

▶ GLOBALIZATION

Risks and REWARDS

THE GLOBAL LANDSCAPE IS CHANGING. Countries once thought of as secondary or tertiary markets are providing opportunities for not only pharmaceutical companies but for their contract research and marketing partners as well.

IMS's 2009 Pharmaceutical Market Forecast reports that growth rates will level out and hold steady with 2008 levels. The global market is expected to total more than \$820 billion in 2008, a growth rate of 4.5% to 5.5%. Further, IMS analysts predict that market forces that have been gaining momentum for the past few years — among them, the shift in growth from developed countries to emerging ones, specialist-driven and niche products playing a larger role, blockbuster drugs losing patent protection, and the rising influence of regulators and payers on healthcare decisions — will play out in full during 2009. Layered on top is the uncertainty in the global economic environment and its effect on demand. These same analysts note, however, that the global pharmaceutical market reflects a new reality for

manufacturers while still providing opportunities for profitable growth.

IMS predicts that a number of events that are likely to occur in 2009 could have a long-term impact on the pharmaceutical market. These include the uptake of biosimilars in human growth hormones and erythropoietins in Europe, the adoption of generics in Japan, the use of contracting strategies across the European Union, the deregulation of the pharmacy sector in Europe, and significant U.S. healthcare policy changes as the new administration takes office.

“As globalization in the life-sciences industry continues, we expect that there will be an increased level of cross-border M&A, licensing, and divestitures, as companies aggressively move into emerging markets, such as India,” says Terry Hisey, vice chairman and U.S. life sci-

ences leader, at Deloitte. “While market entry strategies will continue to vary, we expect companies to enter new markets through partnerships, as well as on their own.”

NEW OPPORTUNITIES

The “pharmerging” markets of China, Brazil, India, South Korea, Mexico, Turkey, and Russia, taken together, will experience the most robust growth in the coming year, according to IMS Health. IMS forecasts that these markets will grow at a rate of 14% to 15%, reaching \$105 billion to \$115 billion. Growth, they say, will be buoyed by increased government spending on healthcare, improved access to medicines, and broader public and private healthcare funding.

“Any markets outside of the United States or

EXPERTS

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There are three key challenges for companies involved in a global environment: global vision, local adaptation, and global teamwork.

European Union will have a big impact on the pharma industry in the coming year and years,” says William Abajian, senior executive advisor, global strategic alliances and business development, at Generex Biotechnology Corp. “Emerging markets are much more entrepreneurial than the traditional leading markets.”

The markets of India and China are attracting the most attention from not only manufacturers but CROs as well.

Analysts at PricewaterhouseCoopers (PWC) last year estimated that pharmaceutical sales in China would more than double by 2010 to \$28.3 billion and by the mid-21st century they are fore-

cast to outstrip sales in every other region. Experts recognize that there are certainly challenges to working in China, but the country has made great progress recently. For example, to date China remains the only country in the world with government-accredited investigators. PWC analysts believe that when China’s regulatory timelines match those of the rest of Asia then the “sleeping giant” of drug development will really take off.

Ross Horsburgh, MBChB, VP, global clinical development – Asia/Pacific, Kendle, says while India has been the star for his company of late, Asia-Pacific will continue to grow in importance.

“Without a doubt, the single biggest global opportunity is the China market,” he says. “China has become a must-win market for global biopharmaceutical companies, therefore making China a must-win market for CROs as well.”

Prabir Basu, Ph.D., executive director of the National Institute for Pharmaceutical Technology and Education (NIPTE), also believes China and India hold the biggest growth potential for the pharma industry in the next few years.

“Only a small percentage of the population in India and China avail themselves of the modern therapies, and as such the potential for sales is also enormous,” Dr. Basu says. “While the pharma industry already is involved in sourcing products for the West from these two countries, pharmaceutical companies will need to make a decision about whether they want to participate



in a bigger way in the domestic markets of these two countries.”

Roger Williams, M.D., executive VP and CEO, U.S. Pharmacopeial Convention, agrees that there will be continued substantial growth in the Indian and Chinese pharmaceutical markets.

“India already is producing hundreds of generic drugs that are sold in the United States and is poised for further growth,” Dr. Williams

KEY DYNAMICS SHAPING THE GLOBAL MARKET

- Robust, double-digit growth in pharmerging markets
- Increased focus on specialty-driven therapies
- Leveling of U.S. growth at 1% to 2%
- Worldwide economic volatility

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

Deloitte provides audit, consulting, financial advisory, risk management, and tax services to selected clients. For more information, visit deloitte.com.

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Dr. Dale Evans *Omnicare Clinical Research* ▶

There will continue to be interest in nontraditional markets, such as Latin America, Central/Eastern Europe, and the Asia-Pacific region, with Africa and the Middle East potentially representing the next great areas for development.



says. “China is a world leader in the production of active pharmaceutical ingredients (APIs). It is estimated that at least three-quarters of worldwide APIs are produced by China or India. China will want to market finished generic products in the United States and elsewhere sooner rather than later, as India already is doing.”

Mr. Hisey advises that as companies enter emerging markets, it will be critical to address the issue of APIs and the supply chain to protect the product’s integrity and quality as the problem of counterfeiting will continue to pervade these markets.

On the research side of the equation, according to Mark Goldberg, M.D., chief operating officer, Parexel International, the Asia-Pacific region is attractive for clinical development because of its large patient population, cost-effective environment, and medical infrastructure, as well as the FDA’s acceptance of clinical data quality from the region.

“The Asia-Pacific region has the fastest-growing pharmaceutical markets in the world and China in particular is expected to become the sixth-largest pharmaceutical market by 2010,” Dr. Goldberg says. “Increasing GDP and purchasing power of countries in the Asia-Pacific region are making these important future markets for the global biopharmaceutical industry.”

Dr. Horsburgh agrees that the Asia-Pacific region will almost certainly have the largest impact on the pharma industry in the near future.

“The region offers better trial delivery efficiency through faster recruitment and access to treatment-naïve patients at attractive costs,” Dr. Horsburgh says. “CROs must offer a substantial presence in this region to be a credible partner on the world stage with biopharmaceutical companies. There are two absolute essentials for successful trials: patients and attitude. With roughly half of the world’s population living in the Asia-Pacific region, the sheer number of potential patients is attractive. China and India alone account for almost 2.5 billion people. Patients and investigators alike have wonderfully enthusiastic attitudes toward clinical development.”

In addition to the Asia-Pacific region, Dale Evans, Ph.D., president and CEO of Omnicare

Clinical Research, believes there will be continued interest in nontraditional markets, such as Latin America, Central and Eastern Europe, with Africa and the Middle East potentially representing the next great areas for development.

“We also see a growing pharmaceutical market in Brazil, a leading economy in Latin America, which is one of the reasons that USP chose to open its third international office and laboratory in the country this past summer,” Dr. Williams says. “In Brazil, as well as in its neighboring countries, the pharmaceutical industry is beginning to adhere to more international standards.”

While the United States remains the dominant market, it will be impacted by a slowdown, according to IMS, which translates into a growth rate of 1% to 2% in 2009 because of mounting patent expiries, a weakening economy, and reduced contribution from new products.

“The United States, once the premier market, has lost considerable ground globally for a variety of economic, political, cultural, and business reasons,” says Richard Minoff, president and CEO at Dorland Global Corp. “At best it will hold ground given economic pressures, likely increased government pricing intervention, and the huge impact caused by patent expiry. At the same time, emerging markets in Central and Eastern Europe, the Middle East, and particularly China, offer tremendous financial and societal opportunities, as the industry learns to better tap into these huge markets given the great strides in patient access and reimbursement that are already changing healthcare professional relationships and their patients’ lives.”

Various market factors mean it is unlikely that the United States will be able to afford to support basic discovery and drug development, says Nicholas Landekic, president and CEO, PolyMedix.

“For many years the ability of companies to charge high prices and generate significant sales in most therapeutic areas in the United States has long supported the discovery and development of drugs for the rest of the world, but with economic conditions continuing to tighten, this is becoming less so,” Mr. Landekic says.

▲ **William Bertrand** *MedImmune*

Varying cultural approaches for risk are being minimized because of the continued financial pressures on the industry.

More scrutiny of drug prices in the United States means there will be more and more pressure on companies to demonstrate authentic value, particularly in light of the other pressures on government expenditures driven by financial market deleverage, says Clive Meanwell, M.D., Ph.D., chairman and CEO of The Medicines Company.

“A positive response from pharma companies and PhRMA — going beyond the usual rhetoric of ‘R&D costs too much therefore prices need to be high’ — will be pivotal to the future of the industry,” Dr. Meanwell says. “Similar, but perhaps less dramatic, pressures may be observed in Europe. The current fascination with the BRIC nations (Brazil, Russia, India, and China) will be maintained, but the ultimate market size may be limited by the value-cost equation and availability of public and private funding for health during global deleverage, valuation deflation, and GDP recession.”

GLOBAL CHALLENGES

Leyla Feyzioğlu, president of Rekmar Brand Innovation, identifies three key challenges for all companies involved in a global operating environment: global vision, local adaptation, and global teamwork.

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◀ **Dr. Prabir Basu** *NIPTE*

Only a small percentage of the population in India and China avail themselves of modern therapies, and as such the potential for sales is enormous.



◀ **Dr. Ross Horsburgh** *Kendle*

With roughly half of the world's population living in the Asia-Pacific region, the sheer number of potential patients is attractive. China and India alone account for almost 2.5 billion people.



◀ **William Abajian**
Generex Biotechnology

Emerging markets are much more entrepreneurial than the traditional leading markets.

strong messages and customer insights, which will be useful in driving brand development and growth in each of the key markets — without getting diluted by local execution — is vital," she says. "Equally critical to global success is executing the global brand vision to a local market without losing the essence of the brand and hitting the local objectives consistently. Finally, neither of the previous goals can be accomplished without identifying win-win processes and solutions for all stakeholders in a global project."

Mark Perlotto, executive VP, managing director, at Adair Greene-McCann, says staying connected locally is a component of a successful global strategy.

"While globalization is an ever-increasing reality, homogenization is not," he says. "Understanding the particulars of local customs, attitudes, regulations, reimbursement, and so on are critical. Though the product may be available on the global market, what works in St. Louis, Mo., is not likely to work in the same manner or possibly not at all in St. Petersburg, Russia."

Adaptation is key, Mr. Perlotto says. In other words, taking what works in one place and figuring out how to adapt it to a different market provides the framework for a successful global strategy.

"Social networking sites are a great example," he says. "MySpace was built primarily to target a U.S. teen audience. The strategy at Facebook was to target an older, college-aged audience with a

focus on Europe, a strategy that is paying off based on faster growth there than MySpace."

Mr. Minoff believes U.S.-based organizations have more challenges to overcome in a global environment than their European counterparts.

"First, Americans often don't understand the significant cultural and working environmental issues; second, we need to learn how to deal with much less straightforward regulatory, reimbursement, and distribution systems; and third, we need to learn how to drive multistakeholder connectivity in a more diverse environment," he says.

Dr. Horsburgh says another challenge for U.S.-based companies working in a global environment is to overcome the "we know best" mindset.

"I have often witnessed companies adopt this bias when entering Asia and other markets around the world," he says. "Companies locked into this mindset fail to leverage the local approaches to working, which can be overcome by embracing the culture and learning to work through local customs. Asia, in particular, places a high value on culture and tradition, so on-the-ground experience and local expertise are critical. I'm convinced that success in this region is based upon leveraging the operating capabilities of local managers as much as possible."

Mr. Abajian, however, takes the view that there are few challenges to working in the global environment; rather, there are opportunities for smaller-sized companies.

"The global marketplace is a potential gold

mine," Mr. Abajian says "When I go into emerging countries that are undervalued in the eyes of the United States, Canada, or Europe, I find that people are very hungry to have access to drugs that work. Before the major pharma companies went into some areas, Generex approached the emerging markets, and we now have established partnerships for manufacturing or importation and distribution in China, Hong Kong, Indonesia, South Korea, the Philippines, Thailand, Vietnam, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Jordan, Egypt, Morocco, and South Africa, to name a few."

As attractive as the opportunities are, Dr. Basu says some of the biggest challenges to working in a global environment are ensuring safety of the drugs and drug components manufactured in countries such as India and China and the adverse effect of locating manufacturing far away from discovery.

"Countries in the Asia-Pacific region are evolving in their regulatory culture and experience just as the United States has over the past 100 years," Dr. Basu says. "It is too much to expect that these countries will equal or better the U.S. standards needed to ensure safety of our patients overnight. In the interim, the burden falls on U.S. taxpayers to fund the FDA so it has enough resources to inspect and regulate the foreign manufacturing sites."

To take advantage of global-development opportunities, biopharmaceutical companies should partner with service providers that have well-established local capabilities and expert resources, experience working with regulatory authorities throughout the world, and a history of conducting ICH-GCP clinical studies in a wide array of geographies, Dr. Goldberg says.

"It is also essential to have access to a network of qualified investigators and familiarity with the myriad regulatory and operational differences for conducting clinical studies in various countries," he adds.



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The reality is that a global manufacturing environment translates to longer, more complex supply chains that make it increasingly difficult to trace pharmaceutical and food ingredients and assure their quality.

THE GLOBAL COST OF DOING BUSINESS

According to the World Health Organization (WHO), it is predicted that the four leading causes of death in the world in 2030 will be ischemic heart disease, cerebrovascular disease (stroke), chronic obstructive pulmonary disease (COPD), and lower respiratory infections (mainly pneumonia). Much of the increase in COPD is associated with projected increases in tobacco use. Deaths due to HIV/AIDS are projected to fall by 2030, yet the disease will remain the 10th leading cause of death worldwide.

Dr. Meanwell points to the shift in patient burden and resources as reflected by the WHO's 2030 predictions and notes that at least three times as many patients who suffer these events will survive.

"A large proportion of survivors and non-survivors will be treated in acute-care hospitals where cost-minimization strategies will be the order of the day," he says. "Despite shifting demands, improving communications technologies, generational changes, and a necessary commitment to the globalization of markets, genuine global human experience is lacking in the industry and many professionals, especially in the United States, remain skeptical or even fearful of reaching for experience in other countries."

Costs are not limited to adapting to changes in the way patients are treated; they also encompass pricing issues and resource allocation.

Mr. Landekic says as global borders begin to break down, the old days of major price disparities among the different markets will recede.

"Pricing will likely converge on the lowest common denominator, the lowest-price market," he says. "The challenge will be to obtain and justify attractive pricing under increasingly difficult conditions."

Nagaraja Srivatsan, VP and head of North America, life sciences, at Cognizant, agrees that one of the biggest challenges to working in a global environment includes managing the pressure to reduce costs and do more with less, as well as managing a diversified set of targets.

"We expect to see new development models and capabilities from overseas," Mr. Hisey says. "A number of major companies are pursuing aggressive cost-restructuring programs in an effort to move from highly fixed to more vari-



able cost structures. This will allow them to maintain an improved earnings performance while dealing with sluggish pipelines."

Mr. Srivatsan contends that today's emphasis on cost reduction, improved operational efficiencies, and productivity is pushing global life-sciences companies to transform.

"First, it is important that pharma companies first define what their core competencies are," he says. "This will enable them to identify and build each process operation as best-in-class; build a pervasive information architecture to help make better decisions; and reduce cost and hasten time to market."

William Bertrand, J.D., executive VP, legal affairs, general counsel, and corporate compliance officer at MedImmune, believes that the financial pressures on the industry have implications beyond price, and indeed may be limiting the appetite for what is considered acceptable risk.

"If we are not careful, I worry that as biotech companies are subsumed into the big pharma arena, coupled with the current financial crush on the industry, the globalization of the industry could negatively impact the level of innovation," he says. "As the large companies acquire biotech, we need to work hard to preserve the innovation and entrepreneurial culture that is found in the acquired companies."

GLOBAL OPPORTUNITIES

IMS Health experts outline several opportunities for pharmaceutical companies to grow. They believe there are several ways in which pharmaceutical companies can be successful. These include: focusing on the "pharmerging" markets; developing specialist-driven products and biologics; uncovering pockets of unmet need and under-utilization in primary care markets; demonstrating the superior value of their medicines; and re-invigorating their established brands.

Other industry experts have identified additional opportunities, including harmonization.

"Of great interest to me personally, and the

**Richard Minoff** Dorland

There is a huge world out there and a quicker shift in marketing will occur as soon as the industry realizes that some countries that once led the way will not in the future. Others that were once seen as inconsequential, secondary, or tertiary targets are now rising stars.

biggest global opportunity in my opinion, is the international harmonization of quality standards for pharmaceuticals," Dr. Williams says.

Efforts to harmonize standards for drugs started in 1989, when the Pharmacopoeial Discussion Group (PDG) was formed. This group consists of the European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and USP and meets twice a year to work on pharmacopoeial harmonization topics. In May 2001, PDG welcomed the WHO as an observer.

"With the global scale of the pharmaceutical industry, the goal of harmonizing testing requirements used to help assure the safety of pharmaceutical products is extremely important," Dr. Williams says.

Because testing requirements vary from country to country, assuring the quality, purity, and strength of pharmaceutical products often results in duplicative testing, which wastes

resources and — most problematic to patients — delays market access to drugs treating or easing the symptoms of a wide range of diseases and conditions.

“Even with the current efforts of the PDG, I think there are still more opportunities to grow harmonization activities with more harmonized drug products and general chapters and more countries participating,” Dr. Williams says. “Harmonized standards are also extremely important in the cases of international crises involving drug quality, such as the recent incident of heparin adulteration. The risk of similar events occurring is all too real — and harmonized standards make shortages of critical drugs, such as heparin, less likely.”

Dr. Evans concurs that the lack of global harmonization is a challenge to be overcome, as are language barriers and cultural differences.

“These are challenges that can be turned into opportunities when the right people and the right expertise to develop successful solutions are in place,” he says.

Dr. Evans says with patient safety now in the spotlight, not only in the clinical development arena but with ongoing product surveillance on marketed products, there is an opportunity to



◀ Nagaraja Srivatsan Cognizant

Today’s emphasis on cost reduction, improved operational efficiencies, and productivity is pushing global life-sciences companies to transform.

diverse and astute leaders who can operate in non-Western style countries.

“There is a huge world out there, and the sooner the pharma industry recognizes those changes, the better,” Mr. Minoff says. “For example, some countries that once led the way — such as the United Kingdom, which is now heavily impacted by NICE — will not in the future, and others that were once viewed as inconsequential secondary or tertiary targets, such as Turkey, are now rising stars.” ♦

realign the core sentiment that biopharmaceutical products ought to provide benefit over risk.

“Gleaning and communicating data signals from a global process would ensure an urgent concern is processed effectively and immediately,” Dr. Evans says.

Mr. Minoff recognizes that change is afoot. To achieve success moving forward in the still-developing global village, companies will have to recraft their senior-level executive and global marketing teams into much more culturally

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