coverage decisions primarily on cost. The amount of focus dedicated to payers’ desired attributes during commercial planning can vary based upon the locus of decision making in the desired market. In a fragmented payer system, drug access is linear and increases as the number of payer systems that reimburse for the product increase. In a centralized system, access is almost a binary “all or nothing” outcome, thereby requiring a significant need to demonstrate the desired value to the payer. In fragmented systems with linear access, deficiencies in Market Access function can be somewhat offset by strong sales and marketing efforts. However, these deficiencies in a centralized market with binary access can be fatal to manufacturers. With the consolidation trend in the fragmented systems, it is becoming increasingly difficult to cover defective Market Access planning simply through large investment in promotion and detailing. An understanding of the payer market structure variations will allow appropriate product strategies that are geared towards attributes required for access.

Product-Level Strategy for Global Commercialization

The rise of the payer and the use of EBM will require that commercial planners conduct more extensive and complex market due diligence to support the commercialization of their products. Identification, evaluation, and prioritization of evidence requirements and barriers are needed across markets. Adding payer requirements and preferences complicates the process of traditional market research and requires more sophisticated analytical methods. One of the key challenges is to find reliable ways not only to assess how payers will respond to a given product profile, but how the payer response will in turn shape physician and patient demand. Doing this accurately will require analysis that incorporates a health system approach in market modeling and forecasting, rather than simply asking physicians how much of a medication they would prescribe should it have a specific profile. The changing landscapes will also require that firms conduct these market assessments earlier in the product lifecycle.

Admittedly, the implications of the rise of EBM will depend in part on the therapeutic area in question. In certain areas where outcome measurement is nebulous or treatment inherently complex, there will likely be less impact. However, in therapeutic areas that are high priority and where competition is likely to change, including when there will be more market entrants or generic availability, clear evidence will likely be required. In addition, payers are likely to pay more attention in therapeutic areas where there are not well-defined outcome endpoints and where there is greater flexibility in the design of clinical trials and interpretation of results.

Insights into the market access environment are important to most of the major decisions along the product lifecycle. Commercial planners in many companies now understand the importance of taking the payer perspective into account in pricing strategy. But because payers can fundamentally affect the competitive dynamics of markets, understanding how payer management is likely to affect market performance is important for most key commercial decisions. Increasingly, companies need to further consider payer perspective in several key product-level decisions (Figure 4) and should pursue more involved payer research during early development in order to validate forecast assumptions.

Figure 4 – Key Product-Level Decisions that Require Payer Perspective

![Figure 4](image-url)
Building an Evidence Generation Framework

In an access environment increasingly determined by the available evidence base, manufacturers need to ensure that a solid knowledge of the competitive landscape and payer requirements are being taken into account during the design of clinical trials. While the knowledge of clinical trial design and scientific medicine rests with the medical and statistical staff in pharmaceutical companies, insights are needed early in the process in order to ensure that payer needs are taken into account both in early- and late-stage development (Figure 5).

For early-stage development, organizations need to increase their focus on generating quality hypotheses. Evidence generation itself is a hypothesis validation activity. Many companies invest heavily in head-to-head trials to validate a false hypothesis, resulting in costly and sometimes fatal mistakes. Organizations need to adjust accordingly by investing further in hypothesis generation activities. Infrastructures and processes need to be established that allow more efficient and effective hypotheses to be created in the first place.

Establishing the evidence generation framework will allow for strategic evidence generation planning on the product-level in order to validate the developed hypotheses. Companies need to actively monitor the payer landscape to determine the proper “value” needed for the targeted market, and plan evidence generation accordingly. Development of the evidence generation plan requires a thorough competitive analysis which takes into account likely payer requirements, study design possibilities, potential competitive or market events, and technical feasibility or chance of trial success. Although in the past companies could get by with clinical data that was enough to gain regulatory approval, registrational data that a drug works is becoming increasingly insufficient to secure optimal market performance.

In addition to registration requirements, late-stage evidence generation programs are also critical for developing the messaging and positioning of the product that will be required for the payer value proposition. Randomized controlled trials are usually top of mind when planning evidence generation. However, increasingly important is evidence that comes from other late-stage non-registrational trials, such as Phase 3b and 4 trials. Ongoing assessments of customer needs and payers’ shifting opinions of value also need to be monitored for future evidence generation plans. This information will allow for adequate planning of lifecycle strategies.

Conclusion: Market Access Looking Forward

Creation of value is now much more dependent on the evidence base than patient preference and marketing muscle alone. In the past, companies have built blockbuster brands with only marginal increases in clinical improvements or convenience. With the rise of the payer as a check point, this has become more difficult and will continue to become more difficult as EBM and HTA are employed around the world.

Payer prominence in global markets will remain a significant challenge for pharmaceutical companies. Multinational pharmaceutical companies have increasingly focused on emerging markets as a cornerstone of their global growth strategies. However, a growing number of emerging markets will likely establish HTA institutions and will be increasingly important gatekeepers to global access. Companies will need to ensure that they track the progress of health policy developments so they can be prepared. This will be easier for companies that have an on-the-ground presence, particularly in health policy or market access. In terms of the Market Access function, some firms maintain a largely virtual global organization, with team members being dispersed around the world in local affiliates who can provide region-specific market insights into important commercial decisions. However, companies could improve upon organizational structures that effectively channel that local knowledge into decisions.

Comparative effectiveness in the US is top of mind these days for pharmaceutical marketers and strategic planners. The current administration’s recent stimulus package included $1.1B for comparative effectiveness studies of drugs, and many have debated how the concept might be implemented into healthcare system. While this remains to be seen, it is clear that it will have a tremendous impact on the nature of competition in pharmaceutical markets. In this new environment, firms that take a strategic approach to adapting to the changing landscape will be best equipped to achieve competitive advantages.

To equip themselves for the rise of the payer, organizations need to adapt their global access strategy. This strategy should develop capabilities to achieve four criteria: 1) a clear view of how payers’ requirements differ across markets; 2) an understanding on how different institutions can impact different markets; 3) a comprehension of the impact that new EBM/HTA regulations or health policy developments have on a product, and knowledge of how to gain competitive advantage by preparing for the possible changes; and 4) a clear appreciation of the types of evidence generation opportunities that are possible for a compound, and which are most feasible from a market and technical perspective. Satisfying these knowledge needs will help prepare companies for the changing global payer landscape.

For questions or comments, contact: Lijing Wang at lwang@campbellalliance.com
Telephone: (919) 844-7100
Toll Free: (888) 297-2001
www.campbellalliance.com