Going... GLOBAL

ompanies are exploring new business opportunities and models to better manage operations located around the world.

THE BUSINESS OF GOING GLOBAL

As technology melts the borders around the globe, life-sciences companies both large and small are making changes in their business models as a way to capture the new commercialization opportunities opening up around the world. Countries such as China, Russia, Brazil, Turkey, Greece, Taiwan, the Philippines, Singapore, Mexico, Argentina, and Korea are all under the emerging market microscope. The opportunities for growth on a global scale have never been greater than now, our experts say.

For example, a recent PricewaterhouseCoopers report shows that countries such as India and China are growing dramatically in terms of opportunity, not only from a manufacturing and clinical-trials perspective but also as an end market for pharmaceutical products.

"The sheer growth in the Asian pharma markets is propelling companies to have an increasing presence in the region," says Mike Keech, director, pharma and life sciences advisory practice, Pricewaterhouse-Coopers. "Initially companies moved toward the Asia-Pacific countries for cost-containment and R&D productivity reasons because of the pricing pressures in the U.S. market, but now the end markets are growing in importance."

According to the PWC study, China is predicted to overtake the United States in the 2025-to-2030 timeframe to become the world's largest economy; India is expected to exhibit equal growth.

"Having a presence in these countries for pharma companies is crucial," Mr. Keech says.

The global pharmaceutical market is expected to grow 4.5% to 5.5% this year, keeping pace with 2008, according to the Global Pharmaceutical and Therapy Forecast by IMS Health. Through sustained double-digit growth in key emerging countries and a leveling off in more established markets, global pharmaceutical sales are expected to surpass \$820 billion.

As the industry reacts to new world challenges — blockbuster drugs losing patent protection, the influence of regulators and payers on healthcare decisions, uncertainty in the global economic environment, and the anticipated impact of a new U.S. administration — by seeking new avenues of revenue, other factors are favoring the globalization trend. Increased global healthcare reform and awareness, rising incomes of the middle classes, global aging, and differences in disease epidemiology by country all support the shift to manufacturing and marketing globally. The good and the bad are coming together to start a wave of multipolar engagements within the industry.

According to Todd MacLaughlan, head of negotiations, oncology



FRED HASSAN • Schering-Plough

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business development and licensing, at Novartis Oncology, another factor aiding the global growth of the industry is the harmonization of regulatory strategies around the world.

Mr. MacLaughlan says a broader synchronization allows companies to more easily commercialize products on a global scale with greater speed and efficiency.

"Internally, companies are expanding their focus globally to address the commercial and regulatory issues within each country," he says. "In the past, a company might have just one person who represented the rest of the world, but now it is much more important to have more feet on the ground in various countries and regulatory expertise in critical regions of the world to ensure the best results. In other words, instead of having just one strategy for Europe with one regulatory person authorized to sponsor the product throughout the region, now it is crucial to have regulatory expertise and marketing

BUSINESS GLOBAL Outlook





DOUG JERMASEK •

Genzyme

Our global perspective is fundamental to our growth strategy for the future.

THE GLOBAL

PHARMA MARKET

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IMS HEALTH

expertise available on a country-by-country basis. This is a new trend that speaks to the need for improved global collaboration."

This is just one example of the changes companies have been making to their business models for the past five to 10 years to adapt to a global environment, our experts say.

According to Derek Winstanly, MBChB, executive VP, strategic business partnerships, Quintiles Transnational, big pharma companies are deconstructing the model that served them well for a half-century — producing blockbusters via a huge, vertically integrated global infrastructure. This transformation to a new business model is accelerating.

"Companies are prioritizing core and non-core functions, divesting underutilized or non-core assets, and using ROI instead of size — people and dollars managed — as the key measure of success," he says. "In the future, companies will be more flexible, more virtual, and more reliant on specialty-care products, biologics, and personalized

medicines. Pharmacogenomics and biomarkers will be key drivers in this new business model, which will rely heavily on risk-sharing alliances. And as part of these changes, emerging markets will become vitally important."

"Targeting multiple markets allows revenue streams to come from various geographies around the globe," says Ray Wodar, director of life sciences and industry strategy, Enovia, Dassault Systèmes. "Companies have remained somewhat stable by diversifying into multiple markets rather than remaining centered in any one market. In the

future, companies will have to further diversify products and product lines for local markets and even individuals. The ability to provide custom-fit products rather than broadly marketed standard product lines will provide a unique differentiation against competitors."

According to Carolyn Buck Luce, global pharmaceutical sector leader, Ernst & Young, there are different stages of global.

"Many companies call themselves 'global,' but I think the word is misused a lot," she says. "Most truly global companies have achieved what I call 'glocal' status — where they are global as it relates to standardized processes and are able to leverage scale in resources, but are perceived as very local by their customers. Ten years ago, most pharma companies were international; now they are moving toward being

CARLEEN KELLY • Surge Worldwide

Consensus building is an effective way to achieve a unified team. This model uses a cooperative approach with the lead country adopting an 80/20 rule in driving decision making.



CAROL BUCK LUCE • Ernst & Young

Ten years ago, most pharma companies were international; now they are moving toward being multinational with an aspiration to being global.

multinational with an aspiration to being global. I'd say many pharma companies fall somewhere between multinational and global."

Ms. Luce says for point of reference, if a company still calls the area of Asia "the Far East," it probably is not a global company.

Although some companies, like Genzyme, are founded on a global perspective, others, like Bayer Healthcare, made a major shift away from a primary-care focus to specialty products as a way to meet global healthcare needs.

According to Doug Jermasek, senior VP, global marketing and strategic development, cardiometabolic and renal diseases, at Genzyme, the company's perspective was global from the very beginning.

"Our business model hasn't changed too much over the years," Mr. Jermasek says. "Our products address small patient populations, and as such we have a very patient-directed approach that is global. Patients in more than 100 countries around the world benefit from

our products, and more than half of our revenue is generated outside of the United States. Our global perspective is fundamental to our growth strategy for the future."

Growing from a global model that already works is an advantage, Mr. Jermasek says — one that larger pharma companies may not have.

"We've created infrastructures in many different countries based on our rare genetic disease platform, which has allowed us to leverage resources that were created quite some time ago," Mr. Jermasek says. "Compa-

nies that have larger footprints in broader disease areas will require larger infrastructures, and that could lead to partnering — the challenge to go global will be greater."

Bayer Healthcare appears to be poised to meet those challenges, as Hans Bishop, president, specialty medicine, Bayer HealthCare Pharmaceuticals, tells PharmaVOICE of the company's dramatic shift to specialty medicine.

"This is one of the most fundamental changes at Bayer in the last few years," Mr. Bishop says. "All of the major strategic moves we've made during this period have been aligned with a shift to focus on specialty products. Bayer was one of the first companies to make this shift."

GLOBAL Outlook BUSINESS

ALFONSO UGARTE • Stiefel Laboratories

Today, we are a globally integrated organization that recognizes and strives to meet the challenges and opportunities that are a reality of the 21st century.

TODD MACLAUGHLAN •

Novartis Oncology

A broader marketing and regulatory synchronization allows companies to more easily commercialize products on a global scale.



Mr. Bishop says a specialty focus on a global stage has many implications for the company.

"Clearly, one of the biggest changes relates to our revenue stream: the majority of the growth in our pharma business last year came from specialty medicines," he says.

Quoting IMS data, Mr. Bishop notes that another sign of the global times can be seen in the shift in markets.

"The 2009 IMS forecast for emerging markets stands at 34% for global growth, with the United States representing only 9% of the growth," he says. "I think it's important we acknowledge that global pharma growth is not just a phenomenon related to markets with the highest healthcare spend as a percentage of their GDP."

This is a big shift considering that in 2000, the emerging markets represented 7% of total sales growth in pharma, and in the United States growth was estimated at 42%.

"Ten years ago, the economics of the industry were disproportionately weighted in the United States and Europe; now, clearly business is much more multifactorial," Mr. Bishop says. "For example, the BRIC markets are very relevant right now."

Another change Bayer made to its business model includes a small-

er salesforce with individuals who have strong scientific and medical knowledge and function more as consultants rather than as sales representatives.

"This approach means taking a more targeted and longer term relationship oriented view of the market rather than a mass-market approach, which is normally seen with primary care," Mr. Bishop says. "Internally, this also means working closely in cross-functional, customer-centric teams."

Stiefel Laboratories, a specialized pharmaceutical company with a singular focus on dermatology and skin care,

has adopted a more global stance over the past decade, says Alfonso Ugarte, senior VP, global marketing, and with that shift has come the challenges of global team building.

"Stiefel's global business model has changed tremendously in the past decade," he says. "Stiefel has grown to become an international organization comprised of 30 subsidiaries competing in more than 100 markets. A decade ago, our company was operating similar to a franchise model — each country ran its business independent of one another. Today, we are a globally integrated organization that recognizes and strives to meet the challenges and opportunities that are a reality of the 21st century. These challenges include a need to be connected not only to one another, but also to all of our customers."





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SENSITIVE, AND

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JIM MERCANTE • TGaS Advisors

Companies need communication synchronization as well as the harmonization of global strategies and tactics with country and regional idiosyncrasies.

ESTABLISHING A GLOBAL CULTURE

Companies need to invest the time and energy into the management of their global operations if they are to truly maximize the scarce resources that they have located around the globe.

Cultural and communication differences from country to country remain challenging for companies operating on a global basis and cannot be underestimated, says Martin Reynolds, managing director, North America, and CEO, at Sharpstream Life Sciences.

"Global companies are increasingly seeking senior and up-and-coming executives who are well-traveled, culturally sensitive, and highly adaptive in their communication and management styles as a way to ensure they get the real picture and the most from their teams," he says.

Stiefel Laboratories' Mr. Ugarte says one of the biggest challenges to effective global team building is the ability to achieve a "shared understanding," which is necessary to move forward with solutions that are universal and that require an acceptable level of resource allocation.

"Within a local market we try to do everything in our power to meet the needs of our customers," he says. "The challenge arises because resources are limited. We cannot invest in every solution, much less in every single customized solution. The most difficult thing to achieve is to

get as close as possible to the optimal solution, not only from the financial standpoint, but also from the customer satisfaction standpoint."

Schering-Plough has created a formula for creating a global team atmosphere, says Fred Hassan, CEO.

"At Schering-Plough, getting 'in tune' and executing with excellence are at the center of the company's way of working," Mr. Hassan says. "We've been working very hard to develop our global culture, and by that I mean the way people can expect to work with each other — or behave with each other — under different circumstances. Developing a strong global culture in a global organization is extremely important, and it can take many years. Our culture of ensuring a passionate focus on customers starts from the top management, who believes in our

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RAY WODAR •

Enovia, Dassault Systèmes

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If global teams can effectively communicate their overarching positioning strategy, but allow country teams the freedom to execute the strategy appropriately, with tactical implementation at a local level, then both parties should feel they bring their expertise to the table in the right way at the right time.





mission and in our products. Our formula that creates winning teams around the world is based on setting clear goals; building faith; building knowledge, skills, and training; and embedding the will to win.

"We maintain our culture by working hard to build trust — trust on the outside and trust on the inside," he adds. "We encourage colleagues to take initiative, to champion new ideas, and to take measured risks. We work hard to break down silos and to work well cross-functionally. We also work hard at making our matrix effective — bringing countries together via common functions such as finance, human resources, and IT — while encouraging local accountability for high local performance."

According to Catherine Van Doren, R.N., executive director global clinical operations, at Global Research Services, navigating language barriers and cultural differences, and ensuring consistency are complicated even for the most globally focused companies.

"One of the challenges is how to best take advantage of diversity to achieve program and management objectives," she says. "As managers, we need to provide the best possible tools that allow a multicultural group to see the similarities in processes and share the same vision. This is accomplished by consistent team training and integration of processes with effective communication. Effective communication is the foundation for project success.

"In my opinion, the most important step in establishing a global culture is to communicate a strong mission statement or vision of the company that motivates multicultural staff to deliver quality services," she adds. "When individuals understand the goals of the company, they understand how their roles fit together and how their contribu-

tions significantly affect the overall success of the company. Understanding the mission of a company helps staff members embrace change and create a corporate global culture that respects diversity."

Multinational companies face a number of challenges when there is a lack of cohesion between global or regional headquarters and the local operating companies. In a recent survey conducted on the emerging markets by Life Sciences, this lack of understanding was a key issue for local operating executives. Global companies will have to invest more time and energy into management if they wish to truly maximize the scarce resources that they have located around the globe.

According to Ajit Baid, managing director at The Research Partnership, global teams and country teams often have different priorities and line reporting, which not surprisingly bring conflict.

"Justifiably, country teams pride themselves on having more local/cultural expertise and want to have control over the decision-making process, but this is not always in line with the global strategy," he says. "If global teams can effectively communicate their overarching positioning strategy, but allow country teams the freedom to execute the strategy appropriately, with tactical implementation at a local level, then both parties should feel they bring their expertise to the table in the right way at the right time."

Setting clear team goals and incentivizing individuals to support those goals are two of the most difficult challenges.

"People are typically rewarded for personal and unit performance, not for contributing to global team goals," Mr. Reynolds adds.

According to Jim Mercante, partner at TGaS Advisors, some of the



HANS BISHOP • Bayer HealthCare

All of the major strategic moves we've made have been aligned with a strategic shift to focus on specialty products.

biggest stumbling blocks to building a global team are not unique to global team building, they are germane to building any effective team.

"Companies need communication synchronization — a communication lexicon, terminology, meanings, idioms — as well as the harmonization of global strategies and tactics with country and regional idiosyncrasies," he says.

Dr. Winstanly offers a couple of solutions.

"First, make sure all employees understand the company's strategy and how they contribute to its execution," he says. "Second, incentivize individuals to support global team goals, in addition to personal and unit goals."

The decision-making process can be complex because there is the need to consider the different components of the group and the countries/markets represented.

"Consensus building is an effective way to achieve a unified team; this model uses a cooperative approach with the lead country adopting an 80/20 rule in driving decision making, which provides greater consistency in work and empowers team members to attain success through collaboration," says Carleen Kelly, president, Surge World-

wide Healthcare Communications. "To achieve this, the lead entity must be willing to receive input and negotiate to ensure that all parties receive some benefit. The primary themes that we see in global companies are the differences in cultures, processes, and attitudes across study teams within the same company and within the same project. There can be a distinct perception of territory ownership even among team members working on the same project who may be located in different countries. Or one team might not like another team, particularly from the United States, telling them what to do or projecting their distinct process and management style on them."

Establishing a strong global team takes time, just like any relationship, according to Patrick Durbin, division VP, global head, Fisher Clinical Services.

"It is important that companies provide opportunities for teams to meet, to get to know one another, and to interact face-to-face," he says. "Team members need the time to work out issues of mutual concern together and come to a consensus approach that balances the needs of the various local businesses." •

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