

## Product/Service Review

# Optimizing Market Access:

## A Guide to Effective Pricing, Reimbursement and Messaging Strategies

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In today's competitive market, pricing and reimbursement strategies are key to maximizing brand success and ROI. Because every country's healthcare system is different—and every product situation is unique—every brand requires a specific access plan, tailored to each market. And you must support each plan with effective messaging that ensures strong product acceptance and uptake.

Experts from TNS Healthcare spoke on this issue in a recent webinar and during an exclusive interview with *Pharma Marketing News*.

Jonathan Kay, Global Practice Area Leader, Brand and Access Management, TNS Healthcare, set the stage by reviewing global market access issues and identifying challenges and opportunities in coverage and payment.

Larry Olson, Vice President and Practice Leader, Payer Markets, TNS Healthcare, looked in greater depth at communication strategies to maximize access, including how to develop compelling messages to build and sustain brand value.

#### Market Makers:

*Challenges and Opportunities in Coverage and Payment*

During the Webinar—which is still available via archive at <http://tinyurl.com/6hgam4>—Jonathan

Kay focused on:

- Exploring similarities and differences in decision paths and key influencers across countries.
- Identifying stakeholders and understanding risk sharing and its consequences. Determining what's at stake and who cares in markets around the world.
- Learning strategies for gaining access despite utilization controls.

In looking at the differences and similarities in various markets when it comes to issues of access, pricing, and reimbursement, Kay pointed out that “there are a number of critical issues facing the pharmaceutical industry today. Pharmaceutical access to market and patient access to treatment are among the most important.”

#### Show Me the Value

More and more health systems, government regulatory agencies, and private payers are asking “what is the value?” (See, for example, “Value-based Pricing,” PMN Reprint 76-04; <http://tinyurl.com/4chyy2>). “How a drug is valued,” noted Kay, “depends on who is doing the valuing. Is it the health system that is footing the bill? A provider who is managing the disease? The patient who knows there is a drug that can help? Or the manufacturers?”

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## Access and Reimbursement Vary by Market

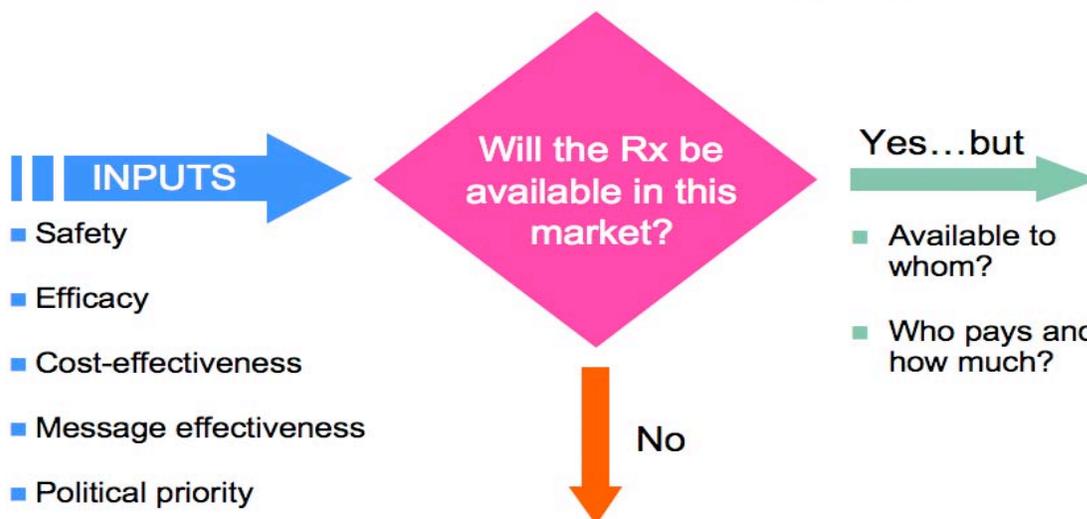


Figure 1: Market access depends on who pays for treatment for whom. Several factors are considered, including message effectiveness.

Consistently across all markets, market access decisions come down to determining when it is worth it to pay for care and for whom (see Figure 1, pg. 1).

In the U.S., safety and efficacy are the two most important criteria that determine market access. Various mechanisms are then employed to manage pricing and reimbursement once the drug is in the market. In contrast, in other countries, cost-effectiveness plays a larger role in driving access and comes into play earlier in the decision-making process.

“Across all markets, message effectiveness will help ensure the greatest chance of success,” said Kay. Knowing who the decision makers are, what their priorities are, what messages resonate with them, and what the optimal timing is to communicate will guarantee the greatest likelihood of success. See “Payer Messaging: Value-Driven Communications Strategies to Maximize Access” in this article for more about message effectiveness.

“When it comes to market access and reimbursement, who plays and who pays are the all-important questions,” noted Kay. “Obviously, when healthcare systems bring a lot of money to the table to pay for treatment, they want a big role in deciding who gets what treatment. Formularies are one way health systems limit access and impose cost-sharing.”

### Cost-Containment Tools

The high level and continued growth of healthcare spending make access and payment key policy issues. The stakes vary by country as can be seen in Figure 2. Some countries spend a third or more of their healthcare costs on prescription pharmaceuticals. As nations spend vast amounts of money on healthcare, they naturally look for cost containment through efficiency and setting priorities.

Effective, novel treatments present a compelling case for access when there are no competing treatments in the market. On the other end of the spectrum, so-called “me-too” drugs tend to offer little evidence of incremental value. “Many drugs fall in between these extremes,” said Kay. “The value they provide needs to be clearly defined and communicated to ensure optimal access to the market.”

In any given market, many entities are involved in determining whether a drug will have access. “It is essential,” said Kay, “with so many key decisions and decision makers, to understand the healthcare system in each country and to target the right decision makers at the right time with the right value message that will have the greatest impact.”

In many markets, key opinion leaders also weigh in to decide when a drug is made available, to whom,

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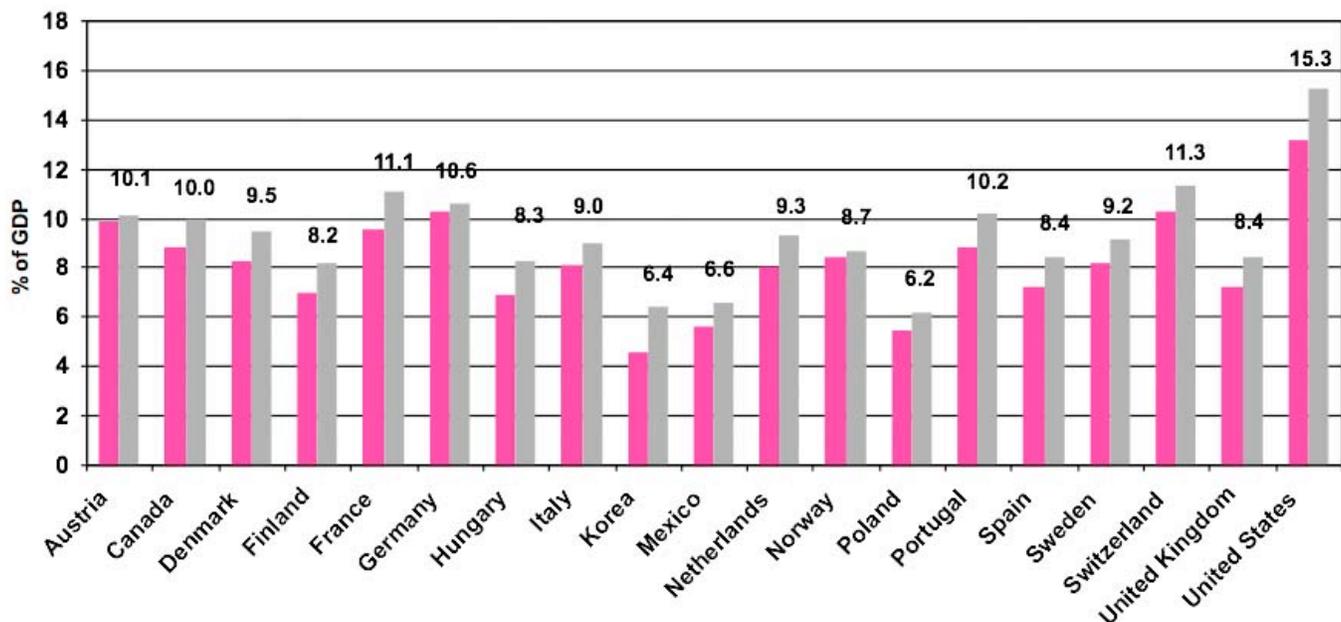


Figure 2: Healthcare as a % of GDP for Selected Countries 2000 vs. 2006. Pink bars=2000, gray bars=2006. Source: OECD Health Data 2008 - Version: June 2008 (Organization for Economic Co-operation and Development).

and under what circumstance. In addition, health systems employ policy tools to affect supply and demand. There are two levers that control cost: price and volume. To contain costs, health systems and payers must move one or both of these levers via tools such as:

- Access Restrictions
- Formulary
- Reference Pricing
- Cost Sharing
- Risk Sharing
- Rationing

### Compare and Contrast Health System Controls

Kay presented several scenarios that illustrated how different countries determine market access and contain costs. A few examples are outlined below.

#### How it works in the US

##### *Safety and Efficacy Determine Market Access*

- Scenario: Should there be access to clinically effective MS biologics in the US?
- Outcome: FDA approval for indications proven in terms of safety and efficacy.
- Implications:
  - FDA's risk management focuses on clinical risk; the market and public/private health systems manage economic risks.
  - The philosophy: If Federal controls can eliminate most of the risks, then an informed medical community will manage the remaining (clinical and economic) risks.

#### How it Works in the UK

##### *Clinical and Cost Effectiveness*

- Scenario: Should there be access to clinically effective late-stage renal cancer treatments in the UK?
- Outcome: UK's NICE recommended against market access for 4 clinically effective renal cancer treatments because of competing economic priorities.
- Implications:
  - Society bears the economic risk. At the macro-level, we need to consider alternatives and tradeoffs.
  - With effectiveness established, companies must think about how to

change a brand's cost/benefit profile. Is the only answer to reduce price (eg, Tarceva)? What are other options for ensuring cost does not become a barrier to access?

"Cost effectiveness is a metric of increasing importance in Europe and in Australia," said Kay. "Companies must find ways to communicate value to ensure access to their brand is seen as a priority."

#### How it Works in Japan

##### *Delays and Price Limit Access*

Japan employs a delayed access strategy, which is a variation of the limiting access approach. In Japan, there is an average 2.5 year delay from US approval. For a number of reasons—including regulatory requirements, the need for clinical trials to be conducted in Japan, challenges around agreement on prices and the value of innovation—30% of the world's top-selling 100 drugs are not available in Japan today.

#### Cost Sharing vs. Risk Sharing

Shifting some costs to the patient, such as with the Medicare "doughnut hole," transfers some economic risk to patients. Cost sharing has been shown to reduce consumption of both needed and unneeded services. Short-term savings can actually result in long-term risks, and cost sharing approaches sometimes can increase morbidity.

Risk sharing shifts the burden to the manufacturer. Kay discussed a scenario in the UK where access is provided to Velcade, an effective multiple myeloma treatment, but payment is contingent on outcomes. The manufacturer was required to refund the cost of the drug to the National Health Service (NHS; ie, payer) for people who did not have at least a partial response.

"Risk sharing is essentially a money-back guarantee," said Kay. "This moves the needle further and further along the trend toward value-based decision making."

Risk sharing can bring innovative drugs to patients and could even accelerate access and establish a preference in the market. This is why some pharmaceutical companies are willing to negotiate risk sharing deals with payers, like the NHS. The success of risk sharing for all parties depends in part on clear and objective outcomes measurements.

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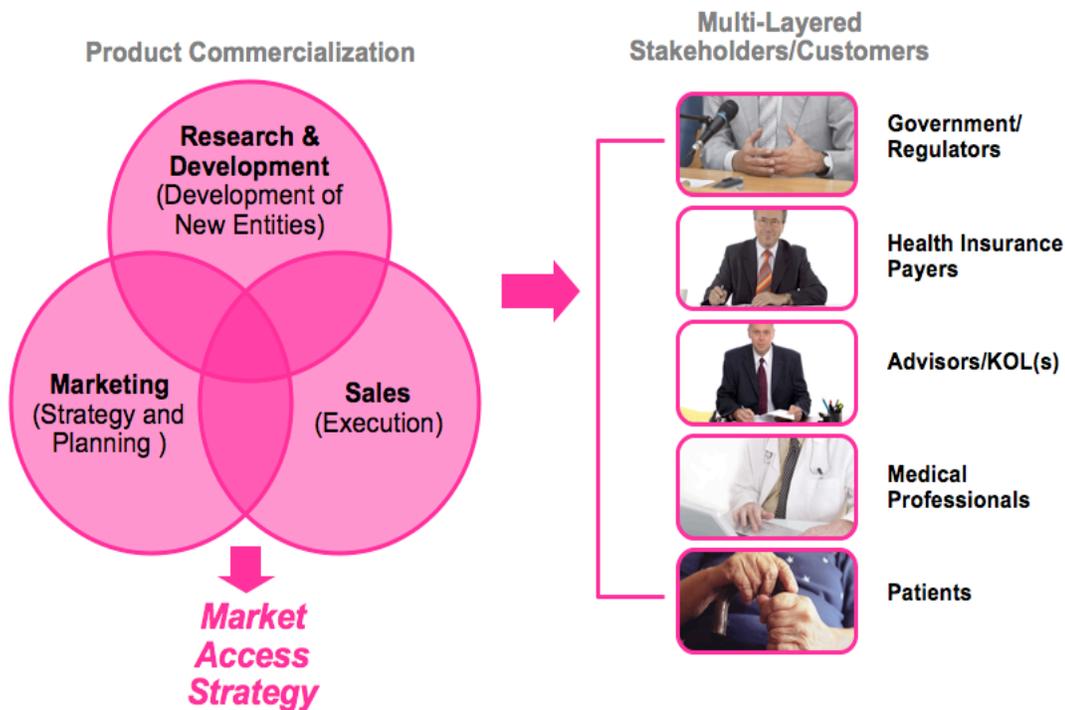


Figure 3: Pharmaceutical marketers need to adapt to new customer needs in order to best optimize market access. To do this, pharmaceutical marketers need to be multi-stakeholder customer-centric.

### Strategic Considerations

Governments and health systems spend large sums on healthcare overall and especially on prescription drugs. Therefore, they are looking for ways to contain costs. As a result, managing clinical risks is not sufficient to guarantee market access. There is increasing focus on managing economic risks as well.

Market access strategies must be addressed well in advance of a product's introduction to ensure maximum uptake at launch. Kay closed his presentation with these important points to remember:

- Consider the best analogs to anticipate how your product will be received.
- In R&D, licensing, and acquisition decisions, consider potential hurdles in access and coverage to arrive at go/ no go decisions and to inform clinical and economic endpoints in studies.
- Even with access, additional barriers must be overcome (who has access, under what conditions, at what cost, etc.). Identify these challenges and create the strategies to solve them.

### Payer Messaging:

*Value-Driven Communications Strategies to Maximize Access*

In his presentation, Larry Olson addressed the increasing importance of payer messaging and the role of value-driven communications in maximizing market access, pricing, and reimbursement. His presentation focused on these strategies:

- Develop compelling pull-through messages that drive favorable formulary placement.
- Understand when to message payers across the product life cycle—and how to segment messages to impact different decision makers.
- Build payer message platforms that support and sustain your brand's value propositions.

"Healthcare reform is a central political issue," said Olson. Recently, for example, Senator Ted Kennedy urged president-elect Barack Obama not to delay initiating his healthcare reform program. "The rising cost of health care is clearly contributing to the troubled economy and needlessly strains family pocketbooks," said Kennedy in a *Washington Post* editorial. "Even worse, these costs are expected to climb higher, more than

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doubling in the next 10 years. We can no longer afford not to act.”

Billy Tauzin, President and CEO of PhRMA also urged Obama to move forward. “We look forward to continuing our dialogue on all of these important issues—and many more—with President-elect Obama and members of the next Congress,” said Tauzin in a press release.

In this atmosphere, “the value of a drug brand has to be very clearly and compellingly articulated in terms of pharmacoeconomic data and outcomes research,” said Olson. With patients, providers, and payers having many more competing brands, not to mention generics, from which to choose, creating brand differentiation and preferences are increasingly important.

“Marketers need to customize communications to create unique, targeted relationships with each customer group,” said Olson. “That’s critical to maximizing brand performance and market access.”

Payers are becoming more proficient at tracking, measuring, and influencing physician prescribing practices. Consequently, it is important to develop messages to payers that support and sustain the value of your brand.

“Today the relationship between payers and the pharmaceutical industry is marked by a notable lack of collaboration,” said Olson. Olson cited payer concerns about lack of staff within pharmaceutical companies to address their specific questions concerning cost-benefit ratios, evidence-based medicine, and the impact on their plans.

The full list of issues critical to payers includes:

- Perceived medical or clinical need
- Proven clinical effectiveness
- Cost-benefit ratio
- Quality of clinical evidence
- Positive health outcomes
- Pharmacoeconomic impact
- Political expediency

“Payers need this kind of information and they are not currently getting it from pharma,” said Olson. “Messages that convey these value propositions will help maximize market access.”

In his presentation, Olson emphasized that as the reimbursement landscape continues to grow in complexity, targeted stakeholder-specific messages that drive market access will become even more important. Brand messages that worked

in the past are not really guaranteeing success as we move on to 2009. “Today,” said Olson, “patient centricity and outcomes need to be the heart of compelling product value propositions to payers. Brand marketers also need to start thinking how they sell their brand’s value story to different customer groups.”

#### **Required Market Intelligence**

Three key information areas are necessary to optimize payer messaging, according to Olson:

1. Clinical Knowledge
2. Policy Intelligence
3. Economic Knowledge

Strategically, it is important to understand payers’ decision making processes and how to influence them. It also is key to know the major market access priorities (e.g. burden of disease, MoA, expected clinical outcomes and quality of life, treatment alternatives, cost-effectiveness, acute vs. chronic disease) and how they might change. In addition, it is crucial to learn from past market access successes and failures and to determine how optimal prices were achieved.

#### **TNS Healthcare’s 5-Step Research Process**

TNS Healthcare has developed a five-step research process to obtain the necessary market intelligence. These steps are:

1. Analyze the Relevant Market: eg, What is the current competitive situation in the relevant market?
2. Analyze the Decision Process: eg, Who are the decision makers? Who are influencers; eg, Health authorities, opinion leaders, patient organization, payers?
3. Assess the Value Profile: eg, Which are the key value drivers?
4. Evaluate Pricing Opportunities: eg, Which price is perceived to be appropriate?
5. Recommendations:
  - Analyze the pricing/ reimbursement strategy, nationally/internationally
  - Create the best strongest t negotiation strategy.
  - Identify the most effective launch sequence.
  - Optimize the product profile.
  - Find and fulfill any need for further clinical data.
  - Determine the next steps in marketing research.

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### Building Value-Driven Messages Along the Product Lifecycle

“One of the most important question regarding building value-driven messages is when to start the payer messaging research,” said Olson. “Most of our clients begin thinking about this way too late in the product’s lifecycle. It’s best to start building your value drivers early on in the pre-clinical stage in order to inform clinical trial design.”

#### Best Practices

Olson identified several key questions to consider when conducting your research for optimizing payer messaging:

- What are payers’ greatest information needs in order to improve outcomes and patient compliance?
- Which product features or combination of features are most important in maximizing Market Access potential?
- Which of the “value stories” resonate strongest among payers?
- Are there any other “value stories” not in the current mix that need to be included?
- What data will be required to support the key elements of the most compelling “value story” among payers?
- What would be considered the “IDEAL” single value proposition that could be constructed that would best maximize Market Access potential?

“This all culminates in telling your story,” said Olson. “Telling your product’s story in terms of its most valuable propositions for physicians and payers will help ensure more favorable market access.”

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### Experts Consulted

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The following experts were consulted in the preparation of articles for this issue.

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