

» AN INDUSTRY OVERVIEW

THE NEXT WAVE OF CHALLENGES

Pharmaceutical companies already beset by changes to their traditional markets and processes are facing a new set of challenges.

In this special issue of PharmaVOICE, industry leaders take a look at the challenges they expect to face in the coming year and beyond, as well as some of the strategies to deal with these issues.

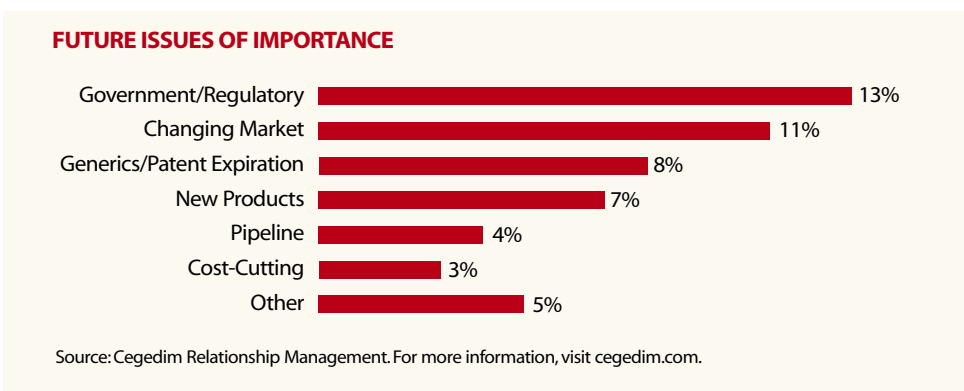
One trend identified by many is the influence of different markets around the world as countries continue to recover at different rates from recent financial crises.

The value of the global pharmaceutical market is expected to grow 5% to 7% in 2011, to \$880 billion, compared with a 4% to 5% pace this year, according to IMS Health. While the overall pharmaceutical market will appear to rebound somewhat in 2011, the underlying constraints to growth in developed markets are stronger than ever. As countries recover from the global economic crisis at different rates, there is growing divergence in the pace of pharmaceutical growth among major markets, IMS Health executives say. The 17 pharmerging countries are forecast to grow at a 15% to 17% rate in 2011, to \$170 billion to \$180 billion. The five major European markets (Germany, France, Italy, Spain, and the U.K.) collectively will grow at a 1% to 3% pace, as will Canada. The United States will remain the single largest pharmaceutical market, with 3% to 5% growth expected next year. Pharmaceutical sales in the United States will reach \$320 billion to \$330 billion, up from \$310 billion forecast for this year.

But IMS Health officials point out that broad measures are being applied by public and private payers to reduce growth in drug budgets. Governments are implementing mechanisms that target drug spending as one way to restore fiscal balance. Multiple markets will be impacted by these measures in 2011.

A NEW ECOSYSTEM

Executives from Ernst & Young say the biggest change that the industry will face is just starting to play itself out: the pharmaceutical industry will soon find itself part of a fun-



damentally different healthcare ecosystem. In fact, new trends, combined with changes already taking place, will transform the industry from one that develops drugs to one that delivers health outcomes.

Ernst & Young executives are calling this Pharma 3.0 where companies will compete and collaborate with those of the current ecosystem — biotech and medtech firms, CROs/CMOs, academic organizations, other pharma companies — but also with entirely new classes of nontraditional entrants, from IT companies to large retailers to nonprofit organizations.

Pharma companies will need to redesign their business models, pay attention to how they fit into others' business models, and partner in creative new ways. Learning how to combine a company's unique assets and attributes into someone else's business model will require pharma firms to develop resources, capabilities, and customer relationships that are largely absent in today's pharmaceutical industry.

Our experts say this will lead to leaner organizations tailored to the needs of local stakeholders, with internal capabilities focused on core strategic capabilities, and greater leverage of partnerships and off-shoring for non-strategic activities.

Already, companies are building partnerships with public and private research entities,

academic institutes, and biotechnology companies, creating a flexible and entrepreneurial approach to research focused on patient needs.

Quintiles executives suggest there will likely be a convergence between clinical development and commercial operations. And our experts say achieving convergence between clinical development and commercial operations requires involvement of commercially oriented employees at a relatively early stage of clinical development. This leads to the establishment of processes that enable critical evaluation of the clinical and market opportunities for products earlier in product development.

Within R&D, experts agree that new ways of working are needed for research and development to continue producing innovative products now and in the future. Life-sciences companies are facing quite a few challenges, including: eroding margins, decreasing R&D productivity, pressure to demonstrate health outcomes and cost-effectiveness, and increased scrutiny over product safety.

Pharmaceutical companies have seen pressures for R&D cost reduction over the past decade. These pressures will continue to increase and intensify as products come off patent in the next several years and the need for differentiated products becomes critical to payers. Comparative effectiveness and the real-

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world evidence of outcomes and the decreasing productivity of R&D and the need to develop and produce innovative medicine take center stage as companies look to address the efficiency and productivity of their efforts and bring innovation back to the pipeline.

A CONSERVATIVE REGULATORY ENVIRONMENT

At the same time, companies are facing a more conservative regulatory environment. The FDA — as well as agencies around the world — is raising the bar on new drug approvals, especially where safety is a concern. Experts say pharma has the opportunity to be proactive in response to increased pressures from the public and other stakeholders to demonstrate greater transparency in the handling of safety issues.

In the marketing arena, companies will face

the same longstanding challenges — with a new twist — in the coming years. Patients, ROI, and an evolving landscape are the factors that have been on the minds of marketers for years, but today success will lie in new solutions and approaches through innovative technology and adaptive strategies.

Our experts tell us that the industry is moving back to its roots as it puts the patient front and center in its focus — and this is true in marketing as well as in science. To meet the needs of the ever-savvy consumer, marketing strategies, messages, and channels will need to change to fit the needs of the patient.

A NEW COMMERCIAL LANDSCAPE

As the industry adjusts to patent expirations, changing customer demands, and a challenging payer landscape, commercial sales

models will continue to evolve and sales forces will undoubtedly go through significant changes in the next five years. Of all the factors that will influence how sales reps perform their jobs tomorrow, our experts have outlined training, specialty roles, and social media as the top three that will most influence the size, strategies, and success of sales forces in the future.

As companies have expanded the definition of the field force beyond the sales representative to include a broader team of resources with specific expertise who can engage in different discussions with the customer compared with that of a traditional sales representative, the customer engagement model has gotten more complex. ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoiced.com.

IMS HEALTH FORECASTS

- Peak years of patent expirations shift major therapies to generic dominance. In 2011, products with sales of more than \$30 billion are expected to face the prospect of generic competition in the major developed markets. In the U.S. alone, Lipitor, Plavix, Zyprexa, and Levaquin, which together accounted for more than 93 million prescriptions dispensed in the past 12 months and generated over \$17 billion in total sales, likely will lose market exclusivity. The full impact of patients shifting to lower-cost generic alternatives for these products, as well as other brands in their therapy classes, mostly will be felt in 2012, due to the timing and expected competitive intensity among generic entrants.
- Broad measures applied by public and

private payers to reduce growth in drug budgets. Governments are pursuing an ongoing wave of budgetary control mechanisms that target drug spending as one way to restore fiscal balance. Multiple markets will be impacted by these measures in 2011. Prominent examples include substantial reductions in the price of generics relative to their branded counterparts in Spain and in Canada, where generic pharmacy rebates are expected to be eliminated; new price negotiation requirements for brands launched in Germany; and across-the-board price cuts for branded products in Turkey and Greece. In the United States, health plans are stepping up their use of pre-authorizations and cost-sharing provisions in an effort to address rising healthcare expenditures.

- Therapy area growth dynamics driven by innovation cycle and areas of unmet need. In 2011, the introduction and uptake of new drugs — a third of which are specialty pharmaceutical products — are poised to fulfill patients' unmet needs and significantly alter treatment paradigms in several key therapy areas. These include innovative treatment options for stroke prevention, melanoma, multiple sclerosis, breast cancer, and hepatitis C. As these new drugs are brought to market, patient access is expected to expand and funding redirected from other areas where lower-cost generics are available. Five potential blockbuster products — defined as those exceeding \$1 billion annually in peak sales — are expected to be approved and launched globally by the end of next year.

Source: IMS Health. For more information, visit imshealth.com.

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*Case Management Society of America. June 2006. Case Management Adherence Guidelines.

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