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The Year of the EXTREME Makeover

Every sector in the industry is in a state of flux.

In this special issue of PharmaVOICE, more than 160 thought leaders throughout the life-sciences industry discuss the changing market dynamics.

According to PricewaterhouseCooper's 14th Annual Global CEO Survey, which looks at the concerns expressed by pharmaceutical and life-sciences company leaders, CEOs are most concerned about competitive threats and industry dyanmics. The survey finds for companies in most industries economic growth forecasts or uncertainty are the primary drivers of changes in strategy.

The more than 160 executives who responded to this Year in Preview issue identified a number of organizational issues, such as innovation, payer models, a growing number of different stakeholders, out-side-the-box partnerships, and outcomes strategies; R&D and pipeline innovation and productivity; outsourcing; regulatory; the Sunshine Act; device-pharma combos; the marketing mix; social media; public relations; market research; publication planning; advertising; patient communities; sales; and global and emerging markets as a few of their hot topics.

These topics and more are explored throughout the print issue and in the exclusive bonus content associated with this special Year in Preview issue, which can be found at pharmavoice.com.

Spending Trends

The IMS Institute for Healthcare Informatics reports that global spending for medicines will reach almost $1.1 trillion by 2015, reflecting a slowing compound annual growth rate 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 United States, 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.

Creating a Culture of Innovation

Pharmaceutical R&D is under pressure to counter rising costs, depleted pipelines, and impending patent expiries. The industry is facing not only a productivity crisis, but also a crisis in innovation. In fact, industry experts say drug research and innovation have already shifted away from pharma.

A recent survey by Quintiles and the Economist Intelligence Unit shows that innovation is key to bringing new, more effective products to market to treat diseases. The research shows that no single model will work for all companies, but that top innovators, which are open to insight from many different sources, generated almost twice as many products and NMEs as other companies in the last three years.

Culture is the primary barrier to improved innovation, the survey found. High costs, complex regulations, and long development time scales also conspire to make innovation difficult.

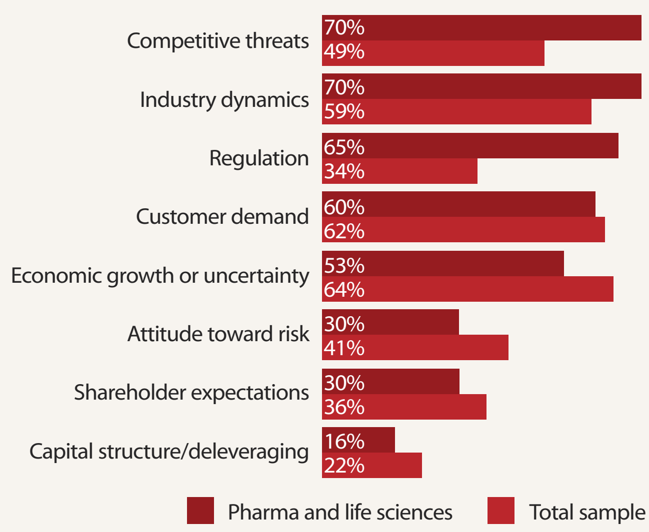
One opportunity is through open partnerships. Open innovation requires a flexible model where innovation comes from both internal and external ideas, where intellectual property is shared as a way to create value.

Experts say the benefits of open innovation for drug development include access to knowledge and talented individuals and high-quality and reliable networks of strategic partners.

At the same time, R&D productivity — the probability of success — has declined. The 2011 edition of the Pharmaceutical R&D Factbook finds that drug success rates continue to show the declining trends of the past decade. There were 55 Phase III drug terminations between 2008 and 2010, more than double the number of terminations between 2005 and 2007; in addition the number of drugs entering Phase III clinical trials fell by 55% in 2010.

This is leading to increases in outsourcing and the development strategic partnerships with CROs and other companies. Attemps to

Factors Driving Change for Pharmaceutical CEOs



* Base: All respondents who stated 'changed in fundamental ways' or 'somewhat changed' at Q2a; Total sample 1,009; Pharma and life sciences, 43

Source: PwC 14th Annual Global CEO Survey decrease clinical trial costs is still a major driver, but increasingly company leaders are seeking partnerships for strategic reasons. These include the ability to access knowledge, talent, technologies, and solutions.

On the regulatory front, experts say companies need a broad, comprehensive, global view of regulatory affairs and have a development strategy that focuses on the needs of multiple stakeholders globally, including regulators, practitioners, consumers, and payers. Globalization is changing the regulatory environment for the pharmaceutical industry. About 80% of the active pharmaceutical ingredients in medications sold in the United States are manufactured elsewhere, according to the FDA. Imports of pharmaceutical products have increased at almost 13% and imports of devices have grown at more than 10%. Between 2007 and 2015, the FDA estimates that imports of all FDA-regulated products will triple, to a 15% growth rate.

As a result, the role of regulatory agencies is changing. In the United States, the FDA is developing plans to address the safety of products on a global basis. In response to increasing globalization, FDA has expanded its capabilities and regulatory authority. The agency has also opened additional offices throughout the world and increased the number of foreign inspections.

Digital Set To Redefine the Commercial Landscape

If there is a common word used among our thought leaders as they predict the future, it would have to be "digital." From innovative ways for sales reps to engage physicians, to social media and patient communities, to better health outcomes for patients, all things digital and technological are moving and shaking the commercial universe.

Forrester Research reports that advertisers will spend almost $77 billion online by 2016, comprising 35% of overall ad spending. But it's not just the spend that will change—strategies will become more about actual engagement with the consumer, building relationships and using consumer feedback to better shape campaigns and messages. Instead of the traditional broadcast messaging, more brands will aim to start a true dialogue with consumers, using their responses to improve processes and identify behaviors that can help add value to the brand.

While scientists gear up for the promise of personalized medicine, marketers will need to align their efforts to more personalized messaging. Our experts say online communication and mobile advertising allow them to bring brands to life by creating a richer brand experience, resulting in stronger relationships with target audiences. Today's new media not only has more potential to reach and mobilize customers, but can do so with laser-like targeting, giving marketers the opportunity to segment like never before.

The increase in smartphone use for both physicians and patients is just one factor that sets the stage for such precise segmenting. According to Manhattan Research, this year alone, 81% of physicians surveyed used a smartphone and 26% of U.S. adults 18 and over have used their mobile phones for health information and tools. Patient communities and empowered patients are being viewed as ripe opportunities for market research, as well as patient recruitment. Companies should be taking advantage of all the information that is available by creating outreach programs that cultivate and activate patient mentors, our experts say.

The hurdle of regulation is still a big player in the equation, but our experts say the industry should move beyond that. Instead of waiting for the FDA, the industry must set its own parameters and get started on creating innovative marketing, customer service, and loyalty programs based on the needs of the customer today and the near future. The rules the industry must abide by are the ground rules of the customer — not the brand or the FDA.

And last but not least, digital is even having an effect on the silos within the organizations. There is no place today for the historic silo-friendly environment of yesterday in the future of digital marketing. This practice can result in a dizzying kaleidoscope of messages, which only confuse the consumer and fragment the brand identity. In today's competitive environment of clutter and cutbacks, every message needs to count. Tactics need to be coordinated and marketers who want to effectively develop a consistent brand message and identity will need to tear down the internal communication barriers.

An Evolution in the Works

We can't predict all the changes that will occur in 2012 and beyond due to ever-growing emergence of myriad market factors in the healthcare space, but one thing is certain, the industry will need to evolve in order to meet the needs of its new technology-savvy consumers. Pharma will not only develop and commercialize drugs, but it will soon be in the business of better health outcomes. Its focus will have to become less product-centric and expand to include patients as well. Through the capture of real time patient data from home and mobile monitoring systems, pharma will become an active stakeholder in managing the health outcomes of its patients. PV

IMS Institute Forecasts Level Spending, Patent Dividends, Novel Therapies

The IMS Institute for Healthcare Informatics predicts that global spending for medicines will reach nearly $1.1 trillion by 2015, reflecting a slowing compound annual growth rate of 3% to 6% over the next five years. Unprecedented dynamics are at play across both developed and pharmerging markets and the report identifies some of those dynamics as the following:

- » Brands accelerate their decline in share of spending. While aging populations in developed markets will continue to drive incremental spending on brands, this will be more than offset by the impact of patent expiries. As a result, spending for branded products in developed markets will remain at the same level in 2015 as in 2010.
- » Unprecedented level of patent expiries brings "patent dividend" to developed markets. Expiring patents for branded products will yield $98 billion in net savings to payers in developed countries through 2015, compared with $54 billion in savings realized in the five years to 2010. Patent expiries will save payers $120 billion by 2015, offset by $22 billion of expected generic spending for these medicines.
- » Novel therapies address unmet patient needs. Recent and upcoming launches of new medicines will bring important new treatment options to extend or improve patients' quality of life.
- » Health policy decisions affect spending in the long term. 2010 policy decisions will affect spending for medications during the next five years. Additionally, rebates and discounts are being applied more extensively by public and private payers, particularly in the United States France, and Germany.
- » Biosimilars evolve rapidly, but adoption will be limited. By 2015, the IMS Institute expects spending on biosimilars to exceed $2 billion annually, or about 1% of total global spending on biologics. New biosimilars are expected to enter the U.S. market by 2014, and European markets will see additional biosimilar molecules introduced during this period.

Source: IMS Institute for Healthcare Informatics.
For more information, visit theimsinstitute.org.