Pharma Survival In A Transforming Global Payer Environment

Economic pressures and technological advances are forcing an unprecedented transformation of the payer environment. Biopharma companies must adjust their market access and pricing strategies to maintain competitively well-positioned and profitable organizations.

Rising costs, increased demand for new drugs and technology advances are transforming the reimbursement environment.

Payers have been forced to engage in extensive cost cutting initiatives such as coverage limitations and increases in co-pays and deductibles, as well as deal with government health care reforms in the US, Europe and elsewhere.

The changing payer environment and tightening evidence requirements will have significant implications for the research-based pharmaceutical industry. Understanding how to address these requirements and changes is critical for continued organizational success.

The drug industry has been frequently criticized for only bringing marginal medical improvements to the market. It is ironic that lifesaving drugs like Gilead Sciences Inc.’s Sovaldi (sofosbuvir) for hepatitis C and Novartis AG’s Gleevec (imatinib) for the treatment of chronic myelogenous leukemia (CML) have recently been drawing heavy pricing criticism. That’s because payers feel trapped by the demand for broad coverage while they are struggling with the budget impact that would be the result of such a coverage policy. Some US state Medicaid programs have been criticized over restricting Sovaldi to patients at a later stage of liver disease. These examples illustrate that lifesaving drugs can pose a large problem for payers, as their value creates a very high demand that is ill-disputed and difficult to contain.

The expected emergence of new and expensive treatment technologies in the economically constrained environment is creating a potential “perfect storm” for government and private payers. Payers will be faced with tough reimbursement decisions as these innovative drugs gain US Food and Drug Administration (FDA) and European Medicines Agency (EMA) approval. The recent US and European reactions regarding Sovaldi for hepatitis C may be a harbinger for challenges to come.

PAYER ARCHETYPES

Let’s consider how innovative new drugs such as Sovaldi or, for example, a future cancer vaccine are impacting different payer systems by examining four payer archetypes as described in detail in The Price of Global Health (Gower Publishing, 2015). Payers globally tend to be very different in their approaches and rules; however, the archetypes tend to be a good starting point in evaluating the main fundamental management principles that are used across the globe.

Exhibit 1 describes four archetype systems: Health Economics-Driven, Therapeutic Referencing, Competitive Insurance-Based and Emerging Cash. Exhibit 2 provides a global map that indicates...
which archetype shows the largest affinity to each system. We should remember that each individual drug may face a slightly different situation in each country; therefore the segmentation by archetype should be considered illustrative rather than definitive.

**Health Economics-Driven Systems**

In Health Economics-Driven systems, such as in Canada, Australia, the UK and Sweden, there are many challenges in gaining price or reimbursement approval. In Canada, the Common Drug Review (CDR) has historically rejected about half the applications on the basis of cost-effectiveness and of the remainder, has often imposed significant restrictions. Particularly for oncology, Health Economics-Driven systems are often challenging. England has instituted a special Cancer Drug Fund for anticancer drugs that did not pass cost-effectiveness requirements as evaluated by the National Institute for Health and Care Excellence (NICE). The recent Value Based Pricing initiative was largely an attempt to address this and some other imperfections of the single cost-effectiveness cut-off point. This initiative has failed to gain acceptance so far.

Ironically, Sovaldi, which offers a virtual cure for hepatitis C, gained positive endorsement from NICE, as over the long term the drug cost is offset by savings in avoidance of liver cirrhosis, hepatic cancer and related medical complications. NICE’s positive endorsement is in sharp contrast with many other situations, where NICE and other Health Economics-Driven systems tend to be much more restrictive than any other payer archetype. The larger challenge in these markets may be on a local or regional level (clinical commissioning groups in England, provinces in Canada and county councils in Sweden), as these groups have to handle the budget impact of these agents.

**Therapeutic Referencing Systems**

Over the last few years, many Therapeutic Referencing systems have tightened their evidence requirements for pricing and reimbursement approval for new drugs. A common theme in the changes is the insistence on head-to-head evidence of improvements in meaningful clinical endpoints versus appropriate comparative therapy. In France, the government was close to approving legislation that would automatically reject drug applications without direct comparisons in clinical trials. The strict requirement did not pass, but pharmaceutical companies should have a very good reason for not providing these data.

There have been similar developments in Germany since the introduction of the AMNÖG price control law, which examines proven improvements in meaningful clinical outcomes for patient sub-populations within the approved label. Lack of evidence, or a wrong choice of comparator, has resulted in withdrawal from launch plans, such as for Boehringer Ingelheim GMBH’s Trajenta (linagliptin) for diabetes.

Therapeutic Referencing systems have historically given more pricing freedom for lifesaving or even curative drugs, such as Sovaldi and oncology drugs with substantial overall survival improvements, when compared with Health Economics-Driven systems. However, recently some of these high cost drugs have become a point of contention. The new medico-economic reviews are likely to affect pricing and breadth of authorized prescribing for these drugs in France. In Germany, oncology drugs have generally received favorable benefits ratings, but as their budget impact increases, sick funds are pressuring for tougher price negotiations. Both countries have also been vocal about collaborating with respect to Sovaldi negotiations.

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**Exhibit 1**  
**Global Payer Archetypes**

<table>
<thead>
<tr>
<th>PAYER SEGMENT</th>
<th>DESCRIPTION</th>
<th>TYPICAL ISSUE</th>
<th>TYPICAL COUNTRIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Economics-Driven</td>
<td>Cost-effectiveness drives price or reimbursement approval</td>
<td>Real-life effectiveness and cost-effectiveness</td>
<td>Australia, Canada, S. Korea, Sweden, UK</td>
</tr>
<tr>
<td>Therapeutic Referencing</td>
<td>Price or reimbursement based on demonstrated value over comparator (health economics can play a secondary role)</td>
<td>Choice of high price comparator; demonstrated meaningful benefits over comparator</td>
<td>France, Germany, Italy, Japan, Spain</td>
</tr>
<tr>
<td>Competitive Insurance-Based</td>
<td>Free market environment with competing private insurance</td>
<td>Preferred tier placement; co-pay impact on prescribing and adherence; PAs; step edits</td>
<td>US (except some Medicaid states)</td>
</tr>
<tr>
<td>Emerging Cash</td>
<td>Primarily cash-paying patients; public and private reimbursement still relatively small or limited coverage</td>
<td>Affordability, patient willingness to pay</td>
<td>China, India</td>
</tr>
</tbody>
</table>

DRUG PRICING

Exhibit 2

Global Payer Segments

Competitive Insurance-Based Systems

In the US the payer and medical communities have become increasingly critical of the high cost of drugs. Pharmacy benefit managers (PBMs), which are only managing drug benefits for employers and health insurance companies, have tightened formularies for high cost drugs. As an example, both Express Scripts Inc. (ESI) and Caremark Rx Inc. have excluded (delisted) a number of anti-tumor necrosis factor (anti-TnF) drugs in favor of a few preferred drugs in the category. ESI has also been very vocal with respect to the price of Sovaldi for hepatitis C. PBMs are particularly sensitive to drug cost, as they don’t benefit from the sometimes substantial cost-offsets from reductions in medical cost associated with a disease, such as liver cirrhosis and hepatic cancer for hepatitis C.

Payers are routinely calling on their medical consultants to help guide decision making on drug coverage. Given the emotional nature of the topic, this has traditionally been difficult and many payers have been hesitant to manage drug coverage for diseases such as cancer. Medical societies have stated publically that they have started to take cost or “financial toxicity” into consideration in treatment decision-making. The American Society of Clinical Oncology (ASCO) has instituted a “Value in Cancer Care Task Force” to evaluate how it can institute value guidance for prescribing physicians and patients in their trade-off between patient benefits and added cost or co-payment.

The US Patient Protection and Affordable Care Act (ACA) has expanded coverage for uninsured patients through healthcare exchanges (also referred to as Market Place), has expanded Medicaid in participating states and has provided incentives for integrated care networks. Increasing co-payments and deductibles continue to increase cost sensitivities with patients, despite out-of-pocket maximums and widespread use of co-pay offset coupons in the private sector. (See “Gilead Plays Hardball With Hep C Patient Assistance” — IN VIVO, August 2015.)

Emerging Cash Markets

By definition, patients in Emerging Cash markets are usually paying for innovative branded drugs out of pocket. In countries such as China and India, only few patients carry insurance programs that include coverage for the generally more expensive branded drugs. Pharmaceutical companies use various income and compliance-based patient access programs for higher cost drugs to reach a broader share of the population.

A challenging issue for pharma companies has been the threat of compulsory licensing. Particularly in India, over the last few years, the government has systematically issued compulsory licensing permits to generics companies for patented oncology drugs. Government funding for universal health care programs is slowly expanding in this market segment. Brazil is one of the markets...
that is covering a fairly basic public program with health economic evaluation criteria (CONITEC) and supplementary private health insurance, which shows great similarities to US managed care. Most emerging cash systems have very limited health insurance and include very restricted or generics only drug coverage.

**FUTURE PAYER ENVIRONMENT**

As noted, the combination of new technological developments, increasing prevalence of debilitating conditions and enduring economic pressures will lead to further funding challenges for payers in most global markets. Payers usually have limited flexibility in their funding. When faced with an increasing need for new and high cost drugs, they can either choose to make a case to increase funding or else they will have to make tough patient access decisions.

**US**

Private US payers have historically been able to pass on increased expenditures to employers and employees through insurance premiums. With insurance premiums rising to levels that are considered unsustainable by many, cost containment has become a high priority for managed care organizations (MCOs), whether through stricter formularies or by passing on higher costs in the form of increasing co-pay and co-insurance rates to patients. The following factors are important to consider in anticipating further changes in the US market access and pricing environment:

- **Payers seem increasingly willing to escalate the issue.** Particularly, PBMs have taken action and have been vocal about it; whether and to what extent other PBMs and integrated plans will follow will drive the speed and intensity of further change.

- **Increasing patient cost contributions/co-pays in US** have raised the stakes for patients and physicians/medical societies.

- **Medical societies and individual physicians seem more willing to accept the impact of cost on clinical treatment guidelines.**

- **Issues and stakes can be very emotional, particularly as payers turn to media and physicians to help make tough choices.**

**European And Other Non-US Payer Markets**

In European and most other non-US payer markets, passing on increasing expenses is usually not an acceptable option. Governments institute health care and pharmaceutical budgets with limited, if any growth allowed. As a result, we can expect further tightening of pricing and market access controls, particularly for high-cost specialty drugs. With an expected rapid growth in oncology drugs, payers are likely to particularly step up controls in this therapy area. When faced with a need to contain budget, there are limited choices available:

- **Further restrict pricing, as Germany has done with AMNOG and France has initiated with its medico-economic requirements for drugs that claim a high degree of innovation (ASMR I, II or III).**

- **Restrict market access to those patient populations for which the provided evidence is most compelling, thus allowing less expensive options to be used first in cases where this is practically feasible.**

Each country will make its own choices to keep drug expenses within the allotted budget. In any case, it will result in higher approval hurdles.

**WHAT SHOULD PHARMA COMPANIES DO?**

The changing payer environment and tightening evidence requirements for market access and pricing approval will have significant implications for the research-based pharmaceutical industry. Understanding how to address the requirements and changes is critical for continued organizational success in the evolving market place.

*What are the most essential ingredients in creating successful market access and pricing strategies in the changing payer environment?*

**Pharma companies need to:**

- **Build and maintain a strong understanding of payers, their preferences, their concerns and their evolving requirements.** In reality, it is often difficult, or perceived to be difficult, to have direct interactions between industry and payers. Many national payers are only able to interact with industry in formal, structured consultation sessions, which does not leave a lot of room for true dialog. However, there are other means of achieving this goal.

- **Focus on demonstrating VALUE in the eyes of payers, the medical community and the broader public for every innovation that is considered for development and commercialization by identifying specific and tangible BENEFITS to payers, physicians and patients.**

A useful framework to analyze the importance of benefits and identify significant value claims across customers is shown in Exhibit 3. It is a simplified example for an oncology drug, of the importance and expected performance of a new drug versus existing standard of care. Stepwise, the following is evaluated:

1. **Identification of the relevant benefit areas for the disease area (in oncology in this case).**
2. **The importance of various benefits across customer groups (payers vs. physicians vs. patients).**
3. **Identifying differentiation evidence (after Phase III results are available) or expected differentiation (in pre-Phase III clinical program decision-making).**

The benefits with high importance and demonstrated differentiation versus the appropriate standard of care are the ones that form the basis of differentiation and should be at the center of a payer value story. Companies are often struggling when a drug’s value proposition is mainly “aspirational” at launch as strong data, for example, for overall survival, are not yet available, thus undermining their ability to effectively negotiate market access and price. *See “The Shrinking Value Of Best-In-Class And First-In-Class Drugs” — IN VIVO, July 2015.*

- **Provide reasonably robust EVIDENCE of the drug’s value in the context of the evolving payer system and market access requirements (payers, physicians, medical societies, patients and patient organizations).**

- **Explore innovative pricing and deal options** in light of limitations in evidence at launch and payer funding challenges. Innovative deals are often mentioned, but very few deals are really bridging pharma objectives and payer concerns in an effective way. Active industry-payer dialog and a mutual understanding and appreciation of the challenges are
needed to overcome existing hurdles to these types of agreements.

Most large multinational pharmaceutical companies have strong functional capabilities to analyze evolving market needs and advise their organization on the best path forward to ensure success in light of increasing payer hurdles. Actual decisions made are often suboptimal in emphasizing speed to market over strength of value proposition. Speed can indeed be of essence. However, in a number of cases the optimal strategy involves longer, more expensive and more risky trials. Decisions to move forward with these will require convincing arguments and complete buy-in on the need by the ultimate decision makers. For this reason, a comprehensive evaluation of options and market testing of the intended value story, benefits claims and supporting evidence are crucial. Companies that do this well are likely to have a substantial competitive edge over their competitors that do not adjust to the rapidly changing market conditions in the prescription drug market.

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