

Forecasting Pharma's Future

Given the volatility of today's financial landscape, companies, more than ever, need a robust forecasting strategy that is clear, effective, and accurate.



“With so much uncertainty in some of the emerging markets, it is important to get cross-functional input when developing country guidelines.”

JUDITH KULICH / ZS Associates



As companies seek to negotiate the volatility of emerging markets, the uncertainties of healthcare reforms, and changing customer demands, accurate forecasting will need to come to the fore as a way to address the changing pharma landscape.

Experts say one of the greatest concerns for the industry is the health of global economies — from lingering concerns related to debt-laden countries in the European Union to trade surpluses fueled by purposefully devalued currencies. The impact of these issues and the stability of global markets and currencies will have significant influence on the pharmaceutical industry.

Ken Fyvie, senior consultant in the life-sciences and healthcare practice at PA Consulting, says countries are spending an increasing proportion of their GDP on health.

“This is not sustainable,” he says. “The current stress in global economies and the pressure on sovereign wealth are sharpening the challenge. But in most cases the responsibility for meeting the current and future demands for healthcare will still have to be met by governments with funding from the public purse.

“Companies are recognizing the need to provide higher value from lower cost options,” Mr. Fyvie continues. “The need to increase the use of generics and more frequent and rigorous assessment of the value for money associated with new medicines make that requirement very clear.”

Mr. Fyvie says both the payer and the provider communities are going to be demanding a great deal more evidence of effect and value from pharmaceutical products.

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“Companies are starting to realize that the days of the traditional sales and marketing model have passed and they need to be thinking about how to engage their evolving community of customers differently,” he says.

Judith Kulich, principal, ZS Associates, points out that the pharmaceutical sector is and continues to be better insulated than many other industries in this and past recessions.

But she says the industry must reduce its reliance on what has historically been the strongest global economies. In the past, pharmaceutical companies were able to forge their revenue from the top seven global economies and global markets.

“The top seven markets may have contributed as much as 80% of companies' global volume,” Ms. Kulich says. “Now, we're seeing pharmaceutical companies looking toward the top 15 to 20 markets to contribute that 80%.”

Emerging markets are going to change the perspective and focus pharmaceutical companies have about their portfolios, says Craig Wylie, senior consultant in life-sciences and healthcare practices at PA Consulting.

“My expectation is that within six years, the direction of companies will be quite different than it is now,” he says.

Matt Geller, Ph.D., president of Geller Biopharm, says the volatility of global markets

2012 Healthcare (Pharmaceutical) Industry Perspective

In keeping with its tradition, Booz & Company paused to reflect on the critical issues the pharmaceutical industry will face in 2012 and how life-sciences companies can position themselves to benefit.

To the drug industry, Nov. 30, 2011, was a landmark date, the day that Lipitor, the most successful drug ever, began to face generic competition. Lipitor's loss of patent exclusivity is a sharp reminder of the patent expiration wave making its way through the industry, increasing pressure to cut costs and improve productivity and innovation.

Pharmaceutical companies confront these patent challenges at a time when growth in the overall industry is slowing and demand is shifting to generic segments and emerging markets. Booz expects these trends to continue in 2012, along with persistent regulatory hurdles; increasingly demanding stakeholders, including payers, providers, pharmacies, and others; and challenges throughout the value chain — from slumping R&D productivity to supply shortages.

Companies can survive and thrive if they adopt highly differentiated strategies. Differentiation goes beyond a shift from me-too products to novel breakthroughs. True differentiation stems from the presence of carefully nurtured distinctive capabilities throughout an organization that endure and are tough to copy.

As pharmaceutical management teams turn the calendar to 2012, Booz analysts pose a simple question: is your company building capabilities that are truly differentiated and consistent with the changing demands of the market? In answering, consider four critical and rapidly changing aspects of the industry — research, commercial operations, supply chains, and networking — that require specific, highly developed capabilities.

The Capable R&D Engine

Many R&D transformation programs do not meet their potential because they comprise a broad set of uncoordinated and overlapping initiatives that are not underpinned by an overarching strategy. A clear focus on a few specific differentiating capabilities can act as a "guiding star" for innovation. Booz research and experience with clients suggest five key capabilities to power a capable R&D engine:

1. Value-driven clinical program design with a focus on explicitly and transparently assessing trade-offs among development cost, risk, and revenue, based on an

understanding of value in the eyes of all major stakeholders, and the design characteristics that drive cost, risk, and revenue.

2. Scientific and clinical leadership development that builds a highly effective cohort of discovery and development managers in the middle, who have extensive external networks, broad disease and pathway understanding, and decision-making authority given established scientific and clinical targets, coupled with performance measures that encourage collaboration and overall portfolio optimization.

3. Disciplined portfolio management based on assessments against rigorous, forward-looking target product profiles that have been externally tested against market and competitive trends.

4. Targeted therapy development involving systematic and early identification of targeted therapy options, analysis of trade-offs, and selective design of tailored drug development programs to focus on patient subpopulations.

5. Scale-up of next-generation clinical development that focuses on rapid and broad rollout of new approaches such as building access to high-quality electronic medical record data for protocol modeling and patient recruitment, remote data collection, and novel approaches to data quality risk monitoring, as well as aligning the design of outsourcing partnerships with strategic development goals.

Booz says there is less debate among clients on what needs to change than on how to make change happen broadly and systematically across complex, global organizations. Rather, their experience has been more focused on developing key capabilities at scale including, for example, performance management systems for functional and therapeutic area teams, and partnership agreements with outsourcing firms.

The Commercially Capable Company

Over the past two decades, large pharmaceutical companies relied on a sales and marketing approach aimed at prescribers in the world's largest markets — the United States, Europe, and Japan. The model spawned blockbusters such as Lipitor and created unprecedented value. Now, however, it is no longer generating growth.

Going forward, four trends will require not just

more significant cuts in traditional resources, but a focus on building distinctive new capabilities.

1. Cost-containment continues to create a more restrictive market access environment with greater pricing pressures, additional reimbursement restrictions, and new or altered drug procurement systems.

2. New product launches are increasingly focused on high-value specialty indications.

3. Trade liberalization is opening new opportunities in distribution and trade channels.

4. Emerging markets, which have very different healthcare models for marketing authorization, pricing, reimbursement, and distribution, are forecast to make up 30% of the global pharmaceutical market by 2015, compared with 19% in 2010.

Booz says certain go-to-market capabilities will be critical in confronting these trends.

Payer engagement capabilities will need to address market access, pricing, and reimbursement (including innovative pricing agreements); joint disease management programs; and the provision of additional patient services that enhance the value of the product. These services may include compliance management programs supported by nurses or telephone hotline services, among others.

Multistakeholder marketing capabilities will need to target all relevant players in the healthcare system, including prescribers, nurses, pharmacists, formulary committees, and payers. Multistakeholder marketing requires close coordination among medical, sales and marketing, market access, and pricing teams to secure pricing and use that reflect the value of each product. It calls for joint-planning and decision-making processes, as well as coordinated execution. It is the organizations that are truly ready to redefine how they plan and operate that are realizing benefits at scale.

Commercial trade channel (CTC) capabilities also need to engage more closely with key stakeholders in the distribution chain, including wholesalers, pharmacists, and patients. CTC capabilities include new distribution models, such as direct-to-pharmacy (DTP), in which manufacturers sell straight to pharmacies, paving the way for targeted loyalty programs. The success of these new CTC models depends on close collaboration among product supply, marketing, and commercial trade functions.

Source: Booz & Company

Forecasting

means more focus by pharmaceutical companies on earnings as opposed to longer-term pipelines.

“There is a tendency for companies to avoid risk; therefore, there is an increasing move toward in-licensing,” he says. “Pharmaceutical companies are relying more and more on biotech companies for their pipelines and most big-cap pharma companies are doing less research and development internally.”

Mr. Wylie agrees, saying more pharmaceu-

Slowing Growth in Developed Markets

The IMS Institute for Healthcare Informatics has reported that global spending for medicines will reach almost \$1.1 trillion by 2015, reflecting a slowing CAGR of 3% to 6% over the next five years. This compares with 6.2% annual growth over the past five years. Lower levels of spending growth for medicines in the U.S., the ongoing impact of patent expiries in developed markets, continuing strong demand in pharmerging markets, and policy-driven changes in several countries are among the key factors that will influence future growth, according to the IMS Institute's new study, *The Global Use of Medicines: Outlook Through 2015*.

In its latest analysis, the IMS Institute identifies the following dynamics:

- » Brands accelerate their decline in share of spending.
- » Novel therapies address unmet patient needs.
- » Pharmerging markets approach U.S. levels of spending on medicines.
- » Health policy decisions affect spending in the long term.
- » Biosimilars evolve rapidly, but adoption is limited.

The IMS Institute also identified the leading therapeutic classes in 2015. These include: oncology, which is expected to remain the leading therapy class but with slowing growth of 5% to 8% as existing targeted therapies already have been widely adopted; diabetes treatments, where spending is forecast to be 4% to 7%, driven by the rising prevalence of the disease and by the uptake of newer oral antidiabetic agents; asthma and COPD treatments, where growth is expected to slow to 2% to 5%; and lipid regulators, where spending will fall to \$31 billion in 2015 from \$37 billion in 2010.

Source: IMS Health

tical companies are looking at in-sourcing products and entering into more partnering agreements.

Effective Decision-Making

Ms. Kulich says companies are relying on more streamlined models and tools for evaluating global markets.

“They are recognizing that the breadth and magnitude of the forecasts they are creating are quite complex and may be limited globally,” she says.

Ms. Kulich says a key trend is a focus on aggregation, consolidation, access, and reporting.

“Because forecasts are to inform a broader group of users, there is a push toward online forecast management and online access such that the latest forecasts are always available to the broadest set of customers,” she says.

Mr. Fyvie says a good strategy is based on good information in the hands of people with the right experience and intelligence.

“Through that combination of experience, even wisdom, access to quality information is what makes for good decision-making,” he says.

Ms. Kulich agrees, saying the tools are only as accurate as the information used.

“The tools themselves will run the math,” she says. “It is much more important to ensure that there is good information going into the forecast models and that people across the company are comfortable with the information.”

In terms of building credible forecasts, Ms. Kulich recommends consistent approaches that take into account the nuances of varying markets, whether geographic or therapeutic area or the life cycle of the product, where there is a level of consistency that can be used to evaluate opportunities in an apples to apples manner.

“We also recommend transparency so the systems are simple enough to use and the models provide clear sources of information that can be documented and assumptions can be culled out and recognized so that any user of the forecast can understand what has gone into the forecast and where any areas of uncertainty may exist,” she says.

Ms. Kulich says with so much uncertainty in some of the emerging markets, it is important to get cross-functional input from within the organization.

Many pharmaceutical companies, she says, are creating country guidelines that include perspectives on market growth in terms of patients, revenue potential, the healthcare system, and intellectual property considerations.

“There are so many differing sources of information and companies have to develop a consistent point of view across the organization,” she says.

Ms. Kulich says to develop as robust a



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CRAIG WYLIE / PA Consulting

forecast as possible and to understand the dynamics in the various countries, companies should evaluate published medical literature, epidemiology studies that have been conducted in the emerging markets, and government publications. They should also tap into panels of experts to inform their thinking and these should include payer groups, government representatives, opinion leaders, and physicians, as well as referring to analysts reports and what the financial markets are doing. **PV**

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