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Pharma Market Access Success: Shifting the Dialogue from Price to Value Through Strategic Communications

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As healthcare costs continue to rise, the decision to cover a new drug and provide access to patients who need it lies increasingly in the hands of payers, not physicians. To achieve uptake of its new product, a pharmaceutical company must reorient itself to show multiple stakeholders how the drug is worth its cost and can be affordable for those who pay for it, and perhaps most importantly, in the context of what suboptimally treated acute and chronic illness actually costs a given global economy.

A recent case in point is described as follows: Hepatitis C is a life-threatening, chronic liver disease, with nearly 150 million people infected worldwide. The disease can lead to liver cancer and death, and until recently, a liver transplant for a very limited cluster of patients offered the only potential cure. Since November 2013, the United States Food and Drug Administration (FDA)[1] has approved four new treatments that cured up to 90 percent of the patients with the disease in clinical trials. One of the four, Sovaldi, is a nucleotide analog inhibitor that, when used in combination with other treatments and depending on the hepatitis C genotype, showed a cure rate of up to 96 percent. Sovaldi is also approved in Canada, Europe and Japan. Yet the marvel of a cure for hepatitis C has been eclipsed by controversy over the "silo" pharmaceutical cost of the new treatments,[2] about US $84,000[3] for a 12-week course.

A cure for a chronic, life-threatening disease is but one of the most innovative treatments that have extended and saved the lives of people around the world, including those with HIV/AIDS and many types of cancer. True breakthroughs in medicine are less common, but even the incremental advancements are not easy to come by. The mean length of marketing exclusivity for first entrants in a drug class has declined by 82 percent from the 1970s through the late 1990s – from 10.2 years to 1.2 years. And in 89 percent of drug classes, the Investigational New Drug Applications of follow-on drugs were filed before the first-in-class drug was even approved.[4]

Marketing exclusivity for first-in-class drugs dropped from **10.2 years to 1.2 years** from the 1970s to late 1990s

These long odds in development, coupled with the rigour of today's clinical trials across geographies and patient demographics, necessitate an investment by manufacturers estimated to be $2.5 billion to develop and bring a single new pharmaceutical treatment to market.[5] Despite all this unprecedented financial investment, the research-based pharmaceutical industry is increasingly perceived as imposing an undue cost burden, with calls for the system to be rehabilitated.

It costs **$2.5 billion** to develop and bring a single new pharmaceutical treatment to market

It's up to a pharmaceutical manufacturer to identify a powerful and convincing value story for its innovative products in perspective with the real costs of poorly treated disease, and to tell the story early and often to all

key stakeholders in given markets in order to lay a foundation for a true value message. Today, more than ever, industry must demonstrate how a new drug improves patient outcomes, reduces the burden of the healthcare system as a whole and is worth its price. Strategic communications can help a manufacturer ensure that value is perceived and finally recognised before a pricing decision is reached to capture the value created by a novel drug, and continue to validate and sustain the value story post launch. To get the best price, fair reward for market-valued innovation and favourable budget allocation, coverage and reimbursement, the focus must shift from the cost of a drug alone to the recognised value of reducing the real total cost of disease to a nation's health system.

Shaping the Environment to Create the Value Context for Innovation

Putting such a strong emphasis on a drug's value context is a relatively new approach for industry. For years, regulatory bodies have reviewed clinical, safety and efficacy data, approved a drug, and it was on its way to a successful launch. Payers looked at the clinical evidence and the price set by the manufacturer, and decided whether to reimburse an approved product with far less urgency and focus on budget savings. A new molecular entity in any therapeutic category was recognised as a valued innovation.

But increasingly, payers around the world place conditions on their coverage of new drugs and in many cases refuse to reimburse for them at all. To stem rising healthcare expenditures, health technology assessment (HTA) bodies in most countries offering universal health coverage evaluate stringently whether the expected additional health benefits of a new drug justify its higher cost compared to existing therapies.[6]

It's not enough for a drug to be innovative; it must show **value above and beyond available treatments**

Today it's not enough for a new drug to be innovative; it must demonstrate *differentiated* innovation, or value above and beyond available treatments.

Successful manufacturers have always regarded the generation of data to substantiate payer value claims as a process that begins in early drug development. Drug makers determined what it would take to differentiate their innovation, and designed their development programme and launch readiness to substantiate, communicate, capture and sustain that value. Now, manufacturers must start the process even further upstream, and involve payer and HTA experts – not just regulatory experts – to understand how value will be judged in the real world and what type of evidence will be required to build credible, compelling, convincing messages.

Value means different things to the various stakeholders in the market access system, and it's critical to bring these parties into the conversation early to capture what will reinforce the value proposition. For the payers and market access stakeholders, the value proposition is the optimal combination of clinical, economic and patient-reported outcomes that achieves market access at an optimal price by validating and communicating the need for treatment and the value of utilising the medicine in question. Waiting to start translating science and clinical data into value recognised by payers and their advisers until after marketing authorisation is entirely too late.

In the Sovaldi case, each stakeholder group likely views value from a different perspective. A consistent message delivered in tailored conversations resonates to support what is important to each:

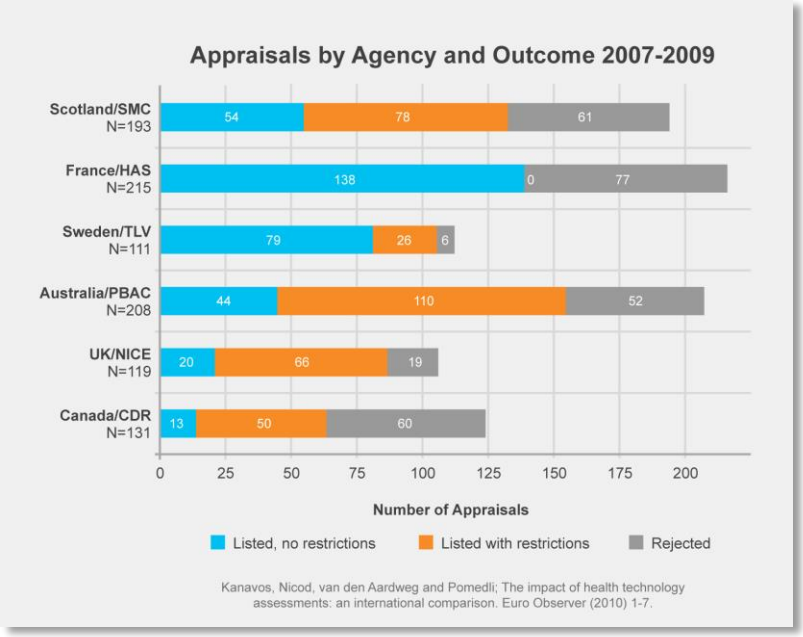
- **Patients:** Those who respond to Sovaldi are cured of their disease
- **Healthcare providers:** You can offer chronically ill patients hope and better quality of life through potentially curative treatment
- **Employers:** Now-healthy employees are more productive
- **Payers:** Better outcomes for money, reduced healthcare costs (e.g., hospital costs, physician office visits, diagnostic lab fees, etc.)

Managing the Integrity of a Global Value Proposition

A value proposition must withstand the heavy scrutiny and be tested for consistency in a highly referenced and transparent "one" global economy. Market access dossiers are a snapshot of a product in time, and can't always capture the entirety of the value story. A comprehensive value communications strategy that begins early in development and continues through global launches and beyond can deliver consistent messages to all stakeholders who view the product through slightly different lenses. Once established and agreed upon by all key internal players, the global strategy can be executed in local markets with an eye toward the specific attributions of each.

- Early development, value assessment and messaging **establishes the disease burden from multiple angles**, including the personal costs to patients and caregivers, impact on the economy and government, and need for treatment.
- Full development messaging, authenticated with the inclusion of payer and HTA experts throughout the process, **proactively advances the best product label and evidence-based payer value claims** that are compelling and credible to all stakeholders.
- Launch messaging focuses on the **health benefits of treatment**, how the product is an improvement over existing treatments and how it will improve quality of life and reduce overall costs.

- Post-launch messaging communicates the **real-world experience with a treatment**, evolving the value story based on the **population health management experience** and benefit seen as patient exposure increases with time or new indications.



Health technology assessment and payer agencies do agree on some efficacy, safety and health economics data required to list a drug, as each product winds its own way to a decision. In a review of health technology assessments in six countries between 2007 and 2009, Kanavos et al. (see chart) finds disparities in the information required, interpretation of evidence, rigour of the appraisal process and stated motivations for listing or not listing drugs.[7]

Each global market presents unique access and reimbursement challenges. A review of the market access and reimbursement process of multiple global markets for GLOBALHealthPR™'s Reimbursography™ illustrates why a manufacturer may choose to launch a product in one country before another, and possibly make the very difficult decision to avoid some markets altogether.

Manufacturers may even face regional differences within a given country. In England, the National Institute for Health and Care Excellence (NICE) conducts the HTA and determines if a product is a good value for money. But while NICE may consider the product to be cost effective, local and regional authorities actually make reimbursement decisions impacting their healthcare budgets.

External stakeholders involved in market access and market penetration require different conversations, but the messages must be consistent and integrated. Message consistency takes greater importance as global operations become more transparent and a pricing decision by one country's pricing and reimbursement authority is referenced by others. Each country's HTA may operate differently, yet countries seek alignment when it comes to price. Out of 27 EU member states, 24 countries use international referencing to set prices of new drugs.[8]

24 of 27 EU countries
use international reference pricing to set prices of new drugs

With five to 15 different disciplines within a manufacturer organisation communicating with external market stakeholders about the clinical (safety, efficacy), economic and patient-oriented value of a drug, there's a risk of inconsistent messaging or even conflicting information. Early integration among internal teams is critical to the creation of a shared value story "blueprint" that can be

deployed across development and commercial functions pre-launch and executed consistently post-launch across all geographies and filtered down to the local or regional level.

Patients represent a key stakeholder group that acts as influencers among other important audiences. Engaging patient advocacy leaders early in the drug development process – including the design of Phase 3 clinical trials – can shape and increase effectiveness of recognised value and appropriate messaging. With an overarching framework for value communications at the global, national, regional and local levels, manufacturers can maximise the value recognised by stakeholders.

Plan and Communicate for Managed Entry to the Market

As new, more expensive drugs, such as the nucleotide analog drugs for hepatitis C therapies and other high-priced biologics, are approved by regulatory bodies around the world, more payer agencies are adopting risk-sharing, performance-based pricing, financial agreements and patient access schemes (collectively referred to as "managed entry agreements"). Payers agree to cover promising health technologies on a conditional basis, while evidence of real-world effectiveness and cost effectiveness is evaluated. Fundamentally, payers are imposing barriers to rapid patient access out of concern for unpredictable cost exposure, particularly for high-priced biologics.

> Payers are imposing barriers to access out of concern for **unpredictable cost exposure**

Besides the European countries, Canada, Japan, Australia, New Zealand, Thailand, South Korea and Taiwan require proof of value for new medical technologies. Lu et al. finds that though different in their development and implementation, the agreements all stem from cost pressures coupled with demands from key stakeholders for access to new drugs.[9] Australia shows the most experience in Asia-Pacific region with systematic evidence review (health technology appraisals) and other Asia-Pacific countries will likely look to this authority for guidance.

Managed entry agreements are growing in European countries, and range from simple price discounts (and other price-volume financial agreements) to complex outcomes guarantee and performance-based pricing schemes with high administrative burden. A strong and evidenced story ensures value is recognised and shifts the focus away from price alone. The story helps position a new drug for rapid patient access and to sustain reimbursement. Manufacturers should be proactive: design, develop early and be prepared to implement a tailored managed entry agreement and align the value communications strategy accordingly in case they are faced with a restricted or negative coverage decision.

The Beat Goes On: Post-Marketing Access Activities

Regulatory bodies around the globe demand that manufacturers conduct post-marketing surveillance and pharmacovigilance efforts to ensure newly licensed drugs, especially biologics with a concerning risk-benefit profile, are safe. Payers, too, want proof that new drugs deliver value above and beyond available treatments in real-world situations and continue to do so.

Value communications must begin earlier
in the process, evolve over time and remain a priority throughout the product life cycle

The marketplace is highly dynamic – a new indication or a competitor's label change will likely trigger a review of the entire category. Payers will expect companies to provide more data to justify the designated level of reimbursement. So value demonstration and value communication must not only begin earlier in the drug development process, it must evolve over time and remain a priority throughout the product life cycle post-launch.

Map Your Value Story – Before Someone Beats You To It

Building a value story in the early stages of a drug's development sets it up to fulfill an unmet need and demonstrates how the product addresses clinical, economic and patient challenges. If you don't start talking about your drug early on, you run the risk of others building the narrative for you that may not be in your favour.

Take PCSK9 inhibitors, for example. Several manufacturers are developing this new class of drugs to treat high cholesterol, projected to gain FDA approval in mid-2015. News coverage about promising results of Phase 3 studies presented at the annual American College of Cardiology Scientific Sessions in March 2015 was eclipsed by reporting about the potential high cost of these drugs. The flurry of news stories, which appeared in Financial Times, Forbes, The New York Times, among others, was prompted by a *Health Affairs* blog post authored by officials at U.S. payer CVS Health. After nearly two decades of cholesterol awareness programmes conducted by the makers of statins, payers such as CVS are now fearful of widespread demand for or over-utilisation and marketing of PCSK9 inhibitors to a broad population. Referring to the Solvaldi price tag, the blog authors warned that PCSK9 inhibitors will wind up costing even more.

What's missing from the conversation is the real value of the product delivered to the patient and/or the healthcare system, such as cost of untreated high cholesterol in the more targeted populations for which the drugs will likely first be approved – hospital visits, emergency care, lost productivity among people with familial hypercholesterolemia or those high-risk patients with elevated levels of low-density lipoprotein (LDL) cholesterol and a history of cardiovascular disease.

There's more to the cost discussion than simply the price of a drug. It's the responsibility of the manufacturer to shape that conversation well in advance of regulatory review, and in a way that underscores the current cost of under-treatment or inadequate therapeutic options, demonstrates value and ultimately justifies pricing and reimbursement. The right communications framework can expand the definition of value and shift the conversation from the cost of a given drug to the value of pharmaceutical innovation.

Creating the right framework for your value story begins with understanding the market dynamics in key markets. GLOBALHealthPR's Reimbursography report provides big-picture insights on the pricing and reimbursement environment in key global markets to be used as a foundation for your value communications strategy. As a team, we see a new way of thinking and believe that by integrating market access and strategic communications much further upstream than is typical within the industry, there is an opportunity to redefine the process and develop more meaningful, credible and impactful value narratives.

For more information please visit
www.reimbursography.com.

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[3] http://www.webmd.com/hepatitis/news/20140414/high-cost-hepatitis-c-drugs
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