Taren Grom

A Shrinking WORLD

Global reach, emerging markets, and cross-divisional expertise are playing an increasing role in all aspects of the life sciences, from R&D and clinical trials to sales and marketing.

According to the IMS Institute for Healthcare Informatics, pharmerging markets will approach U.S. levels of spending on medicines. Over the next five years, the pharmerging markets are expected to almost double their spending on medicines, to between $285 billion and $315 billion, compared with $151 billion in 2010. This will be fueled by strong economic growth and governments' commitment to expanded healthcare access.

Joseph Bedford, Ph.D., director of marketing at Almac Group, says while it is fashionable to state that emerging markets with high growth rates will be the most important, in reality, the U.S. market will remain the key to continued industry growth and prosperity for a variety of reasons.

"The United States remains the largest pharmaceutical market with almost 45% in sales globally according to IMS," he says. "Profits from such sales are invested to support R&D initiatives and innovation. In contrast to European and some Asian markets, the United States is less prone to pricing pressures due to less government intervention in the economy. Therefore, if the vital U.S. market sustains its strength and profitability, it will continue to drive expansion into emerging markets and foster innovation in drug development."

Terry Hisey, vice chairman, U.S. life sciences leader, at Deloitte LLP, agrees that the U.S. market will continue to be the most influential.

"The U.S. market is still the largest, it is still the source of innovation, and it is still the standard that everyone looks to globally," he says. "As we continue to deal with many challenging issues confronting the U.S. market today, such as patent expiration and health reform, the U.S. market will come through as a vibrant, stronger, more dynamic marketplace that will continue to provide leadership to the industry far into the future."

That said, Mr. Hisey notes companies will continue to look holistically at global markets from a business standpoint as a source of talent and manufacturing, while recognizing that pricing pressure and affordability of the global market is not consistent with the West.

"While global markets may represent significant revenue growth opportunities, the same cannot be said for the potential profit growth, which will not be the same as what we would see in other, more developed markets," he says. "The other thing to recognize is that many more modestly sized emerging markets carry with them other risk factors, for example, supply chain integrity and common business practices. These factors could put a company at risk from an FCPA and product/brand reputation standpoint, so companies will need to look at global opportunities from all angles before committing to making the jump."

For Bonnie Brescia, co-founding principal at BBK Worldwide, the greatest X-factor hovering above the entire industry is the health of global economies — from lingering concerns related to debt-laden countries in the E.U., to recent financial saber-rattling related to trade surpluses fueled by purposefully devalued currencies, specifically in China.

"The impact of these issues and the stability of global markets and currencies will have a profound influence on pharma research and development endeavors, especially as so much current emphasis is being placed on emerging markets," she says.

Value Knows No Borders

Outcomes and real-world data will have a significant impact on global market and development strategies, our experts say.

> **"Companies will continue to look holistically at global markets from a business standpoint as a source of talent and manufacturing."**
>
> **TERRY HISEY** / Deloitte

"It is our belief that comparative effectiveness will be the single most important tipping point for the industry, and that, ultimately, when comparative effectiveness is done right, it drives competitive effectiveness," Mr. Hisey says. "Comparative effectiveness is the biggest

objective companies can start acting on now. There is a need to put in place a comprehensive, enterprise-wide capability to deal with access to global product safety and performance information and the governance models necessary to make effective use of the information and insights."

Dr. William Jacobson, executive director, U.S. strategic regulatory services, OptumInsight Life Sciences, says there are new reimbursement models emerging not only in the United States, but throughout the rest of North America as well as in Europe and Asia.

"The relationship between value and price in medical treatment is changing," he says. "Two of Europe's largest and most-influential markets have made a significant change. Currently, Germany has established value-based pricing, where the maximum price allowed for reimbursement of a drug is linked to the value that the drugs adds, over and above existing care protocols. The United Kingdom will launch a similar value-based pricing system in 2014. This approach is being adopted elsewhere, including the United States, as we continue to closely tie value and benefits to costs through payer reimbursement limits. A sound development and regulatory strategy will ensure that the data that demonstrate value are available as novel products and therapies enter the market."

These changes raise the stakes for life-sciences companies. And as genomic and proteomic biology sheds light on the astonishing intricacy of disease pathology, it is clear that drugs addressing multiple targets will be developed in response, Dr. Jacobson says.

"For these reasons, it's vital to provide, as early as possible in the development process, data-based models and projections that are geocentric and provide significant windows into value," he says. "There will be a range of questions that address the issue of value, such as: How will a potential new entry differentiate itself from currently available therapies? What will drive its adoption by patients, providers, and payers? What value does a drug bring to the marketplace? Will the development package be sufficient in and of itself to demonstrate its value, or will there be a need for additional data and trials? What are the benefits related to current health policy, and what are the implications of the novel therapy's introduction, economically as well as therapeutically?

"Such pre-approval stage research is vital, and will set the stage for late-phase, patient-focused outcomes studies to further reinforce the value and benefits of treatment in evidence-based settings," he concludes.

"While it is fashionable to state that emerging markets with high-growth rates will be the most important, in reality, the U.S. market will remain the key to continued industry growth and prosperity."

JOE BEDFORD / Almac

Global R&D

Jamie Macdonald, chief operating officer of INC Research, believes there will be a more focused effort on quality and quality management of global deliverables, such as more thorough due diligence around the site and suitability around a certain protocol, as well as closer monitoring and scrutiny of data flow.

"This will be addressed with a blend of face-to-face communications and advanced technology," he says. "Meeting local teams and establishing relationships are important; this will always be a people business."

Another area of concern is cost management around global operations.

"Questions are starting to be asked regarding the relative costs of conducting trials in different regions and in different counties," Mr. Macdonald says. "We are starting to see rising fees, entry costs, and regulatory timelines in emerging regions that may drive overall cost-per-patient up on a country level."

As a result, he says, sponsor companies are asking CROs to take greater responsibility for overseeing third-party vendors and pass-through costs not directly in their control.

"We have better resources to manage and track the total cost of development, such as clinical supplies, central labs, and cold chain management logistics costs, so pharma companies are looking to CROs to be good custodians of the total drug development spend on their behalf, particularly when analyzing costs on a regional or country basis," Mr. Macdonald says.

A steadfast trend is better use of data, par-

Global Compliance and Supply Chain Management

From a compliance standpoint, companies needs to conduct an assessment — either internal or external — to determine what their current state of compliance actually is. This will be highly influenced by their current relationships/interactions/noncompliance issues with federal or international regulatory authorities. Then they can determine gaps, create a go-forward plan, and implement.

The efficiencies and improvements need to be driven within a compliance framework, such that the evaluation of any proposed improvements — multiple suppliers, cost reduction, inventory level controls, purchasing controls, etc. — are evaluated from both a business and regulatory point of view. The approach needs to rationalize processes, procedures, and organizations such that the end result will be improved risk management, minimized noncompliance exposure, and allow for the development of rational, compliant, business-focused quality and regulatory operations.

Companies need to take a similar approach to ensure that their global supply chains are efficient. Besides conducting a holistic assessment of their global supply chain — either internal or external — companies need to benchmark their operations with others in and outside the industry. The assessment and benchmark exercise should look at all aspects of the supply chain from sourcing and procurement, planning, manufacturing, and logistics and distribution. Besides a process review, companies need to assess technology as well as supply chain organization design and structure. The security of the supply chain also needs to be reviewed in the assessment.

Similar to the compliance assessment, gaps will be identified, and an overall roadmap, with prioritized initiatives, will be developed to drive cost savings, improve service, enhance security, and drive overall improvements. Companies then can go forward and implement these initiatives and monitor results. Both of these efforts can be combined to establish an overall global strategy and roadmap.

Source: Scott Sopher, Principal, Deloitte Consulting LLP.
For more information, visit deloitte.com.

SOUND BITES FROM THE FIELD

The Top Trends Impacting the Global Arena

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1. The evolution within the pharmerging markets. As the China, Brazil, Russia, India, and other BRIC/CIVET markets grow, we expect to see a maturation of the promotional modeling used in these markets.
2. Democratization of global healthcare. As more and more people are able to access healthcare in these emerging markets — i.e., 300 million people in the Indian middle class — we expect to see a more informed patient base and more consumer/patient participation in the healthcare dialogue.
3. Technology driving greater health information dissemination. With health, as in other categories, technology advancements will allow more and more people access to critical health information and education.

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1. The continuing expansion of Phase II and III clinical trials into emerging markets and across the globe is shifting R&D best practices.
2. Patient recruitment, GCP, and adaptation of endpoints have all introduced new complexities to global clinical studies that require a greater investment of time and money to ensure quality programs.

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1. Continuing consolidation. As U.S.-based pharma companies continue to consolidate their agency and communications partners rosters, including master agreements negotiated at the holding company level, the next phase will surely be consolidating those same resources on a global basis. With key networks having in-country offices, or geographic hubs around the world, our clients will want to take advantage of global efficiencies. Coupled with this is the loud drumbeat of "low-cost, off-shore, 24/7 service" that clients are all exploring. Providing options such as digital global asset management/transcreation systems, or creating publications with Ph.D.s in India, will become a key element in the consolidation decision-making process.
2. Clinical globalization. As clients continue to put more focus on serious, critical care and rare diseases, awareness, educational, and promotional efforts will have to globalize. These disease states and therapeutic categories require global populations — sometimes with specific regional emphasis — to accrue enough patients for viable clinical trials. This means investigators, trial sites, and opinion leaders are no longer strictly U.S.-centric. They may not even be G-5 — United Kingdom, France, Italy, Germany and Spain — focused, but rather in many of the emerging markets such as Turkey, Brazil, India, and China.
3. Exploring emerging markets. As the lure of giant patient bases within expanding economies continues to attract the attention of pharmaceutical manufacturers, the desire to learn how to sell into them — coupled with profit pressure — will be a growing theme. It's not enough to point to a map and say Brazil, Russia, India, and China, that's where we should go next. The radically different healthcare models in each country, confounded by issues of government roles, wealth divides, and protection of patent and intellectual property will require singular approaches and solutions per geography, patient type, and therapeutic category.

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1. The shrinking world is increasing globalization and worldwide reach, and this is coupled with the rising influence of emerging markets.
2. While globalization grows, success in any given market continues to be driven by "local" factors and suppliers, raising the stakes for global operations moving into new markets.
3. There is a growing importance of cross-area expertise and the need to break down silos is a key challenge for global life-sciences companies seeking successes from R&D and clinical trials to sales and marketing. More complex drug therapies related to genomics will complicate the approval processes for a time.

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1. Emerging markets. Pharmaceutical companies are now recognizing the opportunity for sales in emerging markets, such as India and China. Although the traditional pharma model needs to evolve and adapt to this territory, there is tremendous scope for extending product lines and clinical research.
2. Generics and super-generics will have a huge impact on global sales.
3. R&D outsourcing and consolidation of major CROs will impact global trials and development.

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1. The first trend, already in full swing, is the shift to emerging markets. With the expansion of middle classes and better access to care, resulting in increased diagnosis of chronic conditions, pharma recognizes the promising opportunities in Latin America, Asia-Pacific, and Eastern Europe.
2. Continued pressure to economize creates the

second trend of coordinated global launches. By cross-pollinating key roles and improving overall efficiency, coordinated global launches will contribute to increased operating margins.

3. Regulatory restrictions of branded pharmaceuticals will result in the emergence of more corporate branding, leading to trend three. Consolidation of franchise focus, in conjunction with the shift to more patient-centric, personalized medicine, will create opportunities for the global pharmaceutical industry to build patient trust through corporately branded, patient-support services.

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1. Worldwide downward pressure on prices will put additional stress on the biopharma industry. With Europe and the United States struggling to stimulate economic growth while controlling their growing debt, public spending on healthcare will come under increasing scrutiny. In emerging markets, the trend to cut prices for both generic and proprietary drugs will continue as affordability and access to healthcare become increasingly important.

2. The industry will seek consolidation as a means to overcome revenue shortfalls as key products lose patent protection. This M&A activity will alter the landscape as companies prioritize their portfolios, rescale their R&D budgets, and seek value-creating innovative external partnerships.

3. Biopharma will focus on pharmerging markets, where up to 70% of global sales growth is expected to occur. The importance of emerging markets will influence placement of clinical studies for reasons ranging from cost-savings and productivity improvements to regional clinical-commercial market strategies. Asia and the Middle East are expected to be the two biggest beneficiaries of this trend, as they are the only two global regions where the current percentage of global R&D spending lags significantly behind the percentage of global sales to be delivered in those regions.

ticularly in a global setting. And the industry has reached a point where there is a good flow of data with IVR/IWR and EDC systems.

Mr. Macdonald says now the focus will turn to integrating that data into business analytics and intelligence to help the sponsor make better and earlier decisions around execution.

Global Market Watch

India and China, by their sheer size, will continue to dominate interest and exploration for the near term, but other countries identified as emerging will also continue to be tapped for their clinical and market opportunities.

"Recent events in India — from the rejection of a cap on pharma M&A to an emphasis on pharma products to build greater bilateral trade with China — have pushed the country to the forefront of the must-watch list for 2012," says Nick Colucci, president and CEO of Publicis Healthcare Communications Group. "In the coming year, all eyes will be on India, as it seeks to address infrastructure and policy issues that stand between its distinction as a true biopharma powerhouse."

In addition, he says, Shanghai, specifically, has emerged as a mecca for pharma R&D.

"Companies such as Novartis, GlaxoSmithKline, and Pfizer are investing heavily in the region, building capabilities from full-scale drug discovery to early-stage development," Mr. Colucci says. "One measure of increased R&D presence is the growth of clinical trial patient recruitment. Asia doubled its percentage of patients enrolled in clinical trials from 2002 to 2008; with a particular increase in Phase III trials."

Aside from the clinical opportunities, Mr. Colucci says two converging realities make China one of the ripest opportunities for biopharma — the growing middle class and the government's emphasis on healthcare reform.

"China is on the radar of both industry and analysts as a major driver of global pharma sales," he says. "A recent report by Bain & Co. predicted the healthcare industry will grow to about $600 billion in 2015, at a rate of 15% annually. KPMG states China will play a significant role in the future of drug R&D, testing, and regulation. Coupled with the industry's focus on building infrastructure and manpower in the region, China is positioned to move beyond its current spot as the world's third-largest drug market."

Mr. Hisey agrees that the biggest advances will come from China.

"This prediction is based on the significant movement of many multinationals, the commitment of many provinces toward the development of innovation parks and R&D centers, coupled with the strong relationships between the healthcare delivery system, academic institutions, industry, and economic development counsels," he says. PV

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