

## » AN INDUSTRY OVERVIEW

## THE YEAR AHEAD

A number of events may occur in 2010 that could have a long-term effect on the pharmaceutical market. These include the **POTENTIAL FOR PASSAGE OF COMPREHENSIVE HEALTHCARE REFORM IN THE UNITED STATES**, as well as **LEGISLATIVE OR REGULATORY ACTIONS IN OTHER COUNTRIES**, and the **TIMING AND EXTENT OF THE GLOBAL ECONOMIC RECOVERY**.

Looking back to the varying changes and pressures the industry has endured, and ahead to how the industry will need to reinvent itself to continue to prosper, companies are adapting to longer-term marketplace trends and evolving patient needs.

The industry is facing pressure from the economic, regulatory, and R&D environments. The industry's movement toward transformation in business models, marketing strategies, and R&D processes is a sign that difficult times are upon us.

According to Rich Fante, president of AstraZeneca US, the business environment is driving the greatest era of change the pharmaceutical industry has ever experienced.

"Transformation must include first-class customer capabilities that deliver services in ways that make sense to our customers now and in the future," he says. "It also requires disciplined internal processes that ensure we are operating efficiently and consistently allocating resources where our business needs them most."

While Mr. Fante may not have been speaking about cost-cutting, there has been a lot of that in the industry, and as the third-quarter results rolled in last month, most companies had improved third-quarter profits as a result of keeping costs down, not through sales.

According to Mark Trudeau, president, US region, executive VP at Bayer HealthCare, cost-cutting measures are not always the wisest choice.

"To improve earnings in the short term, we could cut back on research, but that would not be a sustainable strategy; it would simply be short-sighted," he says. "Our investment in research and development is intended to drive our growth and produce groundbreaking innovations."

This allows the company to safeguard growth as well as jobs and prosperity.

"Success tomorrow demands investment today," he says.

Cutbacks, layoffs, buyouts, mergers, patent expirations, and acquisitions are the challenges that are likely to have major ramifications for the way in which pharma markets and sells the medicines it develops. This special Year in Preview issue covers all of these challenges and how the industry is preparing to tackle them.

## CORPORATE ISSUES

In this era of safety first, pharmaceutical companies have an opportunity to differentiate themselves and positively impact healthcare delivery. Industry experts say new regulations are going to have significant impact on the industry. Earlier this year, the FDA strengthened the required risk minimization and action plans for opioids. While the burden on manufacturers has increased, experts say such classwide regulations also level the playing field and provide opportunities for partnering with other healthcare professionals in the delivery of care.

Additionally, healthcare policymakers and payers are increasingly mandating or influencing what doctors can prescribe, and collaboration will need to enter into the industry's vocabulary. Pharma will need to work much more closely with healthcare payers and providers, and target their messages to a more-influential patient, according to PwC's experts.

Other than cost savings, the industry is facing completely new paradigms in pricing and marketing when the much ballyhooed healthcare reform bill is finalized.

With the battle over healthcare reform still under way, many in the marketing and sales arena are moving forward to prepare for whatever incarnation of the original bill gets passed. E-detailing, physician education, and social media are all marketing and sales buzzwords of the future.

The shift to a more powerful, informed patient and the clout wielded by payers will have profound implications for the industry's sales and marketing models. There will be

fewer sales reps, and they will be more specialized and proficient in both technology and science, focusing more on servicing physicians with the information they need for prescribing, rather than selling a product.

By 2020, the role of the traditional sales representative will be largely obsolete. Moreover, one of the principal tools pharmaceutical companies currently use to get access to doctors — the distribution of free samples — will be irrelevant in most cases, according to PricewaterhouseCoopers' 2020 report on marketing.

## R&amp;D ISSUES

Pharmaceutical research and development is facing many pressures, from decreased productivity to the impact of the economy to changing technology to an increasingly global environment.

Much has been made over the last few years of the industry's decline in R&D productivity. It is true that the number of new drug applications (NDAs) under review at the FDA declined 47% from 1995 through 2007, according to data from Parexel Consulting, but there was a 22% surge in original NDA submissions in 2008.

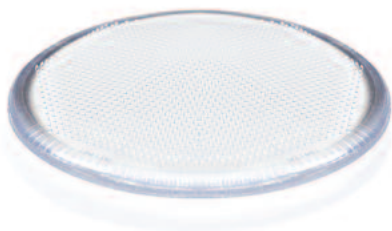
Industry experts consulted by PharmaVOICE find that while obstacles remain for bringing innovative products to market, the industry is adapting and working to address those obstacles.

Additionally, the developing world has been an attractive destination for the clinical development and marketing of new products. These markets are growing in size and in importance for drug developers. Countries outside the traditional markets of the United States, Europe, and Japan are revamping their regulatory and legal systems and reforming their healthcare systems, and they are expected to contribute more to the global pharmaceutical industry.

Companies are seeking these opportunities elsewhere because of the increasing difficulty in



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recruiting patients for clinical trials in the United States and Europe. According to the nonprofit Center for Information & Study on Clinical Research Participation, 80% of clinical trials in the United States are delayed at least one month because of unfulfilled enrolment.

Industry experts tell PharmaVOICE that biotechnology, personalized medicines, RNA expression, and stem cells are a few of the areas where innovations will come from. Researchers say a technology that will have a

tremendous impact on pharmaceutical research in the next five to 10 years is RNA-based therapeutics. RNAi (RNA interference) represents a breakthrough in understanding how genes are turned on and off in cells. If successful, this research has the potential to change the drug discovery process.

Companies are looking for solutions, but industry experts say the answer may lie in the R&D business model, and companies throughout the industry are experimenting

with new models designed to tackle the pipeline productivity challenge.

A report by PwC released earlier this year predicts that by 2020, the old business model — where companies employ a strategy of placing big bets on a few molecules — will no longer meet the market's needs. ♦

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PharmaVOICE welcomes comments about this article. E-mail us at [feedback@pharmavoices.com](mailto:feedback@pharmavoices.com).

## IMS HEALTH — KEY MARKET DYNAMICS

The global pharmaceutical market in 2010 is expected to grow 4% to 6%, exceeding \$825 billion, driven by stronger near-term growth in the U.S. market, according to a recent prediction from IMS Health.

The forecast projects global pharmaceutical market sales to grow at a 4% to 7% compound annual growth rate through 2013 and takes into account the impact of the global macroeconomy, the changing mix of innovative and mature products, and the rising influence of healthcare access and funding on market demand. The global pharmaceutical market value is expected to expand to \$975+ billion by 2013.

IMS also raised its expectations for five-year pharmaceutical market growth by one percentage point, partly due to the stronger demand being experienced in 2009.

Other market dynamics include:

### Growth prospects in the U.S. market improve.

Near-term growth prospects in the United States have strengthened in recent months, reflecting both sustained levels of price increases and changing inventory stocking patterns. Pharmacy chains are more tightly managing their inventory levels based on expectations of patient demand, which has led to greater purchasing volatility than in previous years.

This also has played a role in unusually high sales growth in the first quarter of 2009 relative to forecast expectations. U.S. market growth is now expected to be 4.5% to 5.5% in 2009 and 3% to 5% in 2010.

While payers seek to limit price increases and boost the use of lower-cost generics, pharmaceutical manufacturers are expected to maintain their pricing practices, competing on the basis of

clinical evidence and value. Current pricing practices by the industry also include the use of off-invoice discounts and rebates, which are not reflected in IMS's forecast and reported data, and are understood to be increasing.

### Economic downturn affects markets to varying degrees.

Growth has slowed in countries where there is high out-of-pocket spending on pharmaceuticals and steep declines in macroeconomic activity, especially in Russia, Mexico, and South Korea. At the same time, growth has been less affected to date in countries where drugs are largely funded publicly, such as in Germany, Japan, and Spain. But new cost-containment measures expected to be introduced during the forecast period likely will impact the pace of growth in these markets.

In the United States, pharmaceutical manufacturers' efforts to expand access to and awareness of patient assistance programs, as well as co-pay subsidies for patients in need, are limiting the impact of the economic downturn to some extent.

### Impact of the innovation/patent loss imbalance dampens growth prospects.

Consistent with trends of the past several years, the next five are expected to reflect a significant imbalance between new product introductions and patent losses. This is the primary factor limiting global pharmaceutical market growth to the mid-single digits through 2013. During the next five years, products that currently generate an unprecedented \$137 billion in sales are expected to face generic competition.

At the same time, new products that will enable innovative approaches for treating

patients suffering from diseases such as osteoporosis, respiratory ailments, thrombosis, multiple sclerosis, and cancer are not expected to generate the same magnitude of sales as products losing patent protection.

### Pharmerging markets in aggregate sustain strong growth.

Despite economic conditions significantly affecting some markets — notably Russia, Turkey, South Korea, and Mexico — the seven pharmerging countries are expected in aggregate to grow by 12% to 14% in 2010, and 13% to 16% over the next five years.

China's pharmaceutical market is expected to continue to grow at a more than 20% pace annually and contribute 21% of overall global growth through 2013. Russia and Turkey may be impacted significantly by new measures intended to reduce the level of healthcare spending in those two markets.

### Healthcare access and funding under intensifying pressure.

The economic climate has heightened concerns by payers about healthcare funding and intensified their efforts to limit access to non-generic drugs. During the next five years, markets will be impacted by numerous payer actions, including the imposition of price cuts on existing drugs, the raising of standards required to achieve reimbursement of innovative therapies, and the use of economic incentives for prescribers and pharmacists to drive a shift to generic alternatives.

Evidence of the value that medicines bring to healthcare systems will be required to achieve access and funding in both developed and emerging markets.



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