

The Continued *Influence of* GLOBAL MARKETS

Across all aspects of the business, the life-sciences industry can no longer afford to think and act locally.

From changing demographics, emerging markets increasing in influence, and an increasing focus on both biotech products and generics, pharmaceutical companies will see a changing market globally. Our experts say it will be necessary to create partnerships with stakeholders in global pharma products to ensure success.

As leaders broaden their engagement of the global scientific community, expect to see a more open environment thanks to several types of collaborations, says Miguel Barbosa, Ph.D., VP, head, immunology research and external innovation, at Janssen Research & Development LLC, part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

"Partnerships between pharmaceutical organizations and venture capital groups that historically took a more competitive, adversarial stance are becoming more frequent as exemplified by co-development partnerships earlier in the R&D cycle," he says. "The co-investment agreements in particular show a common realization that fostering innovative science is critical to fill the industry pipeline and address unmet global health needs."

Globalization of the pharmaceutical and life-sciences industries promises significant benefits, including revenue growth opportunities and lower costs for companies, says Joshua Pagliaro, director, management consulting, at PwC Pharmaceutical and Life Sciences.

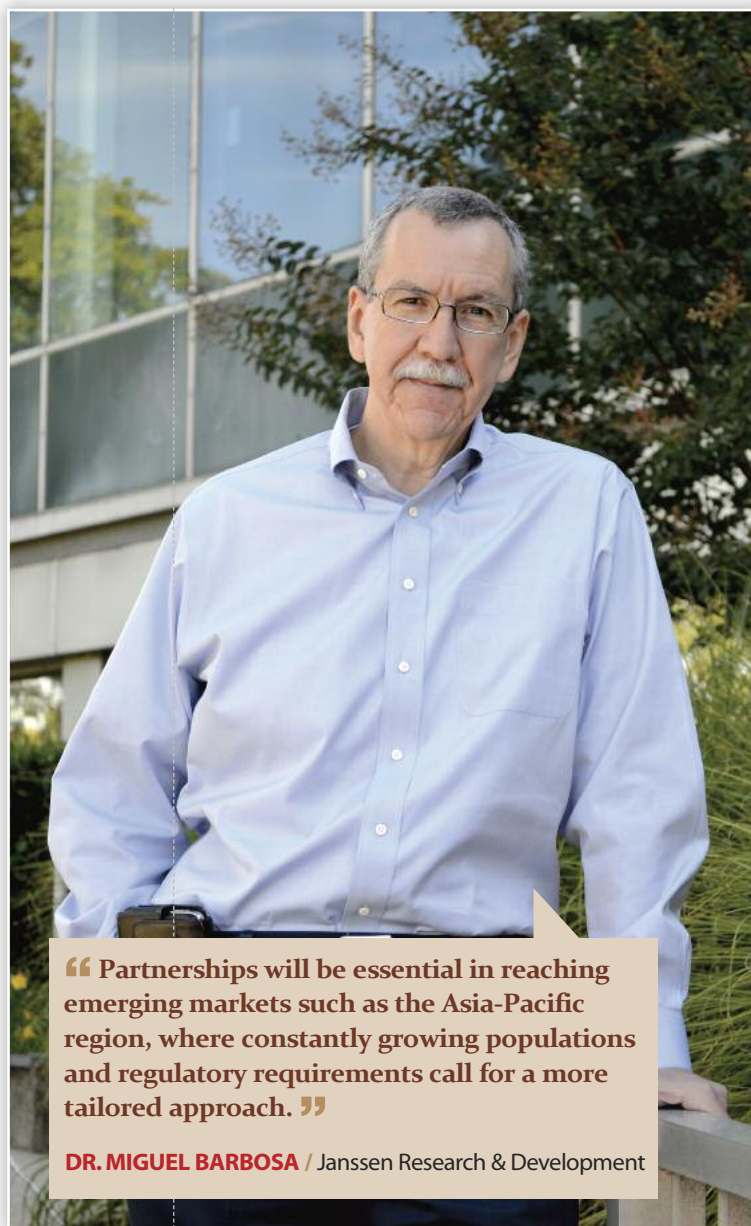
"While emerging markets represent significant potential, the pace of growth has been slower than expected for some companies, and new risks have emerged along the way," he says. "With aggressive efforts in both developed and emerging markets to contain health spending, the demand for innovation and overall value is increasing, with new requirements being

placed on the pharmaceutical industry to demonstrate how new medicines take cost out of healthcare budgets. In addition, a consistent perception of what constitutes value varies greatly by market, increasing the importance of early stage planning and analysis to ensure these varying global factors are captured early on in the commercialization process. The pricing of products and services is under increasing pressure. In some cases, companies must reassess their revenue projections, while right-sizing their global operations to meet these changing marketing factors."

Mr. Pagliaro predicts there will likely be more collaborative development models similar to the newly formed TransCelerate BioPharma industry alliance.

In September 2012, 10 biopharmaceutical companies formed a nonprofit organization to accelerate the development of new medicines. The companies are: Abbott, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly and Company, Glaxo-SmithKline, Johnson & Johnson, Pfizer, Genentech, a member of the Roche Group, and Sanofi.

They launched TransCelerate BioPharma to identify and



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DR. MIGUEL BARBOSA / Janssen Research & Development

FAST FACT

GLOBAL HEALTHCARE SPENDING IS PROJECTED TO INCREASE TO MORE THAN \$7.5 TRILLION IN 2020 FROM \$5 TRILLION IN 2010.

Source: PwC

solve common drug development challenges. Five projects have been selected by the group, including: development of a shared user interface for investigator site portals, mutual recognition of study site qualification and training, development of a risk-based site monitoring approach and standards, development of clinical data standards, and establishment of a comparator drug supply model.

Mr. Pagliaro says the convergence of providers, the transformation of the primary care markets, the institution of new outcomes-based payment models, and the shifting of risk from payers to providers increasingly dominated by generic products and new market participants will require new operating models for an industry already in the midst of restructuring.

“Pharmaceutical companies will need to aggressively adapt — or risk their long-term viability,” he says. “While the blockbuster model may still have some merit, anticipation over the end of an era is playing out with new mergers and alliances between big pharma and generic players, mass salesforce reductions, divestitures, and cost reductions. The questions for top management are: ‘What kind of company do you want to be in five years, and will it be shaped by outside forces or can it shape a market in which it can dominate?’”

Top performing pharmaceutical companies are employing a mix of business approaches to succeed in a particular therapeutic or geographical area, according to a recent report from GlobalData.

The report suggests that as there is no one-size-fits-all strategy for success in the pharmaceutical industry, and major pharmaceutical companies are being forced to find innovative strategies to compensate for losses stemming from the patent cliff.

GlobalData estimates that total corporate revenue from the top 25 pharmaceutical companies increased 6.8% year-to-year, from \$634.9 billion in 2010 to \$677.9 billion in 2011.

While this growth was solid, it did not reach even half of the growth rate achieved in 2011 when revenue from these top 25 companies increased 11.7% from \$568.5 billion.

GlobalData attributes the slower growth rate to these companies experiencing signifi-

cant revenue erosion due to the impending patent cliff, which is having a negative impact on the financial performance of companies.

Emerging Markets

According to PwC, global healthcare spending is projected to increase to more than \$7.5 trillion in 2020 from \$5 trillion in 2010. Spending in Brazil, Russia, India, and China (BRIC) and other nontraditional economies is expected to drive most of the growth. Services, both clinical and nonclinical, will account for an estimated 30% to 45% of spending in 2020.

Our experts say the United States, Europe, and Japan will continue to be the most influential markets. India and China hold the greatest opportunities for R&D, while China remains the largest untapped market for marketing and sales.

The growth and structural development of the BRIC countries is an opportunity for the pharma industry, says Yuichi Iwaki, M.D., Ph.D., president, CEO, and founder of MediciNova.

“Furthermore, as these markets advance, other new emerging markets will develop — for example, in Indonesia and Africa — to further expand global opportunities,” he says.

Life-sciences companies are looking at the BRIC countries but also to the pharmerging countries to focus their global expansion efforts, says Nagaraja Srivatsan, senior VP and head of life sciences, North America, Cognizant.

“The healthcare needs of developing countries are quite different; these countries also pay for healthcare differently,” he says. “Life-sciences companies need to have a focused approach for these markets. A one-size-fits-all model will not work. Organizations need to evaluate what disease states have the most demand in the target country and have a country-specific model for growth.”

Success in this environment, Mr. Srivatsan says, is dependent on transparency around goals and objectives for the market.

“An understanding of the local issues and challenges, setting the right expectations, and governance to ensure that there is ongoing alignment are critical,” he says.

While many people automatically think China and India when they hear the term emerging market, the arena is much broader, says Fran DeGrazio, VP, global research and development, West Pharmaceutical Services.

“There are opportunities in Asia, Latin America, and Eastern Europe, and each of



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NICK COLUCCI / Publicis Healthcare Communications Group

these areas requires a deep understanding of their unique business considerations to ensure success,” she says. “How a company deals with these considerations in each of these locations can determine if the company is placing the right products at the right price in each of these locations.”

Jay Licther, Ph.D., managing partner of Avalon Ventures, says one of the biggest trends will be the emergence of Russia as a major player in the space.

“There is a huge effort, a lot of money, and a lot of unmet medical need in Russia,” he says. “There isn’t a lot of medication available there, and there will be plenty of pharma and biotech companies that emerge to fill that need.”

In China, Dr. Licther says the continued evolution of intellectual property laws will impact how business is conducted there and what kind of partnerships evolve with that region.

In an attempt to save time, money, and resources, international pharmaceutical companies are increasingly outsourcing clinical trials to countries in Asia, Latin America, and Eastern Europe, according to a recent report by GBI Research. In fact, in 2010, Europe carried out 25% of all clinical trials, while East Asia accounted for 10%. Canada, the Middle East, South America, and India followed with 6.1%, 4%, 3%, and 2.5%, respectively.

Emerging regions, especially Latin America and Asia, are going to play a much bigger role in clinical development going forward,

“The most successful pharma companies will be those that recognize, respect, and realign practices to meet the cultural imperatives of emerging markets.”

BILL COONEY / MedPoint

says Dieter Seitz-Tutter, Ph.D., VP, global clinical development, Europe, at Chiltern.

“In the not-so-distant future, their contribution could become as large as one third of patients recruited on a global scale,” he says. “Much progress has been made in many of the countries in these regions toward improving the regulatory environment, the quality of the data, and putting processes in place to safeguard the well-being of study participants. Large populations of potential trial subjects as well as of potential consumers of pharmaceutical products later on, and a comparably low cost base are the main drivers behind this trend. From an operational point of view, performing more activities in these countries requires substantial investments in building infrastructure and in training and development of staff as the existing pool of experienced clinical research personnel is not sufficiently large enough to handle all of the additional work.”

The potential for pipeline innovations to refuel the market’s enthusiasm for the biopharmaceutical industry, as well as the industry’s confidence in itself, is an important trend, says Matt Giegerich, chairman and CEO of Ogilvy CommonHealth Worldwide.

“Few of these new medicines have the blockbuster, multibillion-dollar sales potential of decades past, but the promise of meaningful strides in the treatment of complex, chronic disease is the only stable platform on which to build the future,” he says.

Another important global trend, Mr. Giegerich says, is the continued rise of patient empowerment.

“Fueled by the technology-enabled free flow of information and a growing emphasis on wellness, patients are seizing more control of their health destinies as all forms of global payer systems are simultaneously putting more responsibility on the individual,” he says.

Dr. Barbosa says one key trend that will play a dominant role is the transition of R&D in emerging markets from a cost-basis service model into a more independent, innovation-driven model focused on addressing local unmet medical needs.

“This transition has great potential to deliver transformational patient solutions that, by addressing the challenges of an emerging



economy, will become very competitive in the developed markets,” he says.

Ms. DeGrazio says having an effective supply chain is paramount as well.

“To be effective, a company must be able to deliver and manufacture anywhere around the globe,” she says. “A piece of the emerging market puzzle is ensuring a source of supply. Supplies and raw materials may be coming from parts of the world where a company may not have done business before. This may require greater sensitivity to materials produced in emerging markets. Companies may need to adjust their testing processes and evaluations to ensure that the materials are of the consistency and quality needed.”

Success in Global Markets

High growth rates for pharmaceutical sales in the BRIC nations and other emerging economies are already impacting pharma companies’ business models, says Jim Murphy, president of Almac Clinical Technologies.

“This is apparent in the way firms are approaching drug development and commercial activities,” he says. “In terms of the former, pharma companies are shifting their development efforts from Western Europe and the United States to the BRIC countries and other

Achieving Success Globally

» Determine the type of arrangement.

Providers can enter into consulting agreements, assume management of a facility or department, enter into joint ventures, or make an investment in a foreign enterprise.

» Screen target markets based on strategic priorities.

Organizations should develop strategic priorities and operational goals before considering foreign markets and measure each opportunity against these criteria.

» Join a consortium.

A consortium of strategic partners offering bundled products and services can be an effective way to enter BRIC and other emerging countries, which benefit from receiving a complete solution often at a lower overall price point.

» Find a local partner.

Providers need to partner with a local entity that understands the economic and political climate, knows the pertinent regulations and laws, has relationships with key healthcare personnel and decision makers, and knows the nuances of providing healthcare in the target market.

» Identify what international entities are seeking.

Operators outside the U.S. often look to major American academic centers for their expertise and expect the not-for-profit to bring clinical staff to the facility. For-profit providers are typically expected to provide funding.

» Commit resources to due diligence.

BRIC and other developing countries generally have not adopted U.S. standards for transparency, so getting reliable data can be difficult.

» Involve local practitioners in up-front planning.

For new developments, early input from primary care and other referring physicians can be key to avoiding glitches at a later date as well as fostering facility usage.

» Consider alternative pricing schemes.

BRIC and other countries may not be able to manage U.S. pricing and payment terms. Bundling of products and services is frequently used to sell in these markets. Pay-per-use pricing is an emerging method applicable to select areas in healthcare.

Source: PwC



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JOSHUA PAGLIARO / PwC

high growth areas. Typically, trial sponsors are outsourcing many functions that were previously conducted by their own staff, a huge change in their business models. In terms of commercialization, large pharmaceutical companies are investing heavily in building relationships with physicians on a global basis and putting in place global commercial operations teams (consisting mainly of marketing, sales, reimbursement, medical affairs, and regulatory professionals) that can grow markets abroad. Such teams are increasingly interfacing with drug development professionals in order to maximize the potential of new products in the BRIC and emerging nations.”

Mr. Murphy says the greatest opportunities for sales in emerging markets reside in Asia, particularly in China and India.

“Both countries have very large populations and have undertaken huge efforts to improve their technology and commercial infrastructures,” he says. “Additionally, both China and India have increasingly adopted Western medical practices to supplement traditional therapies. Given the growth in such nations, it seems they no longer fit into the category of ‘emerging.’ Some of us would argue that China and India have already ‘arrived.’”

Looking across pharma, the industry is putting more focus and resources against campaigns and support for global and emerging markets, says David Zaritsky, president of

Roska Healthcare Advertising.

“The emerging markets, especially China and India, represent robust but untapped growth for brands that may seem anemic by comparison in the United States,” he says. “Even brands that have had LOE are enjoying double digit growth in these emerging markets due to the distrust of generic manufacturers overseas.”

Mr. Zaritsky says in marketing globally, however, there are some pitfalls that the U.S. marketer must be wary of.

“First, do not assume what works here will work there,” he says. “This seems obvious, but culturally there are many filters a campaign must be put through in order to create an impact, and even some U.S. campaigns might be regarded as suspect simply because they were generated in the United States. That is why it is vital to work very closely in a strategic manner with the specialized groups within the pharma companies that have responsibility with these markets. They know all too well the politics and hurdles within each market. That being said, the global and emerging markets are benefiting from umbrella strategies and global tool boxes that offer these markets configurable choices. Configurable choices give the market the ability to keep the strategic imperative of the company and brand consistent but allow them to manipulate the tools and tech-



“ Horizontal trends, such as technology-enabled secure supply chain, will help increase ROI and reduce losses and threats from counterfeit operations and IP infringement. ”

DR. ANAND IYER / WellDoc

nology to fit within their unique circumstances. This is particularly effective in Latin America and Europe where local agencies can customize the tool box but do not have the expenditure to create those tools from scratch.”

Nick Colucci, president and CEO of Publicis Healthcare Communications Group, says pharma companies will need to tread carefully in these markets.

“They have to recognize that the opportunity to bring health products to new patient populations must be matched with on-the-ground needs of those communities,” he says. “While many are sure to expand their business model to incorporate new markets, the ones that will be successful are the companies that will adapt their sales and marketing approach to best support the local health system.”

Bill Cooney, president and CEO of Med-Point, says there are profound differences across cultures in how people interact and communicate.

“An understanding of these differences is essential for any endeavor in emerging regions,” he says. “Indeed, the recent maxim ‘culture trumps strategy’ might be better said, ‘culture trumps all.’ Over the last 30 years, medical practice has evolved to a near-uniformity among traditional markets in North America and the EU, but that is not true in nonradi-



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DAVID ZARITSKY / Roska Healthcare Advertising

tional markets. The most successful pharmaceutical companies will be those that recognize, respect, and realign practices to meet the cultural imperatives of emerging markets.”

Pricing and reimbursement environments in most countries are in a state of constant flux, says Mohan Purushothaman, Ph.D., executive VP at Alliance Life Sciences Consulting Group.

“It will be important to price products appropriately and competitively to succeed,” he says. “Any realistic assessment for pricing will depend heavily on meticulous scenario planning and the use of advanced analytics to estimate likely outcomes. A sound launch price strategy is the ultimate expression of a product’s value and its realization from an economic perspective. A company must bring together clinical and economic data to provide a clear understanding of a product’s overall value proposition in the context of current therapies, and the role that the new product will play in changing current treatment paradigms. Properly pricing a product in the international market is the difference between success and being overtaken by the competition.”

Forging Partnerships

PwC executives say entering into arrangements with other strategic partners and gov-

ernments can be an effective way to enter new geographies and manage risk. Success, they say, requires rigorous due diligence, including placing key employees in the target market or facility and leveraging local resources, where possible.

Mr. Colucci says in emerging markets in particular, governments, payers, and NGOs are the gatekeepers that can help pharma companies

understand their needs and the obstacles they will face from poor road infrastructure in rural areas to a lack of education and understanding about a disease.

“Forging partnerships with these stakeholders will be incredibly important to the success of pharma products in new markets,” he says. “Cultural awareness must be coupled with business savvy. On-the-ground messaging has to target the right customer audience and focus on helping meet real medical needs, which may not always mean the newest and latest product, but a tried-and-true medicine with potential to reach new patients. Knowledgeable, local marketing professionals are a critical asset.”

Balkrishan Kalra, senior VP, life sciences, retail, consumer goods, at Genpact, says life-

FAST FACT

BRIC AND OTHER EMERGING COUNTRIES ARE LEADING ROBUST GROWTH IN GLOBAL HEALTHCARE SPENDING.

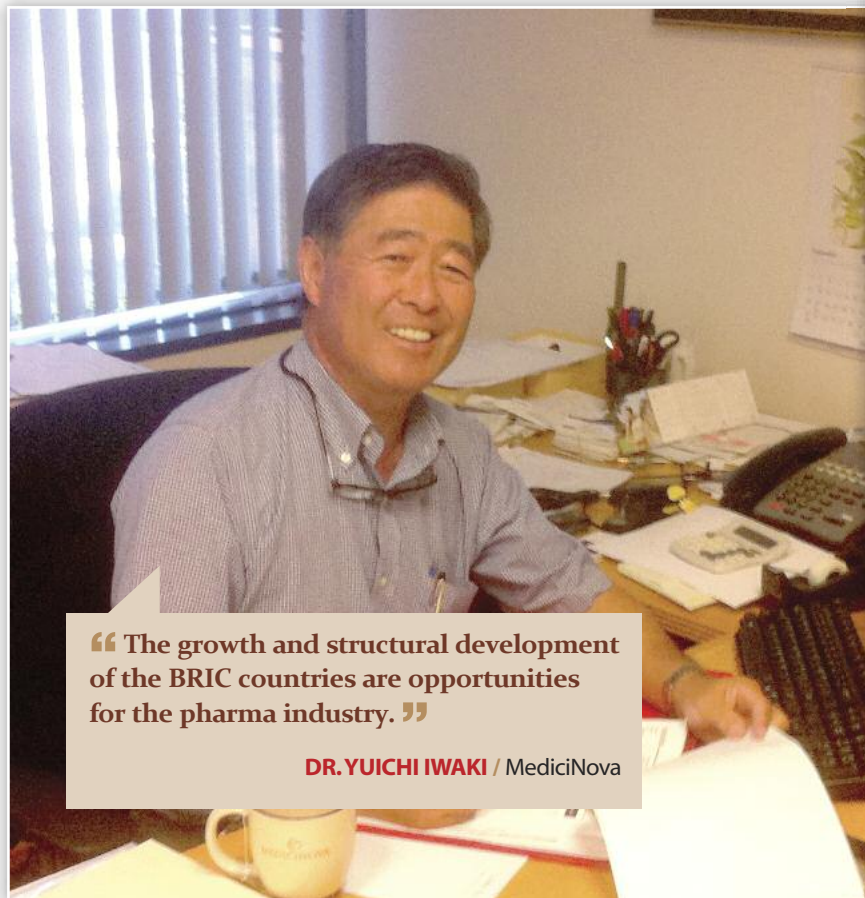
Source: PwC

sciences companies are looking to leverage the growth in emerging markets to offset slow growth in the United States and the European Union.

“To expand the infrastructure in these regions and embed local demands, partnerships will play a key role in quickly and effectively providing the launch pad to take advantage of these growth opportunities,” he says. “Pharmaceutical organizations that can crack this code timely and effectively will benefit and outcompete in these emerging markets, which provide significant growth opportunities.”

Mr. Kalra points out that life-sciences companies are facing increased pressure due to managing rising costs in new product development, leveraging their mature pipeline products, as well as adhering to the growing stringent regulatory and compliance hurdles of doing business.

“Global operations will need to look for opportunities to convert fixed cost to variable cost models to improve efficiency and productivity while focusing on R&D ROI,” he says. “Several large life-sciences companies are leveraging business process management to optimize their safety and regulatory processes, commercial operations, and R&D operations, apart from F&A, HR, and IT functions. Strategies to create the business model to reduce costs will continue to be a key focus in



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DR. YUICHI IWAKI / MediciNova



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Alliance Life Sciences Consulting Group

the coming years, which will further separate the visionaries from the followers.”

Partnerships will be essential in reaching emerging markets of interest such as the Asia-Pacific region, where constantly growing populations and regulatory requirements call for a more tailored approach, Dr. Barbosa says.

“One can draw confidence that leaders in the industry are making these key strategic choices that will drive a more collaborative environment, fostering innovation and increasing R&D productivity,” he says.

Shortcomings in companies’ existing information management activities have been holding companies back from taking advantage of emerging markets, says Gillian King, head of global consulting, global professional services, CSC Life Sciences.

“Where organizations have focused extensively on the United States and Europe but now want to tap into opportunities in Brazil and the Middle East, for example, they have found that they need to complement centralized data management with local knowledge to ensure they can comply with the specific requirements of each individual market,” she says. “Striking the right balance is a challenge that may require external expertise.”

It is, she says, a result of many of these trends that outsourcing has gained a lot of favor among life-sciences organizations.

“Overstretched internally, companies are now willing to reach out for help in managing

these now hefty administrative burdens, which are expensive if taking time away from skilled staff,” Ms. King says. “From safety to R&D and the maintenance of products and associated information, pharma companies are turning to outsourced service providers to plug the gap and deliver positive change faster. This is a massive cultural shift, but the cost savings associated with offloading non-core tasks to a dedicated specialist can be substantial.”

She says companies have to draw on external expertise because this offers a way of getting up to speed within markets they know less well.

Anand Iyer, Ph.D., president and chief operating officer, at WellDoc, says the ability to create relationships with pharmaceutical manufacturers through strategic partnerships will allow a company to have “base, gold, and platinum” like products and services around their drugs that can create critical mass in a therapeutic or drug category.

“Forming these partnerships can help cross the chasms created by economic constraints of healthcare accessibility and affordability globally,” he says. “In addition, horizontal trends such as technology-enabled secure supply chain, can help a pharma company secure its assets from creation to consumption and will help increase ROI and reduce losses and threats from counterfeit operations and IP infringement.”



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FRAN DEGRAZIO / West Pharmaceutical Services

He says some pharma thought leaders are investing heavily in mobile-enabled, information-driven strategies to optimize the compliance, persistence, and patient days-on-therapy of existing drugs in the market.

“These companies are innovating in the numerator; that is, they are not merely cutting costs, streamlining operations, etc., but are actually growing the size and flavor of the pie,” he says. “This is an important trend that will attract other innovators to the party.” **PV**