BY ROBIN ROBINSON

Global OPPORTUNITIES

THE PHARMACEUTICAL INDUSTRY IS BEGINNING TO EXPLORE AREAS OUTSIDE THE BRIC COUNTRIES OF BRAZIL, RUSSIA, INDIA, AND CHINA FOR INVESTMENT OPPORTUNITIES. Looking beyond these borders at new emerging market opportunities comes down to assessing regulatory risk, product access, infrastructure, political climate, and patient populations. This month's forum discusses the opportunities, challenges, and trends of the emerging markets.

According to Ernst & Young, the sheer volume and growing economic muscle of consumers in emerging markets provide powerful investment incentives for multinational companies (MNCs). In particular, current and projected growth rates for pharmaceutical markets in the BRIC countries and Mexico exceed those in the more mature markets in the United States, Europe, and Japan. While the latter markets represent a significantly higher proportion of global pharmaceutical sales, industry executives are honing their strategies to dominate the higher-growth emerging markets.

IMS has identified what it calls "pharmerging" countries, being China, Brazil, Mexico, South Korea, Turkey, India, and Russia. Among the leading 15 markets from 2008 forward, these countries are predicted to have a higher compound annual growth rate between 2006 and 2011, a transitional disease profile, growing access to medicines, and expanding public health programs.

According to IMS, pharmerging markets, which are expected to have market growth of 12% to 13% in 2008, are striving to broaden access to healthcare schemes; developing primary care in rural areas; providing greater access to medicines, both innovative and generic; and growing private health insurance. All in all, pharmerging markets are expected to account for 24% of the total market growth, while the top seven markets — the United States, Japan, and the top five European markets — are expected to contribute just less than 50% of the growth.

Pharma is interested in two types of opportunities: increasing global sales and reducing costs both from a manufacturing and R&D standpoint.

ERIC RAMBEAUX Solvay

Beyond BRIC: New Areas of Growth

Many multinational companies (MNCs) have already turned their focus to the BRIC countries of Brazil, Russia, India, and China, and they may consider those countries as emerged as opposed to emerging. As these countries move to the forefront, there is a growing interest in the opportunities that Korea, Mexico, and Turkey might bring. Forward thinking companies are starting to investigate the Next Eleven, or N-11 countries, which include Vietnam, Indonesia, and the Philippines.

In general, pharma is managing a greater number of risks entering emerging markets compared with other sectors.

CHRIS GRAY Ernst & Young

RAMBEAUX. SOLVAY. It is now generally accepted that BRIC countries could be the El Dorado for the pharma industry. We could probably add countries like Indonesia or Mexico. Pharma is interested in two types of opportunities: increasing global sales and reducing costs both from a manufacturing and R&D standpoint. From a sales opportunity standpoint, we should not forget that even if the population of these countries is enormous, their healthcare structure is very limited. Pharmaceutical products are geographically and financially available only to a limited number of people. Prevention — vaccinal or pharmacological — practically does not exist. Although the populations are huge, I do not foresee innovative drugs quickly and sustainably penetrating these markets. The opportunities lie in the drugs with strong brand equity and that are inexpensive compared with more recent drugs. Considering noncommercial opportunities, I think the situation differs greatly by country. India offers many opportunities in terms of manufacturing outsourcing. Indian companies have developed an expertise in chemical engineering, cost-efficient manufacturing, and pharmaceutical development. Many Indian plants are EMEA and/or FDA approved. From an R&D standpoint, pharma views India as the ideal ground for clinical development — quick, cheap, and in principle, having reliable clinical trials. Many CROs have emerged to grab part of this market. India also offers opportunities in terms of state-of-the-art pharmaceutical development. In terms of compound sourcing, Indian companies are investing a lot of resources in R&D,

THOUGHT LEADERS

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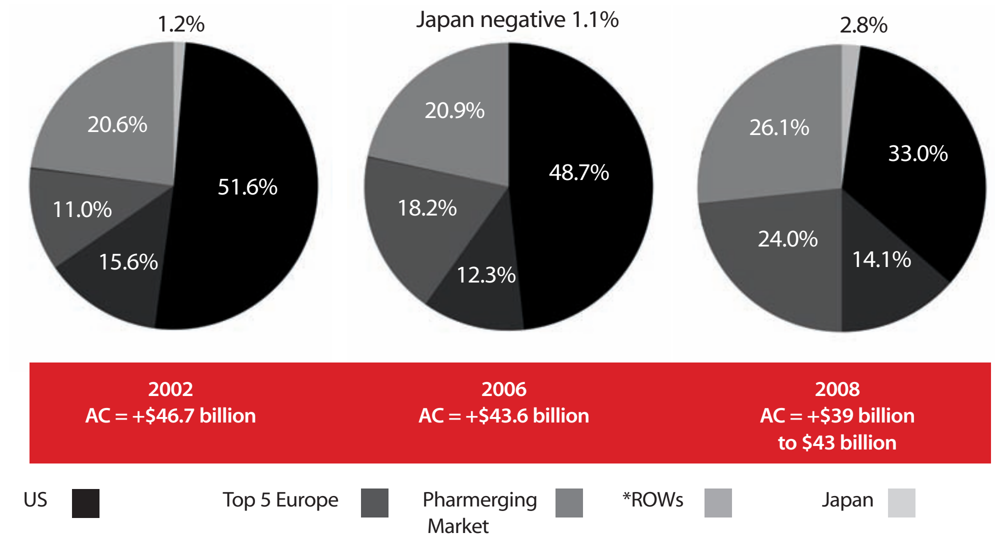
EMERGING MARKETS

TOP 7 MARKETS CONTRIBUTE JUST LESS THAN 50% TO GROWTH IN 2008; PHARMERGING MARKETS CONTRIBUTE 24%.

PHARMERGING MARKETS INCLUDE: CHINA, INDIA, BRAZIL, RUSSIA, MEXICO, TURKEY, AND SOUTH KOREA



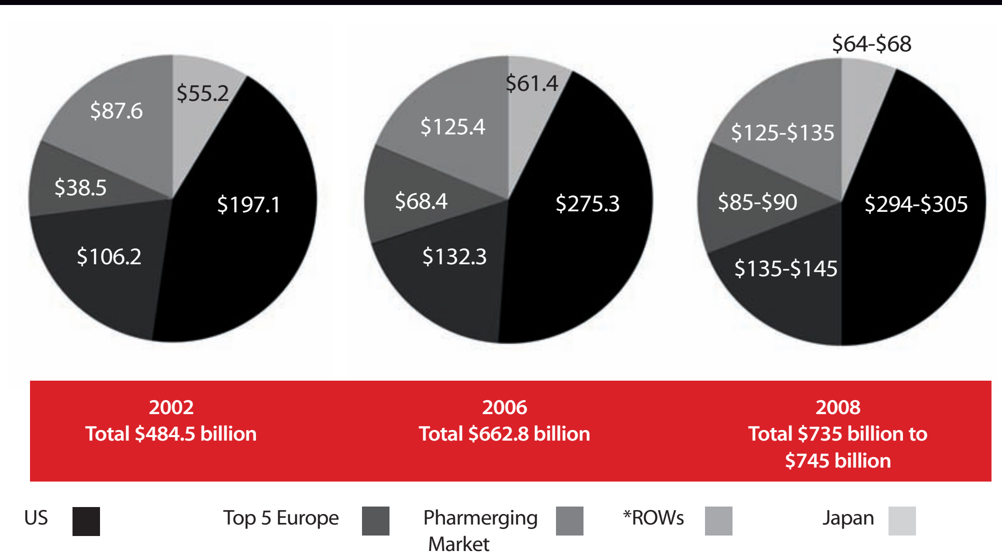
Notes: % of Absolute change (AC) in constant dollars; * ROW = rest of world

Source: IMS Health, Market Prognosis, September 2007, Norwalk, Conn. For more information, visit imshealth.com.

PHARMERGING MARKETS SALES SHARE GROWING

U.S. AND TOP 5 EU SHARE OF SALES REMAINS CONSTANT.

PHARMERGING MARKETS INCLUDE: CHINA, INDIA, BRAZIL, RUSSIA, MEXICO, TURKEY, AND SOUTH KOREA



Notes: Dollars are in billions

Source: IMS Health, Market Prognosis, September 2007, Norwalk, Conn. For more information, visit imshealth.com.

they are signing partnerships, and they have legitimate ambitions. But they are not there yet. In China, even cheaper manufacturing sourcing opportunities may exist, but the infrastructure does not meet regulatory compliance yet. The area in which China can take a real leadership role in the future is discovery. China is positioning itself as a discovery hub. Unfortunately, there are a number of hurdles to overcome before the dream becomes a reality. I believe that these hurdles are more political than scientific, but China has demonstrated that when it wants to accomplish something, it can.

POTTS. TNS HEALTHCARE. About 10 to 15 years ago, Goldman Sachs coined the term BRIC. The pharmaceutical industry has been focusing on the BRIC countries for some time. In the past year or so, Goldman Sachs put forward the term Next 11, or N-11, to describe a list of 11 countries that have promising outlooks for investment and future growth. The first country in the N-11 list is Korea (BRIC gets its K), which is accepted as one of the strongest developing countries. But it is questionable whether it can still be identified as developing. Korea is on par with Japan and is one of the top six or eight pharma markets today. Other developing countries on the N-11 list that are showing quite a bit of promise include Vietnam and Indonesia. In these countries, there is a growing upper class or upper middle class that can now afford brand products. In Malaysia and Indonesia — where thick, cream-based curries are a big part of the diet — obesity is prevalent and that represents a growth opportunity. Pharma's presence in these countries is growing quite significantly. It's all private market, but it is growing.

GHOSH. BOSTON ANALYTICS. Most of the growth is happening in two or three regions of the world for very different reasons. One set of growth opportunities is purely because some countries are growing rapidly, which leads to more people having access to healthcare and living longer. Another growth opportunity relates to aging populations; I am quite optimistic about the growth opportunities in Japan, the United States, and Europe because of the demographic shifts of aging. In Japan, one person in five will be about 65 by 2025. The increase of this age group and its need for greater healthcare access will be two reasons why growth will be driven for those segments of society. The third area of growth relates to the fact that the world is becoming more humanitarian. People all over the world are very eager to solve some of the persistent health problems in Africa, Latin America, and Asia.

GRAY. ERNST & YOUNG. The results of our Emerging Markets Risk Survey in 2007 showed China and India as a high priority for

EMERGING MARKETS IMPORTANT TO GROWTH STRATEGIES

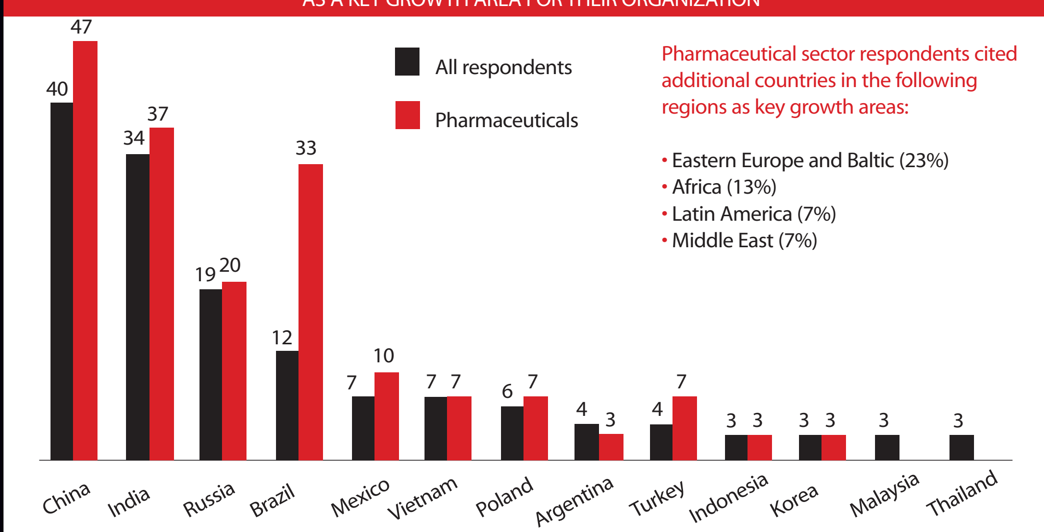
According to Ernst & Young, prospects for faster growth in emerging markets are accompanied by the potential for greater risk. To determine trends and risk management strategies for emerging markets, Ernst & Young surveyed more than 900 senior business and financial executives responsible for risk management across different industries, including the pharmaceutical industry and from both developed and emerging markets.

Of those surveyed, 36 were from the pharmaceutical sector and, of those, 15 were from developed markets and 21 from the BRIC markets (Brazil, Russia, India, and China). Consistent with the industrywide BRIC respondents in the survey, the 21 respondents from pharmaceutical companies in the BRIC markets included a mix of executives in subsidiaries of companies with headquarters in developed markets and executives in companies in the BRIC countries.

While both the industrywide findings and the pharma industry findings consistently rate the BRIC countries and Mexico as the top growth areas among emerging market countries, the results for Brazil are significantly higher for the pharmaceutical sector in contrast to other industries: 33% of pharmaceutical respondents cite it as a key growth area, compared with 12% of all respondents.

Organic growth, followed by partnerships and alliances, was the leading strategy for expanding in emerging markets. Also, companies have moved from the traditional view that the primary objective for investing in emerging markets is cost savings. Twenty percent of emerging market pharmaceutical subsidiaries point to profitability or return on investment as the strategic objective driving their investment.

PERCENTAGE OF RESPONDENTS WHO IDENTIFIED EACH COUNTRY AS A KEY GROWTH AREA FOR THEIR ORGANIZATION



KEY RISKS FACING OPERATIONS IN EMERGING MARKETS — DEVELOPED MARKETS PERSPECTIVE*

*** Pharmaceutical executives in developed markets, with company affiliations in emerging markets, named their company's most important risk (black), then named two other key risks (red).**

Source: Ernst & Young, New York. For more information, visit ey.com.

pharma, as they were for other industries as well. These are the two countries that are at the forefront of pharma companies' attention. Half of the survey's pharmaceutical respondents ranked China as the country that had the highest potential for growth and 35% thought India had potential. There have been lots of discussions in the industry related to the competitiveness of India and China and the ability of each country to woo pharma into its market, particularly for outsourced manufacturing or R&D facilities. Relative to other industries, pharma seems particularly attracted to Brazil for growth. Brazil was ranked third in terms of countries the industry wants to explore. Almost one-third, 29%, of respondents in pharma indicated that Brazil would aid their future growth, while only 12% of the other industries that responded believed that Brazil was that important. The high level of interest may stem from Brazil's recovering economy. And as the medium income per family increases, healthcare is one area where disposable income is being spent, whether it's self care or self treatment or through physicians and access to prescription products. An increasing middle class and a decrease in the bottom echelon of the socioeconomic pyramid will continue to favor the pharma market in Brazil for the foreseeable future.

CONMY. IMS. We strongly believe that the pharmerging markets of China, Brazil, Mexico, South Korea, Turkey, India, and Russia offer the greatest opportunities for growth. These markets are forecast to grow between 12% and 13% in 2008, representing about $85 billion to $90 billion in sales. China and India also have experienced significant GDP growth and have extremely large populations, and we expect that growth will continue in these markets. In particular, both countries have defined healthcare, and more particularly healthcare access, as a key government policy priority. This will enable further pharmaceutical growth and create additional opportunities for companies as a result of better infrastructures, increased reimbursements, and greater access.

HISEY. DELOITTE. When considering growth from a market standpoint, many companies are looking to India and China for the approval and adoption of new products, as these markets are seen as underpenetrated and underserved. Companies that look to these markets will be winners since these countries have the population base and growing economy to support new innovation, as well as an increasing level of purchasing power that stems from an educated middle class that understands and is seeking to reap the benefits from a variety of new treatments. Further-more, the BRIC countries continue to increase in appeal from growth and operational standpoints as these relate to research and discovery, drug development, and a source of product production.

CAMERON. CHILTERN. In line with pharma companies, clinical research organizations are also looking to the emerging markets with increasing focus. The objective is for further globalization of clinical trials while balancing quality, timelines, and patient recruitment. Cost is also a factor, but remains secondary to the other aspects. The outcome is the steady globalization of clinical research, advancing in countries with a stable regulatory environment and improved quality. Some of the countries that offer the highest potential for the pharmaceutical and the clinical research companies are also the countries that carry the highest level of financial and legal risk. China tops the list, followed by Brazil.

POTTS. TNS HEALTHCARE. China and India are the hot spots and are often referred to as Chindia. Big pharma has been involved with these emerging markets for a while, and now the biotech industry is looking at them as new emerging markets. It is important to remember that although there are a number of countries that offer opportunities, some are more developed than others. Korea, for example, is very developed with a strong infrastructure, as are Taiwan and Hong Kong. And then there are some countries that are going to be a real struggle because the infrastructure just isn't there, such as Vietnam and Indonesia.

Risks and Challenges

All the countries in the emerging markets carry risk, mostly in the form of infrastructure instability, internal political unrest, unfavorable intellectual property practices, and an excessive number of regulatory requirements.

RAMBEAUX. SOLVAY. The greatest challenge will be to have innovation protected and paid for. This being said, from an ethical standpoint the big challenge is also to provide these markets with products that fulfill their medical needs, which are just enormous. Thus, while there may be a lot to win in terms of productivity, cost reduction, or even business, if things are not well managed, there is a lot to lose in terms of investments, as well as reputation for the industry as a whole. Of course, political stability can always be a question mark, but I am not sure that this is a significant risk today. All these countries are willing to be a part of the globalization game and they have their own rules and their own culture. A risk for the pharma industry is to disregard the cultural gaps, as well as the local needs, and to try to apply the Western standard. This has happened a couple of times already. The industry has a lot to lose if it does not understand both the key local market drivers and what drives the people. Consolidation is another risk for Western pharma companies. For the time being, Indian companies are far too small to acquire a big player in the United States or Europe. Some attempts have been made, for example efforts to acquire Merck's generic business, with the help of funds, but none have been successful. Indian companies are involved in small acquisitions but this remains marginal so far. Another risk exists around local investment funds. China is supposed to be sitting on $2,500 billion. It could use it to acquire a lot of our so-called big pharma companies. In China, the risk is mainly around intellectual property. This is still seen as an issue, which may be preventing investments, and is probably putting research at risk.

China and India are the hot spots, and are often referred to as Chindia.

STEPHEN POTTS
TNS HEALTHCARE

POTTS. TNS HEALTHCARE. Access to medicines is one of the biggest challenges, especially in a country like Indonesia, where less than 5% of the population has access to branded products. The industry is trying to increase access to private medicines. Historically in these countries, a doctor would assume what patients could or couldn't afford and they wouldn't bother to offer them the more expensive branded product if they were thought to be lower to middle class. Pharma is now trying to educate doctors to change their behaviors and offer the best medicines as often as possible and allow patients to make an informed decision, instead of having the decision made for them. And patients in those countries are gaining empowerment through the growing amount of healthcare information available on the Internet. Even though they may not have a computer in their homes, they have access at work or at Internet cafes. Pharma companies also are trying to drive access through the private sector by investing heavily in reimbursement efforts. In some countries, companies have whole departments dedi-

COMMON ELEMENTS OF THE PHARMERGING SEGMENT IN 2008

ISSUES

Rising GDP increasing access and improving climate for IP

- Pharmerging the key targets for global pharma
- China demographics similar to Western Europe
- Improved diagnosis rates
- Increasing demand for chronic therapies
- IP improves gradually, especially in India
- Midsize players doing well

Increasing access stretches government finances

- Generics preferred across the pharmerging markets
- Russia DLO 2008* financing secured, but with price cuts
- 19 price cuts in China since 1997
- Tighter reference pricing in Turkey
- Some countries looking for rationale to break specific patents (HIV, biosimilars) as cash-strapped governments try to secure treatment for large patient populations

Private market and better insurance schemes favor MNCs**

- Enable greater access to life-threatening innovations, e.g. biotech
- MNCs have greater marketing and sales skills than local players
- Inward investment generally welcomed
- Innovative product launches by MNCs have good prospects
- Rising incomes increase drug purchasing power

Note: Pharmerging markets include: China, India, Brazil, Russia, Mexico, Turkey, and South Korea; * DLO is Russia's state reimbursement program; ** MNCs = multinational companies

Source: IMS Health, Market Prognosis, September 2007, Norwalk, Conn. For more information, visit imshealth.com.

PHARMERGING MARKETS ARE POCKETS OF POTENTIAL FOR PHARMA

PATCHWORK OF DIFFERENT DYNAMICS

ISSUES

Asia Pacific

- Cultural sensitivities are a key to success
- India/China backyard
- High physician turnover
- Growing wealth
- Parallel trade
- R&D ventures by MNCs increase rapidly

Common Characteristics

- IP continues to haunt pharma
- Rapidly growing primary-care sector
- OTC consumer driven
- Lack of infrastructure
- Mix of infectious and chronic diseases
- Local corporations enjoy preferential treatment

Latin America

- Compulsory licensing
- Cheap local generics
- Expanding access high on political agenda
- Hospital tendering
- Low-cost retail chains drive consumption

Note: Pharmerging markets include: China, India, Brazil, Russia, Mexico, Turkey, and South Korea
Source: IMS Health, Market Prognosis, September 2007, Norwalk, Conn. For more information, visit imshealth.com.

cated to obtaining national reimbursement. Korea and Taiwan are very strong reimbursement markets. Their governments have historically invested quite heavily in healthcare. China, however, is a real headache; each local authority approves reimbursement, and there are literally hundreds of these. A manufacturer has to apply to each authority separately, so pharma employs reimbursement representatives that function much like a salesforce.

GHOSH. BOSTON ANALYTICS. One big challenge is defining the price point in different markets and for different segments of society without being careless about the cost of research and development of new molecules or the economics of the consumer. On one hand, pricing should enable the medicines to be affordable and in line with the healthcare policies of the local government. On the other hand, the pricing strategy should respect the economics or the cost of developing the pharmaceuticals. The second challenge that global pharma companies have to deal with is how to compete with the local pharma companies in a manner in which such competition is positive for the local economy. Striking a balance between what is good for the company and what is good for the country can be a challenge. If a multinational company enters a new market and wipes out all the local companies, it then basically wipes out the local innovation power. From a holistic point of view, this is not healthy.

GRAY. ERNST & YOUNG. Political risk was one of the top concerns reported in our survey; it came in as the No. 2 concern in the pharma industry even above compliance and pricing, which was surprising. Of the 36 pharma respondents, 27% named it as their first mention, and 32% mentioned it first or second. These numbers speak volumes about the other sub issues, including intellectual property, reimbursement, and drug approval. Any instability in the political environment will translate into higher risk for any of these issues.

CONMY. IMS. While it is hard to point to any individual country, we expect the pharmerging markets to carry more risk than the traditional markets because of their changing dynamics. Some of these risks include intellectual property rights, law enforcement, erratic/contradicting regulation, corruption, highly entrenched local (generic) competition, and problems related to a high-growth environment, such as personnel shortages/turnover. In addition, national disasters, such as SARS or poor harvests, can still have significant economic impact and hence affect growth curves. The mature markets are more advanced and the environment offers more stability as well as vastly improved medical security systems, which lead to less fluctuation in demand. Risks in the mature environments tend to center on pricing or restriction of access instead of the expansion of access and out-of-pocket costs of the emerging markets. Some of these risks include restrictions on sales promotion activities, price cuts, government initiatives to reduce healthcare costs and restrictions on the number of reimbursed products, and shifts in the hospital and pharmacy sectors. The biggest challenges in both China and India are finding access to rural populations, maintain-

Entering foreign markets with partners that are already established in those countries can mitigate risk.

R.T. HISEY Deloitte & Touche USA

ing/building the organizational model in sync with the high-growth environment, and ensuring flawless tactical execution of plans. For example, the Chinese government has announced plans to reform the healthcare system so that all citizens will be covered by medical insurance by 2010. Currently, only employed urban residents are allowed to participate in the national health-insurance program, but reform that extends coverage is being piloted in 79 cities, including all of the provincial capitals. This coverage will then be extended to the rest of the country. Of course, the funding and implementation approach to this vast expansion of healthcare remains uncertain, but the government is clear in its intent to provide access to healthcare to all of its citizens.

HISEY. DELOITTE. Risk of varying types can be found in all markets, including the U.S. domestic market. As we think about entering major markets such as India, China, and others, there are risks that need to be understood and mitigated from a number of standpoints. Risks of intellectual capital protection have been well chronicled at each stage of the process — drug discovery, research and development, and process manufacturing. Additionally, there is risk that needs to be managed related to marketing, sales, and distribution of products. Companies need to understand allowable practices and ensure the integrity of the product distribution network from the point of finished goods production through to the point of administration and dispensing to a patient. In response to these types of challenges, some of the world's leading companies are embracing comprehensive brand protection programs with a specific eye toward emerging markets. In more mature markets, there are better defined, more commonly understood processes and systems of checks and balances already in place as compared with markets where people have less familiarity with laws, customs, and standard business practices. As an example, companies cannot approach a physician in China, who is actually a government employee, the same way they can an independently practicing private physician in the United States, because how physicians contract for and distribute products varies within each market. Based on our observations, more U.S.-based companies are entering these foreign markets with partners that already have established operations in those countries.

CAMERON. CHILTERN. The countries that have the most risk are located in Asia, more specifically China. Latin American countries also carry a fair amount of high risk. CROs are very interested in moving into China because of the great potential for patients, but this is balanced by risks related to the regulatory environment, patent infringement, bureaucracy, quality of data, culture, language, and timelines. As a result, very few studies are conducted in China and no rapid expansion is expected to take place in this market until these factors have improved. Latin America is receiving renewed interest, particularly from U.S. pharmaceutical companies. Although issues still exist with regard to quality and study timelines, rapid patient recruitment and improved training of investigator site personnel have resulted in greater interest and expansion in the Latin American market. India has also realized a large expansion but the impact on CROs has been more in support services related to biometrics activities because of the well-educated and IT-focused employment market. Clinical studies, however, are still

THE NEXT ELEVEN

The Next Eleven (or N-11) is a short list of countries named by Goldman Sachs investment bank in December 2005 as having promising outlooks for investment and future growth. Goldman Sachs used macroeconomic stability, political maturity, openness of trade and investment policies, and quality of education as the criteria.

1. Korea
2. Vietnam
3. Indonesia
4. Philippines
5. Iran
6. Turkey
7. Egypt
8. Pakistan
9. Bangladesh
10. Nigeria
11. Mexico

Source: Goldman Sachs, New York.
For more information, visit goldmansachs.com.

limited because of some risk factors associated with the quality of investigator sites. Currently there is a series of networks of experienced research physicians with expertise in selected therapeutic areas, such as oncology. Countries within Central Eastern Europe (CEE) are no longer considered a major risk as they have made rapid advancements in the last decade. Russia, in particular, has seen rapid expansion in activity in the last few years. The CEE already is a key area for CRO operations and this will continue as access to patients and quality keeps improving. If regulatory trends continue to improve and a better IP environment exists, then the potential for China to become a major player is tremendous. The risk is that an explosion of studies may result in quality issues, if they are not carefully managed. The risks are lower in Latin America where, although political aspects can affect the regulatory environment, the opportunity for patients offsets the challenges. To meet these goals, experienced clinical research staffs are needed and this in itself is a challenge that needs to be overcome.

POTTS. TNS HEALTHCARE. There are three factors to consider when assessing risk in the emerging countries: infrastructure, volatility of political situation, and the talent pool. The resource pool in these countries is growing and improving but it is much better in some countries than others. India has a huge wealth of talented, very highly qualified people, especially in IT and communications. India is one of the biggest local pharma markets in the world. Many generic companies have grown up in India and are now taking the world by storm by producing high-quality generics; India has a strong and vibrant capability. Korea is the same. The Philippines is very strong in terms of its talent pool, but an N-11 country like Vietnam may not be as strong. It may be difficult to hire qualified people locally without having to pay higher salaries to the few local people who are available.

GRAY. ERNST & YOUNG. Companies based in emerging markets — not multinationals but those with headquarters in an emerging market — report they have a documented risk-management strategy in place specifically covering these markets. More than half of these companies — 64% — had documented risk strategies in place and only 33% of those based in developed markets and that also had subsidiaries in emerging markets had processes in place. So there is obviously room for improvement in increased risk mitigation. Three-quarters of emerging market subsidiaries of multinational parents strongly agreed that they were doing sufficient audits on their internal processes but among developed market parent companies only 53% said they were doing sufficient internal audit testing. In terms of the types of strategies companies reported using to achieve growth, 79% of respondents indicated organic growth in emerging markets, second highest or most frequent was partnerships and alliances at 57%, 21% reported forming a joint venture, and 29% reported acquisitions.

HISEY. DELOITTE. One of the ways to prepare for risk is to take a proactive approach. Risk management is the responsibility of all employees, and risk intelligence needs to become an attribute of an organization where the responsibility lies solely with a centralized group. All employees need to understand and focus on all types of risk, including strategic, regulatory, and compliance, and companies need to have the right process in place to deal with and assess risk. By having this process in place, it allows companies to build in a system of checks and balances to execute properly and catch deviations.

CONMY. IMS. In such a highly volatile environment, pharma needs to constantly assess which risk factors create the biggest swing factors — positive and negative — in the projected growth of revenue and profitability. By focusing on the top market factors in each of these countries, pharma companies can mitigate their risks through proactive strategies as well as create alternative fallback options.

CAMERON. CHILTERN. In the end, the risks of conducting clinical research in emerging markets always come down to the quality and the integrity of the data collected and acceptance by the key regulatory authorities in Europe and the United States. The lack of intellectual property protection in emerging markets also is of great concern to the pharmaceutical industry. While some countries have put legislation into place to address this

Some of the countries that offer the highest potential also carry the highest level of financial and legal risk.

LEWIS CAMERON Chiltern

The biggest challenge in both China and India is finding access to the rural populations.

DIANA CONMY IMS Health

concern other emerging markets such as China are not there yet. Increasingly, CROs are driven to address these risks as Western countries struggle to fulfill clinical studies while also being under pressure to develop drugs in shorter periods. Clinical research in emerging countries needs to take a very local approach. Global processes and quality programs should be driven at a local level with experienced clinical research personnel. This will ensure that all of the regulatory requirements are adhered to and that training of local staff and participating clinical investigators is conducted — all in an effort to obtain high-

Sound Bites from the Field

PHARMAVOICE ASKED EXPERTS TO DISCUSS HOW THE INDUSTRY CAN COUNTER THE CHALLENGE OF ACCESS IN DEVELOPING MARKETS. IN OTHER WORDS, HOW CAN COMPANIES SELL PRODUCTS TO A POPULATION THAT CAN'T AFFORD THEM, OR PERSUADE GOVERNMENTS TO REIMBURSE THE PRODUCT, OR GAIN ANY TRUE POWER IN THE MARKET.

JOHN CAHILL is Asia Pacific Regional Director for McCann Healthcare Worldwide and President of McCann Healthcare Japan, a provider of worldwide marketing healthcare, medical, and pharmaceutical services. For more information, visit mccann.com.

"Establishing true power in developing markets requires companies to pursue a multipronged strategy to fully address issues of access in a way that underscores their social responsibility. For access to be equitable it must be open to all in need, regardless of differences in age, health, wealth, status, or location. To achieve this, the industry must first work closely with government in developing and augmenting the national and regional health delivery infrastructure to ensure ready availability of health services. In this regard the industry needs to explore opportunities for forward vertical integration into health-service delivery through diagnostics, clinics, and pharmacies as potential growth areas. At the same time, the industry must partner to develop high-quality, low-cost (generic) formularies focused increasingly on prevention of communicable disease, and over time these should encompass chronic diseases. Pipelines must reflect this. In approval and formulary construct, governments are focusing on reimbursing only those drugs that have demonstrated significant incremental clinical benefit over other, cheaper therapies creating potential biotech opportunities moving forward. As health improves, so does national wealth and the demand for premium drugs and services, with industry partners in prime position to capitalize on the private market. Alongside these longer-term strategies, early positioning of key therapies — to be funded by government in the public interest, for example immunization — can help drive shorter- term returns while consolidating market power. Whichever approach is taken, partnership is the key to power and profit in developing markets."

LISA FLAIZ is VP, Group Director and National Pharma Practice Lead with the Philadelphia office of Avenue A | Razorfish, an interactive healthcare agency. For more information, visit avenuea-razorfish.com.

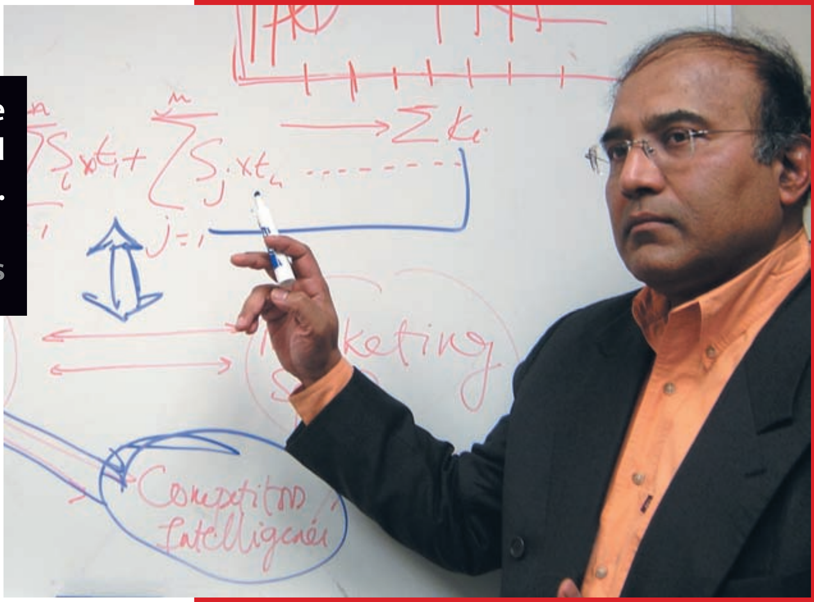
"In these markets there is typically significantly greater access to generic medicines. Perhaps more pharma companies should think about supporting their late life-cycle and off-patent products in these developing nations. Also, continued economic growth in the developing world will help to shift the focus of healthcare away from infectious disease toward more chronic conditions such as diabetes or cardiovascular disease. This presents an opportunity for pharma companies to present long-term cost data to the governments, which could support the case for reimbursement."

MATTHEW GANTZ is CEO of Acureon Pharmaceuticals, Berwyn, Pa., a biopharmaceutical company primarily focused on specialty therapeutics to improve patient outcomes in the hospital, especially in the areas of infectious diseases, transplant, and ICU. For more information, visit acureonpharma.com.

"In emerging markets, such as Brazil and Turkey, we relied extensively on local distributors. But this process varies widely from market to market. Many of these distributors do everything from shipping product to getting product reimbursed to working directly with key opinion leaders. I recall much of the distribution is driven in a top-down fashion. KOLs are much more crucial in driving actual sales than in more Westernized markets. One key strategy that we employed was conducting studies with these key opinion leaders. For higher priced medicines, the funding would come from regional government entities, not just national, and because of that we found that the better off regions were the only ones that could afford them. Considering strategic market entry, whether a company opts out of a market or supplies product gratus depends on a host of factors. For smaller pharmaceutical companies it is much easier to opt out, especially if there is a real threat that it might not get the pricing it needs to support a global pricing strategy.

For Tobi we opted out of Australia for exactly that reason, even though we still maintained a compassionate use program that was started ahead of the regulatory approval process. But if it's a big multinational company opting out is harder to do, especially with HIV drugs. More and more of these companies are doing business gratus as a way to deal with sociopolitical pressures and to enhance their global images. Hospital consortium groups offer an alternative approach to dealing with these challenges. It is a way to de-risk market entry and offers a united front with other multinationals and local players."

> **The next 10 to 15 years will be a renaissance period with pharma having a more global perspective and looking at adjacent areas of the industry for solutions.**
>
> **PARTHA GHOSH** Boston Analytics



quality data. This significantly reduces the risk and improves the perception of pharma, the FDA, and the EMEA to accept these data in regulatory submissions.

A Global Future

The promise of future growth for the industry in emerging markets is as varied and diverse as the countries themselves. While some companies may stick with the more established BRIC countries, forward-thinking companies may look for smaller opportunities in the less-traveled N-11 countries.

RAMBEAUX. SOLVAY. Emerging markets are very high on the agenda of most pharma companies today. They actually think more about manufacturing cost reduction and product sourcing than of actual sales increases. This goes together with some of the current burning issues that we are facing: pressure on price and therefore on cost. Wall Street is driving this, which is still very demanding in terms of bottom line. This also goes with the dire decrease in R&D output. No pharma companies are striking gold in terms of delivering NCEs that can be approved. They all hope that, given their supposed flexibility, low cost, and talent, China and India will deliver what their Western colleagues are struggling to deliver. But, should it be the case, plundering the intellectual assets of these countries only for the benefit of the developed world without taking into consideration the medical and social needs of these markets may trigger some very negative reactions in public opinion. And we know how public opinion can push politicians to act.

POTTS. TNS HEALTHCARE. The salary burden on pharma is much higher than it was. There was a trend about five years ago identified as the brain drain, which meant in Asia many good resources and highly talented people were recruited to more developed countries in Eurasia, the United States, and Europe. These people, particularly those from India, are now returning to their homeland and expecting Western salaries. The people who have been trained in how to do business in the U.S. or European way but also understand the local culture are highly attractive to multinational companies and can enter into senior positions and request high salaries on par with the United States. The salary burden and direct cost of running a business in India has grown tremendously in the last five years. Salary costs are going up in China as well.

CONMY. IMS. We are seeing greater involvement and adjustment by MNCs to enter the pharmerging markets. Overall, the top 20 pharmaceutical companies increased their sales in the seven pharmerging markets by about 10.5% in the 12 months to September last year, considerably above the total market growth. Of the top 20 pharma companies, European-based companies are generally performing better, with Sanofi-Aventis, Novartis, Boehringer Ingleheim, and Bayer all experiencing a significant share of their global growth coming from these seven markets.

CAMERON. CHILTERN. The CRO industry is continually expanding in the CEE with increased focus in Russia. The next area of growth is Latin America, particularly in large countries such as Argentina and Brazil. Asia, specifically China, is not well advanced but companies are looking closely at the rapid growth potential it represents. In summary, CROs have been moving into emerging markets because of the saturation that exists in the United States and Western Europe for clinical trials. The impetus to recruit patients and to meet ever-shorter clinical development timelines has pushed CROs toward CEE, Latin America, and lately Asia. As the quality of data, overall timeliness, and the business climate in emerging markets continue to improve, these trends bode well for future investments in these countries by the pharmaceutical and the clinical research industry. ✦

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

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