Kim Ribbink

HOLA MÉXICO: Pharma Drawn to U.S. Neighbor

Growing health coverage, high medical standards, a motivated patient population, and huge geographic advantages make Mexico an appealing market for the pharmaceutical industry.

With a population of around 110 million people and a growing focus on healthcare, Mexico has fast become a profitable market for the pharmaceutical industry.

The Mexican pharmaceutical industry is now the second largest market in Latin America, after Brazil, and is growing at an estimated rate of almost 5% per year.

Mexico also is the 11th largest market worldwide, with a pharmaceutical market valued at about $13.2 billion, according to Ernst & Young. This is projected to reach $17 billion by 2014.

"Mexico accounts for about 25% of pharmaceutical sales throughout Latin America, and is currently among the 10 largest producers of medicines worldwide and is Latin America's leading exporter of pharmaceuticals, at about $1.5 billion as of 2007," says Sandra Sánchez y Oldenhage, general manager, Amgen Mexico.

While the country currently only invests 6% of GDP into health, compared with 12% to 14% in the United States, this is quickly rising due to increased coverage and also the increased demand for higher quality products, says Ayse Kocak, directora general at moksha8 México.

Government spending on medicine is also growing rapidly. According to a report from Espicom, the government intends to cover 102 million people in 2011, with increasing insurance being provided by Seguro Popular, the social security institution that eventually will give universal healthcare coverage to all Mexicans.

"In the last couple of years, Seguro Popular has raised the number of affiliates it has from 16 million to 42 million," Ms. Kocak says.

One of the great strengths of the Mexican pharmaceutical market is price flexibility in the private market.

Good Medicine

"The pharmaceutical market in Mexico is strong and growing," says Dennis Hurley, Dr.Sc., VP, Latin America, INC Research. "Mexico is included among IMS' Pharma Emerging 7."

Mexico has many highly skilled physicians

trained according to top standards, as well as high-quality healthcare centers.

The biotech industry has also become an area of growing importance within the country, with annual growth estimates of 25%.

"Amgen selected Mexico as the first location for its Latin American operations in 2006, due to the size and strength of the market," Ms. Sánchez y Oldenhage says. "Not only is Mexico the largest pharmaceutical manufacturer in Latin America, it is also the second-largest market in the region after Brazil."

She notes that Mexico is now one of the top 10 countries for the development of research protocols in innovative medicines and is recognized as a benchmark and key influencer across Latin America.

"The authorities are aware of the importance of developing R&D centers of excellence and regulatory timelines for study protocol approvals are being revised as the impact of relying on local data is recognized," Ms. Sánchez y Oldenhage adds.

Amgen has brought several products to the market in Mexico. Last November, the company introduced Nplate (romiplostim) in Mexico, the first biotechnology treatment developed for the management of adult chronic immune thrombocytopenic purpura (ITP). ITP is characterized by a low count of platelets in the blood and risk of bleeding, and affects five out of every 10,000 people in Mexico.

"Before Nplate, there was no drug approved for this disease, which can be extremely distressing for patients who have to endure the daily fear of experiencing a serious bleeding episode," Ms. Sánchez y Oldenhage says.

Then in April 2011, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), the regulatory body that approves products, approved three additional Amgen medicines. These include Vectibix (panitumumab), for patients suffering from metastasized colorectal cancer, the fifth most common cancer in men and women in Mexico; Aranesp (darbepoetin alfa), for the treatment of cancer and chemotherapy induced anemia and anemia caused by chronic kidney disease; and Prolia (denosumab) to treat osteoporosis in postmenopausal women, which reportedly affects 24.5 million Mexicans and 16% of women older than the age of 60.

"We are currently working to establish a strong presence in oncology in Mexico as this is certainly an area with significant unmet need for patients," Ms. Sánchez y Oldenhage says. "And in nephrology, we are working with institutions to help avoid complications or hospitalizations by treating illnesses, such as chronic kidney disease, as early as possible, given the cost burden of these types of patients to the government."

FAST FACT

IN MEXICO, GOVERNMENT SPENDING ON MEDICINE IS GROWING RAPIDLY AND THE GOVERNMENT AIMS TO COVER 102 MILLION PEOPLE IN 2011.

Source: Espicom

Clinical Conduct

Industry insiders say the clinical study arena is growing rapidly in Mexico.

Amgen, for example, is now involved with 237 research centers in the country and has 42 trials either completed or ongoing.

Marlene Llopiz, M.D., CEO of Clinica Responsable Operativa, says the main focus in clinical research in Mexico is Phase II and III studies, though some late-phase research is also conducted.

Dr. Llopiz notes that Mexico has many advantages to conducting clinical research, such as large, drug naive patient populations with common and special disease profiles; rapid and compliant patient recruitment; motivated and experienced investigators; U.S. and EC-equivalent medical standards; and highly experienced monitoring and project management teams thoroughly trained on GCP and ICH guidelines.

"Conducting studies in Mexico provides sponsors with a patient pool for testing drugs; reduced costs for strategic multicenter studies; credible and objective results for marketing approval submittals; and highly professional staff members at hospitals and throughout the country who are bilingual, graduated in allied health and medical fields, and trained and experienced in analyzing and monitoring clinical trials," Dr. Llopiz says.

Dr. Hurley adds that Mexico is such a good destination for clinical research, because there is a need for Hispanic patients in global studies.

"As the largest ethnic minority population

"Competent authority timelines for approval are excellent in Mexico, which is very attractive to drug developers."

DENNIS HURLEY / INC Research

"Mexico is recognized as a benchmark and key influencer across Latin America for the development of research protocols in innovative medicines."

SANDRA SÁNCHEZ Y OLDENHAGE
Amgen Mexico

in the world's largest pharmaceutical market — the United States — it is crucial for biopharmaceutical companies to test their products and therapies in this population," he says.

The country's close proximity to the United States is another advantage, particularly when it comes to hands-on Phase IIa proof-of-concept trials.

"The reduction of already fast timelines is very attractive to sponsors," Dr. Hurley says. "Obtaining Competent Authority (CA) authorization can be done in as little as three weeks in some instances."

The Connected Physician

Physicians in Mexico are much more likely to first turn to digital sources, such as websites and mobile apps, to learn about new pharma product information than they are to rely on traditional offline sources, such as sales reps and offline journals. This trend, among others, indicates an opportunity for pharma companies to extend the classic rep relationship by providing online content and services to physicians in Mexico.

These findings come from Taking the Pulse Mexico, a new study from the pharmaceutical and healthcare market research company Manhattan Research.

The study also found several other trends highlighting opportunities for pharma to leverage digital media as a way to provide innovative and best-in-class service in Mexico:

- Online physicians in Mexico are digitally savvy in terms of their Internet and mobile behavior compared with online physicians in other high-growth pharma markets, such as China and India.
- More than nine in 10 physicians who are online for professional purposes in Mexico visit pharma corporate or product websites, with properties from Pfizer and AstraZeneca being the most popular. Pharma-sponsored services, such as patient education, are in high demand among online physicians.
- There is an unmet need for digital rep access in Mexico. Online physicians surveyed in Mexico have one of the lowest electronic detailing adoption rates compared with those in other high-growth pharma markets, but show strong interest in participating in various types of online promotional programs.

Source: Taking the Pulse Mexico. Manhattan Research. For more information, visit manhattanresearch.com.

The pharmaceutical industry has often turned to Mexico as a rescue country when recruitment is difficult or incomplete in different regions, Dr. Llopiz says.

"It is much better to include Mexico in a trial from the start for rapid patient recruitment than at a later stage in a trial," she says.

Patient Perspective

Even with all of its advantages, there still remain challenges within the Mexican healthcare sector due to changing demographics and an evolving epidemiological profile, with an increasing incidence of obesity-related diseases, including hypertension, diabetes, and heart disease, Espicom notes.

Dr. Hurley says there is a strong emphasis on type 2 diabetes clinical trials in Mexico because of the frequency and devastating health consequences of the disease.

With more than 70% of the population considered obese, related chronic diseases are a major health concern. These two poles of the epidemiology make Mexico a very interesting area for clinical research.

Ms. Kocak says Mexico also has a high rate of incidence of other diseases, such as infectious diseases including, flu, gastrointestinal infections, and urinary tract infections.

Both the government and the pharma/biotech industry are looking to address these health concerns, Ms. Sánchez y Oldenhage says.

One example is peramivir, which is a neuraminidase inhibitor used to treat influenza, specifically H1N1.

"Peramivir is the only drug in its class that is delivered intravenously," Ms. Kocak says. "Our partner, BioCryst, the manufacturer of peramivir, started Phase III studies worldwide in 2009. There are 11 centers in Mexico that are participating in this ongoing study. The Mexican authorities' responsiveness and support of this trial helped in the effort to save lives as this study was initiated during the H1N1 crisis."

To date, however, Ms. Sánchez y Oldenhage says public purchases have focused mainly on generics, due to government budget constraints, adding that price and volume can at times override quality and cost-effectiveness.

"We are working closely with the National Basic Formulary institutions to ensure pharmacoeconomics is a central piece of decision-making," she says.

There are also a number of fragmented and different reimbursement systems that complicate the process for both the industry and the patient, Ms. Sánchez y Oldenhage says.

As a result, institutions often prefer generic medicines.

"Unfortunately, in some cases today, decisions do not take into account the true value of innovative medicines, which can help to avoid complications and increased hospital visits, and can therefore contain hospital costs in the long term," she says. "For example, Amgen has done considerable work with biomarkers — such as KRAS — to help identify the right patients for the right treatment."

Ms. Kocak notes that because most private product sales are out-of-pocket expenses for patients, consumers are central to the decision-making process.

"Of course, ultimately the physician is the decider for what product and therapy the patient should receive, but the consumer has a clear say in which brand he or she will actually pay for," she says. "Therefore, marketing must take into account the physician, the pharmacist, and the patient."

Innovation and creativity in marketing are also important and required for success.

"One of our brands, Rocephin, received an award for its 2010 promotional campaign from the marketing division of Universidad Anahuac, one of the biggest universities in Mexico," Ms. Kocak says.

Regulatory Demands

For the past few years, companies have been facing lengthy delays in approval of their products from COFEPRIS.

Regulatory hurdles — such as limits on market access, lengthy approval processes, and public budgetary constraints — are particularly prevalent when it comes to innovative products, Ms. Sánchez y Oldenhage says.

"These cost constraints have caused a high penetration of generic medicines and limited access to innovative treatment options in the public sector, meaning many at-risk patients do not have access to important treatment options," she says. "Often innovative medicines are only launched in the private market; launching these products in the public sector is a lengthy process ranging from one to three years, and even once included on the formulary, many institutions may not purchase them."

Ms. Kocak says companies have also found it difficult to get access to the reviewers for open communication to ensure an efficient process.

"Recently the agency has changed some of its practices to speed up the overall process and is still defining the framework to make it even more efficient," she says. "The whole in-

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dustry is very excited about these changes and we are already seeing some of the fruits of this labor."

The government's position on "linkage" and data protection has also been a challenge, Ms. Sánchez y Oldenhage adds.

"Despite being a mechanism that has been in effect since 2003, whereby the Ministry of Health and the Patent Office (IMPI) work together, there still needs to be effective implementation on linkage," she says. "IMPI and COFEPRIS need to be aligned with numerous court precedents to establish a broader scope of patent linkage for the full range of pharmaceutical patents. Full linkage will avoid resorting to costly and long litigation proceedings for the publication of formulation and use-type patents."

Ms. Kocak notes that Mexico is a signatory to the NAFTA agreement, which aims to ensure patent laws are respected.

Ms. Sánchez y Oldenhage agrees that the number of free trade agreements Mexico has in place does make it a competitive market. She adds that the implementation of obligations under NAFTA and TRIPS is still pending. She notes that the industry is working closely with COFEPRIS and government institutions to have specific regulations to guarantee these obligations for test and other data submitted by pharma member companies to prove safety and efficacy.

"We need to prevent unauthorized use by third parties seeking marketing approval for generic versions of innovative products," Ms. Sánchez y Oldenhage says.

"As an industry, we are working very closely with the government to ensure the enforcement of regulations, elimination of violations, and the aggressive pursuit of forfeit products," she continues. "The current framework is acceptable, but there is also opportunity for improvement."

Mexico Healthcare Fast Facts

Population	109.6 million
Life expectancy at birth	76
Total expenditure on health per capita (2009)	$846
Total expenditure on health as % of GDP	6.5%
Per Capita Income	$14,340

Source: World Health Organization.

Last year, COFEPRIS raised the bar on product approvals.

For drugs to be marketed in Mexico, Phase I to IV clinical trials must be conducted to prove their safety and efficacy, Dr. Llopiz says.

"All medicines have to have standard documentation and a bioequivalence study conducted with Mexican people," Ms. Kocak says. "All medicines previously approved had to resubmit their regulatory files with the required supporting data. These efforts aim to increase the quality of medicine in the Mexican market."

Dr. Llopiz says one of the main concerns of the Ministry of Health in reference to pharmaceutical companies wanting to enter the marketplace in Mexico is their capability in manufacturing quality drugs.

The Ministry of Health is focused on making sure that all new drugs are tested through serious clinical research and in Mexicans, and it has been very strict with companies trying to introduce drugs or devices to be marketed in Mexico.

"All pharmaceutical companies wanting to establish an office or plant in Mexico must comply with the rules set forth in the General Health Law of Mexico," she says.

COFEPRIS is working diligently with other organizations such as AMEIFAC (the Association of Medical Specialists in the Pharmaceutical Industry), CANIFARMA (National Pharmaceutical Chamber of Commerce), AMIIF (Mexican Association of Industries in Pharmaceutical Research), legislative bodies, and other organizations to reach consensus in formulating new ideas and strategies for the betterment of drug testing and marketing.

> **"Mexico is an attractive pharmaceutical market with a steadily growing middle class, with 60% to 70% of medical spending being direct pay."**
>
> **AYSE KOCAK** / moksha8

She notes, however, that Mexico provides one of the shortest timelines in Latin America for protocol review and authorization in clinical research.

"Most ethics committees review protocols for trial conduction are within two to three weeks," she says. "The Ministry of Health has shortened its timelines in reviewing submissions, which allows for global trials to start earlier and in the end, saves time in conducting trials and marketing drugs in Mexico." PV

EXPERTS

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