### >>> GLOBAL TRENDS

# A GLOBALLY FOCUSED

## **INDUSTRY**

Emerging countries will continue to play a vital role in the pharmaceutical industry.

here will be an overall shift in the pharmaceutical industry from a very Western-centric model to a global one. Disease areas that were once considered niche are now given priority and the more prevalent disease therapeutic areas in the mature markets have taken a backseat. Vaccines, biologics, over-the-counter (OTC) products, and generics are the principal revenue generators in the emerging markets, say experts from Frost & Sullivan.

While some experts say the United States and Europe continue to hold the greatest opportunities for research and development, there is increasing innovation from India and China that will also generate opportunity. These areas are expanding rapidly — China is predicted to become the third largest pharma market next year — and will drive new opportunities for many years to come. Frost & Sullivan experts say the Asia-Pacific area suffered a recession similar to the United States and Europe, but recovered significantly faster than its western counterparts.

John Vann, executive VP, corporate development, at Chiltern, says Asia-Pacific will be the most influential market in the global pharmaceutical industry.

"This is based on performance across so many industries; countries in the region are attuned and responsive to the opportunities," he says. "This influence will serve to strengthen competition, which I predict will be healthy for the industry globally."

Ken Kramer, Ph.D., senior VP, medical director, Alpha & Omega Worldwide, part of The Core Nation, points to a recent report from IMS that predicts the global pharmaceutical market should grow between 5% and 7% in 2011 to \$880 billion, up 4% to 5%. Almost 6% of that increase, about \$50 billion, will be driven by robust growth in emerging markets such as China, which is expected to grow between 25% and 27%.

China has been working to improve its healthcare system through incremental changes implemented over the past decade. The push for major change in the system, however, began in 2005, prompted by a State Council report that found great disparity in access to care throughout the country. The dramatic moves China took in 2008

demonstrate a commitment to providing and distributing healthcare resources more equitably, efficiently, and effectively. By 2011, an additional 900 million Chinese will enjoy a basic level of healthcare compared with 2004 coverage level.

China continues to be a tier unto itself and is expected to drive \$40 billion in market growth by 2013, says Jay Bolling, CEO and president of Roska Healthcare.

"That said, each market carries its own challenges," he says. "The successful pharmaceutical company will be able to align its existing products with those high growth opportunities."

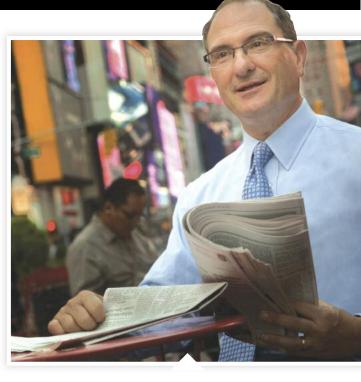
But, Frost analysts say, weak intellectual property (IP) laws, escalating drug costs, and low reimbursement rates for drugs still plague the current healthcare system in China.

"The globalization of clinical studies has been driven by several factors, including the need to access larger patient populations for the larger trials and the need to reduce the expense of conducting those trials," says Mark Goldberg, M.D., chief operating officer, Parexel International.

#### MARKET DRIVERS

Healthcare reform programs in emerging markets have dramatically improved the level of healthcare coverage in these countries.

"Now that the big seven countries in the



#### **Nick Colucci**

Publicis Healthcare Communications Group "Unlike other emerging markets, China has encouraged higher Western-level prices on many new patent-protected drugs, fostering technology transfer and strengthening long-term domestic producers."

#### **GLOBAL TRENDS**

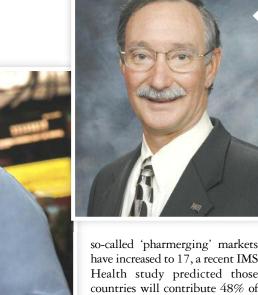
#### **Global Market Drivers**

- Increased use of specialty pharmaceutical products
- Expansion of emerging country markets
- Biopharmaceutical expansion and blockbuster revenue performance
- Population factors: age shift, better understanding of patient subsets

#### **Global Market Restraints**

- Intense competition from generics
- Maturation of developed countries to slow/low growth at the macro level
- Biosimilar emergence on the global stage
- Increased scrutiny and impact from payers and health technology economic assessments

Source: Frost & Sullivan. For more information, visit frost.com.



have increased to 17, a recent IMS Health study predicted those countries will contribute 48% of annual market growth in 2013, up from 37% last year," Mr. Bolling says. "The most significant growth will most likely be in the therapeutic areas such as cardiovascular where sales in the developed markets have reached a plateau."

Phil Deschamps, president and CEO of GSW Worldwide, says China certainly holds the lead position as the highest potential emerging market.

"Presently this market is made up of locally made generic products and internationally manufactured 'branded' generics," he says. "Over the next five years, the government seems to be committed to moving on intellectual property rights to help the industry develop in the latter half of that time period. By then, pricing pressure will start to rise but the non-generic market should begin to take hold, which will create tremendous growth as medicine becomes available to an ever broadening middle class."

Unlike other emerging markets, China has encouraged higher Western-level prices on many new patent-protected drugs, fostering technology transfer and strengthening longterm domestic producers, says Nick Colucci, president and CEO of Publicis Healthcare Communications Group (PHCG).

"In India, a number of recent developments have helped foreign drug investors, including the establishment of intellectual property rights (IPR), a rising middle class, emerging rural markets, and improvements in medical infrastructure," he says.

#### THE BRIC-PLUS MARKETS

Experts from IBM Institute for Business

#### Dr. Robert McNally

"In the global pharmaceutical industry, there is great potential in the developing world where there are many unmet medical needs."



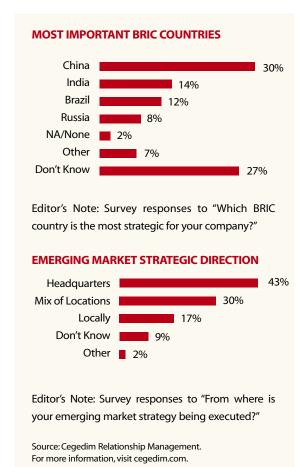
John Vann Chiltern "Based on performance across so many industries, countries in Asia-Pacific are attuned and responsive to the opportunities."

Value say because of the rapid development of the Chinese pharmaceutical market, both local and multinational pharmaceutical companies have made efforts to expand their presence in the market, which has lead to increasing competition. Pharmaceutical companies in China are facing challenges in four main areas:

- · Sales complexity: Diversified procurement models in different regions magnify the complexities of sales and market access.
- Increased challenges to growth: Steep competition and higher regulations on drug manufacturing and management make it more difficult to increase market share.
- · Downward pressure on pricing: Pressures on retail pricing and reforms to procurement processes will result in margin erosion.
- · Development of new markets: Healthcare reform will lead to new opportunities in rural markets.

IMS experts say companies wishing to serve the Chinese population will need to understand how the incidence of disease varies by rural area, how to reach out to the tens of thousands of village clinics and township health centers, and how to choose the best commercial model to engage with the various stakeholders in the system.

Branded generics, which have a strong position in the Chinese market, are apt to thrive in the newly opened community health centers and rural markets. Multinational players are already seizing the opportunity to enter the branded generics business, which is largely controlled by domestic marketers.





#### Dr. Mark Goldberg

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#### Phil Deschamps GSW Worldwide "Since most of the worldwide

"Since most of the worldwide growth is going to come from major manufacturers, the U.S. base of business is going to influence how the other markets around the world grow."

#### **Sound Bites From The Field**



#### JOHN BLAKELEY is Executive VP, ERT, a global provider of technology and services to the pharmaceutical, biotechnology, and

medical-device industries. For more information, visit ert.com.

Include the most important and influential future markets. They are both largely underdeveloped markets, and I believe the whole life-sciences R&D industry will be looking toward these countries both in terms of drug development and sales.

COPD in China, for example, is already the single largest market in the world, and the level of diagnosed patients is low compared with the population. Going forward both China and India will continue to be very important.



#### MARK GIANFORCARO is

Chief Marketing Officer, i3, a global pharmaceutical services company that provides integrated strategies and solutions throughout the product lifecycle. For more information, visit i3global.com.

By 2020, China is targeting an investment of 2.5% of GDP into pharma R&D, putting it into the range of the United States in terms of R&D spending. Increasingly, disease patterns and prevalence in China resemble those in the West.

**ANDRIN OSWALD** is Head of Novartis Vaccines and Diagnostics, a division of Novartis, focused on the development of preventive treatments. For more information, visit novartisvaccines.com.

In emerging markets where vaccination rates are still low compared with the United States or Europe, we are seeing a rapid increase in demand. This is not surprising given that more than 80% of all babies are born in these regions. And parents, as well as governments, who can afford it want to protect their children.

From a regulatory point of view, as in other industries, we see the growing influence of China, a country that is less and less willing to accept the existing standards from the West.

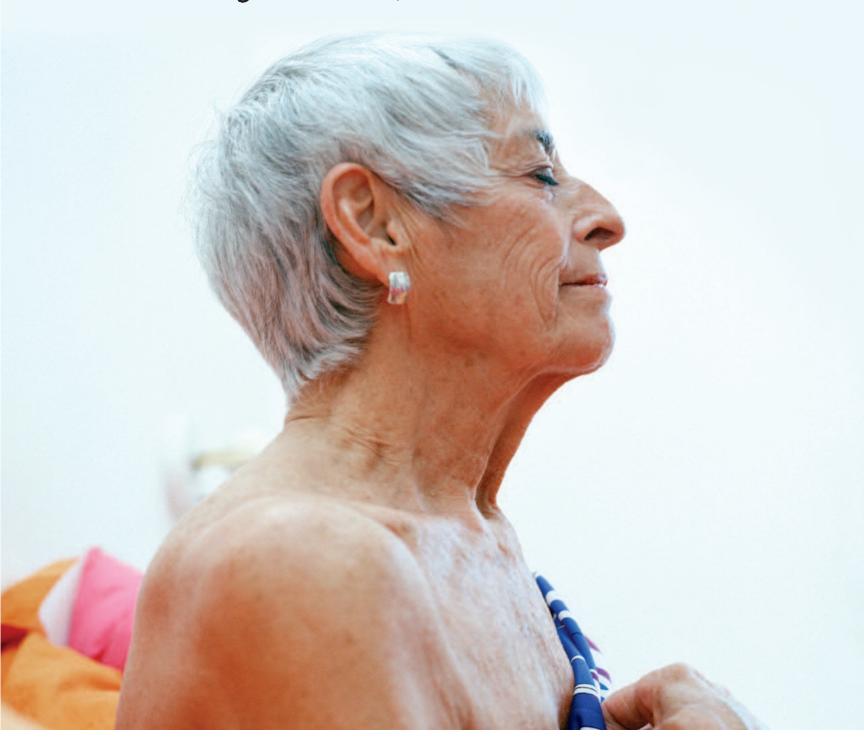
But we also see new markets that are not

limited to geographical boundaries, but are following global trends. Two important examples are increasing demand for travel vaccines and vaccines for the elderly.

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India and China hold the largest promise in terms of R&D for the following reasons: they have large pools of patients who can be signed on for a lifelong protocol; they are extending their leverage from current clinical data management and CRO outsourcing capabilities to clinical research BPO; biosimilars and generics are already a core competency in these markets; and fully integrated pharmaceutical networks are being created to launch a new interface with researchers across the world, especially to leverage research talent out of India and China to focus on several disease areas.

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#### 2011 YEAR IN PREVIEW

In general, off-patent drugs will be under pricing pressure, and those on the essential drug list (EDL) will be hardest hit as the government works to limit or remove profit margins along the supply chain. The tradeoff, though, will come with the increased volume that accompanies a spot on the EDL, IMS executives say.

Max Jackson, CEO, EMEA and APAC, Sudler & Hennessey, says China's current market potential offered by a large population needs to be tempered by the ability to pay for innovative medicines, reducing the actual market potential from just over a billion people to between 80 million and 100 million.

"But the growth rate and speed of change in the market are unmatched globally," he says. "Beyond the domestic market, the continued relocation of regional headquarters to Shanghai will only increase the significance of China. BRIC markets continue to show the greatest sales opportunities, purely from a scale and market opportunity perspective. But the potential of other markets, such as Turkey and certain Middle Eastern markets, should not be ignored. Many companies are taking a BRIC-plus approach to cover this potential."

Dr. Kramer says Africa and South America will be responsible for significant growth in the global vaccines market.

"In the past decade, new vaccines for human papillomavirus, meningococcal meningitis, pertussis, and rotavirus have been approved," he says. "These vaccines are now making their way to underserved regions of the globe. The uptake of these vaccines will be responsible for a significant portion of worldwide pharmaceutical sales over the next five years."

#### Max Jackson

Sudler & Hennessev

"Without a doubt China will be the most influential market in the next few years; the growth rate and speed of change in that market are unmatched globally."

Other experts agree on the potential of the African market, especially for unmet medical needs.

"There is great potential in the developing world where there are many unmet medical needs," says Robert McNally, Ph.D., president and CEO of GeoVax Inc. "This applies very specifically in the HIV and AIDS vaccine market, where there is a desperate need for help in the developing world, especially in India and sub-Saharan Africa. Clearly, for the number of people at risk and/or infected with HIV, two-thirds of HIV vaccine product would be used in sub-Saharan Africa."

When considering an emerging market, decisions should not be driven exclusively by market attractiveness, Mr. Colucci says.

"Jordan, while less attractive because of prescription spending, is the most politically stable, with a highly educated medical profession and high acceptance of pharma messages," he says. "It may just be the springboard for expanding sales within the Middle East." •

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