Kim Ribbink

Olá BRAZIL: *Latin America's* BIGGEST Market Accelerates

With every passing year, the pharmaceutical industry becomes more global in its outlook and reach. In recognition of our shrinking world, PharmaVOICE is taking you on a journey across the globe. Our first stop is Latin America's largest market, Brazil.

Brazil is familiar territory to the pharmaceutical industry, which has been operating in the country for decades. Today, with its stronger economic outlook, political stability, and a public healthcare system that gives all residents access to basic treatment, Brazil offers great expansion opportunities to companies.

According to a report from Cutting Edge Information, Emerging Markets Clinical Development Series, Brazil is on the verge of emerging into a world power, perhaps even surpassing the other BRIC countries (Russia, India, and China). It is already the largest market in Latin America, representing 38% of the market compared with 21% for Mexico, 16% for Venezuela, and 9% for Argentina.

Brazil's healthcare spending represents almost 8% of GDP, and of its population of nearly 200 million people, 20% have private insurance and make use of both private and public-health services.

This means growth in pharmaceutical spending, and a report prepared by Osec, a Swiss business network, finds that demand for pharmaceutical products is growing 10% per year.

But as Cutting Edge analysts point out, companies also need to create market access strategies, either through risk-sharing agreements or pricing schemes for the government or by partnering with local companies to develop branded generics.

Near and Far

Brazil has established a network of homegrown pharmaceutical entities. According to Osec, there are 270 private and 20 state-owned pharmaceutical laboratories in business, and many have started to make their mark. This growing local business has been driven by the government's industrial policy, enhanced regulations, and the introduction of generics. The government supports investments through special credits and encourages innovation through subsidies and strong IP protection, Osec notes.

For example, in May 2005, an anti-inflammatory drug from a native plant known as maria-milagrosa received the approval of the Brazilian regulatory authorities. Developed by Brazilian pharmaceutical company Aché Laboratórios Farmacêuticos, Acheflan, which is available as a cream and aerosol, was the first medicine to be entirely researched and developed in Brazil.

Leading Brazilian Pharma Companies

- Aché
- Americano
- Biolab
- Cimed
- Cristália
- EMS
- Libbs Farmacêutica
- Mantecorp
- Moksha8
- União Química

Source: Espicom. For more information, visit espicom.com.

The country is also home to a growing number of small biotech companies, predominantly clustered around public universities and research centers.

In addition, numerous global pharmaceutical companies are using Brazil as a production platform, and there are small, but growing R&D opportunities in the country.

"The government and private industry are starting to make significant investments in R&D to strengthen capabilities by working together with Brazilian universities," says Alex Howarth, chief business officer of Moksha8, a specialty pharmaceutical company with full commercial operations in Brazil and Mexico.

However, Nilton Paletta, president of IMS Health, Latin America, says development remains fairly confined, though the country is working to catch up.

"Aspects such as the country's ethnic diversity do foster clinical research, and national companies have been trying to improve their R&D investments to face the multinational companies," Mr. Paletta says, adding

> An important aspect of the market is promotion at the point of sales: pharmacists have a large influence at the final stage of purchase.
>
> **NILTON PALETTA** / IMS Health Latin America

> Brazil has a robust infrastructure of qualified physicians experienced in conducting clinical trials.
>
> **ALCIONE BRAGA** / Kendle Brazil

Brazil: Healthcare System Fast Facts (2005–2009)

Population	200 million
No. 1 cause of death	Ischemic heart disease
Average life expectancy	72
Total healthcare spending	$74.6 billion
Pharmaceutical market	$15.4 billion
Healthcare spending per capita	$371
Out-of-pocket spending per capita	$114
Government Healthcare budget	$22.9 billion
Spending for primary health	$3.5 billion
Spending for family	$2 billion
Health program Physician Density (per 10,000 people)	12
Percentage of patients with private insurance	21.7%

Source: Cutting Edge Information.
For more information, visit cuttingedgeinfo.com.

that there is still a gap with local R&D. "However, local companies compete not for development capacity, but for distribution and promotion where they are very effective, showing higher performance than multinational companies."

Pharmaceutical companies in the country target a broad range of therapeutic areas. For example, AstraZeneca's portfolio of medicines in Brazil encompasses the oncology, respiratory, cardiovascular, gastrointestinal, and infection therapeutic areas. The company also intends to launch select branded generics and local in-licensed products in Brazil.

Patients Please

For companies seeking to investigate products in Brazil there are many reasons to conduct clinical trials in the country. Among these are expedited enrollment, good patient retention, and high-quality data, says Alcione Braga, general manager of Kendle Brazil.

"The country provides a robust infrastructure of qualified physicians experienced in conducting clinical trials along with a strong history of producing quality clinical development work," Ms. Braga says. "In fact, Brazil has never had an FDA inspection with a negative result."

Kendle has established a strong network of qualified sites experienced in handling every phase of clinical development and is seeing greater interest from customers in the wake of an increased focus on global patient recruitment.

Factors including sustainable growth, economic stability, improved income distribution, and an aging population are leading to growth in urban diseases, such as diabetes, hypertension, high cholesterol, etc., as well as neurological diseases, such as Parkinson's disease and Alzheimer's, Mr. Paletta says.

"Companies with R&D capabilities in the country are launching new medicines with a high value in therapeutic categories, such as urban diseases and neurological diseases," he says.

To reach the population that has access to medicines because of the improved economic environment but that doesn't have the money to buy more costly drugs, pharmaceutical companies are increasing their investments in producing generics, Mr. Paletta says.

In recognition of the need for a blend of high-quality brand products and branded

> “The need to attract and retain talent in Brazil is critical for us.”
>
> **ALEX HOWARTH** / Moksha8

generics, Moksha8 has partnered with Watson to commercialize a portfolio of branded generics and with Roche and Pfizer to provide high-quality branded products to physicians and patients. An example is in the CNS area.

“Increased identification and diagnosis of CNS disease is resulting in the growth of key products, such as Lexotan, to treat anxiety disorders,” Mr. Howarth says.

One thing to take into account, Mr. Paletta notes, is that products purchased at the pharmacy are an out-of-pocket expense, while those received at a hospital are paid for by the government.

That’s because for patients in hospitals, the law requires the government and private insurance companies to pay for treatment.

“High-cost treatments, such as for HIV, multiple sclerosis, among others, are paid for by the government,” Mr. Paletta says. “However, retail consumption is almost entirely paid for by patients.”

AstraZeneca executives say when they think about how to ensure patients in Brazil have access to their medicines, the company looks first at the market dynamics.

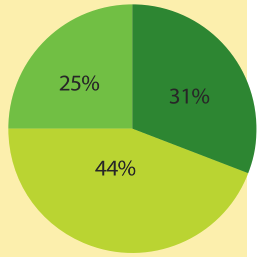
Of particular importance, the company says, is the growth of the middle class, given that most medicines are still purchased by patients paying out of their own pockets.

According to an AstraZeneca spokesperson, previous experience shows that patients in Brazil who can afford to are willing to pay the premium for innovation and a guarantee of quality associated with multinational companies.

While public reimbursement is limited, the government has begun targeted increases in spending on healthcare, including pharmaceuticals, and certain chronic and debilitating conditions are now covered in full.

Brazil’s Health Spending by Sector (2005)

- Out of pocket
- Government
- Private Insurance



Source: Cutting Edge Information. For more information, visit cuttingedgeinfo.com.

In addition to GDP driving growth in the retail channels, the government is projected to continue growing its spend on healthcare, which will broaden access to the pharmaceuticals market.

Maneuvering Around Obstacles

Companies seeking to market original products do face some barriers. To keep down rising healthcare costs, the government emphasizes the use of generics over branded products, regardless of whether these are patent protected. Moreover, Cutting Edge points out, registering an original product can take 12 to 14 months, several months more than registering a generic. The registration fee for generics is also discounted by Agência Nacional de Vigilância Sanitária (ANVISA), or the National Health Surveillance Agency.

In terms of patent protection, according to Emerson Ferreira Queiroz, Ph.D., scientific manager at Aché, Brazil, who was quoted in recent article, this does not allow for patents to be issued to pharmacologically active compounds that are isolated from nature, only for the process of obtaining the molecule and for its application. Dr. Queiroz also points out that Brazil’s regulators have not agreed on what is classifiable as chemical prospecting and there is no national policy on traditional knowledge and compensation.

For the most part, those working in the market say the challenges are much the same as those faced in any other high-growth market.

“The need to attract and retain talent in Brazil is critical for us,” Mr. Howarth says. “As the market is growing, employees are increasingly seeking opportunities for career growth and development. Creating a climate that is challenging and achievement-driven is key to retaining our employees.”

In terms of promoting a product in the country, direct-to-consumer advertisement is only permitted for OTC products, Mr. Paletta says.

“Prescription-bound pharmaceuticals are promoted through pharmaceutical representatives, congresses, and specialized publications,” he says. “Another important aspect of the market is promotion at the point of sales: pharmacists have a large influence at the final stage of purchase.” PV

Emerging Market Lineup

- **FEB.:** China
- **MARCH:** India
- **APRIL:** Russia
- **MAY:** South Korea
- **JUNE:** Turkey
- **SEPT.:** Mexico
- **OCT.:** South Africa

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EXPERTS

ALCIONE BRAGA, R.PH. General Manager, Kendle Brazil, a global CRO providing a full range of early- to late-stage clinical development services for the biopharmaceutical industry. For more information, visit kendle.com.

ALEX HOWARTH. Chief Business Officer, Moksha8, a Sao Paulo, Brazil-based pharmaceutical company that was established in 2007 with the goal to become a leading pharmaceutical company in Latin America by commercializing high-quality therapeutics. For more information, visit moksha8.com

NILTON PALETTA. President, IMS Health Latin America, a provider of market intelligence to the pharmaceutical and healthcare industries. For more information, visit ims.com.

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Kim Ribbink

CLINICAL Perspective

There is a severe shortage of patients for clinical trials in the major markets of the United States and Europe, yet according to Value on Insight (VOI) Consulting, almost 52% of all newly registered industry sponsored trials in 2008 had at least some U.S. activity, the same as in 2006.

Nevertheless, there is increased interest in emerging markets, and in particular the BRIC nations of Brazil, Russia, India, and China. This is not without its challenges. According to a report from Cutting Edge Information, Emerging Markets Clinical Development Series, questions of quality, regulatory guidelines, intellectual property laws, culture, and cost plague clinical development teams.

Brazil, with its population of almost 200 million people and varied ethnic groups, represents a gold mine to research companies. With a well-established clinical infrastructure in place, Brazil is fast becoming a go-to destination for clinical trials. According to Cutting Edge, if key concerns such as the regulatory environment and intellectual property protection can be resolved, Brazil should see an influx of new trials from large pharmaceutical companies as well as interest from small and midsized companies that have not yet ventured much beyond their borders.

One key advantage is that Brazil is recognized as trustworthy and ethical.

The disadvantage of operating clinical trials in Brazil is minimal cost savings and a longer timeline due to hold ups in regulatory authorization. Companies planning to run clinical trials in Brazil are advised to be well-prepared to handle regulatory requirements before trials get under way.

This is a major task, since pharmaceutical and device companies looking to run clinical trials in Brazil must deal with three key regulatory bodies: Agência Nacional de Vigilância Sanitária (ANVISA) — the Competent Authority; Comissão Nacional de Ética em Pesquisa (CONEP) — the National Ethics Committee; and the local ethics committees. The country is working to streamline the regulatory process, however, and in 2008 passed Resolution 39 whereby the ANVISA leg — monitoring and ensuring sanitation in the production and marketing of pharmaceutical products — and the CONEP leg — the ethical watchdog for human research — run in parallel.

Experts say there is pressure on the industry and all players to improve this timeline with the goal of reducing review times in the coming year.

In addition, CONEP requires a medical and ethical rational for protocols with placebo arms before approval, which increases the time it takes to get regulatory trial approval, according to Kendle experts.

Patients also have to be given access to study medications after the completion of the trials as well, based on investigators' judgement.

Pharmaceutical companies find that outsourcing at least part of their clinical operations in Brazil makes economic sense. According to Cutting Edge, with a local CRO industry that has proven itself through successful trials and random auditing, and the growth of large, multinational CROs in the country, companies are more comfortable outsourcing more of their trial operations. Companies, however, still need to investigate operations in the region before beginning contract negotiations. PV

Global Fast Facts

Europe

In 2009, the adult flu vaccine market in Europe reached new heights due to products developed to address the H1N1 flu pandemic. The market posted almost $1.6 billion in revenue, up 81.4% from the previous year.

Source: Kalorama Information, European Vaccine Markets. For more information, visit kaloramainformation.com.

The European gastric band device market is projected to be valued at $41 million in 2010, with revenues doubling by the end of 2015. Increased awareness of health issues surrounding obesity, coupled with an expanding patient pool tied to rising European obesity rates, is expected to drive significant growth in the gastric band market over the next five years.

Source: Millennium Research Group, European Markets for Laparoscopic Devices 2011. For more information, visit mrg.net.

Latin America

The eight primary pharmaceutical markets in Latin America are worth an estimated $50 billion, representing 474 million people with a GDP of $3.4 trillion in 2008. The region is better prepared to face global instability than in the past, but economic growth is expected to slow in 2009 and 2010 after a recent period of remarkable growth.

Source: Espicom Healthcare Intelligence, The Outlook for Pharmaceuticals in Latin America. For more information, visit marketresearch.com.

Three key market trends are affecting manufacturers in Brazil

THREE FUNDAMENTAL SHIFTS IN BRAZIL'S MARKET LANDSCAPE

1 Commoditization in retail

- Similarly to the rest of the world, innovation is declining in the retail segment
- Outpatient therapies are being addressed by commoditized drugs, notably unbranded generics
- Generic players are growing stronger, while innovators seek opportunities in niche segments or turn to careful investment in mature lines with strong brands (ex. Sanofi, Novartis, MSD, Pfizer)

Generics (branded and unbranded) winning

2 Sophistication of payers in non-retail

- On the public side, the creation of a economic evaluation agency (CITEC) became a technical and political barrier of product inclusion in funding programs
- On the private side, payers are becoming more sophisticated, tending to avoid over-expenditure on complex therapies

Cost-effectiveness and good price strategy is unavoidable

3 MNC portfolio shift to non-retail

- The unmet medical needs in complex diseases favors innovative nonretail drugs, mostly developed by MNCs
- Commoditization in retail, on the other end, drives the migration of the MNCs to the non-retail arena, where technical differentiation of new products prevails over commercial aggressiveness of local companies

Multinationals competing in the non-retail arena

Source: IMS Health Consulting 2009. For more information, visit imshealth.com.

Brazil's Pharmaceutical Industry

- With total revenue exceeding $26 billion per year, **Brazil is an emerging pharmaceutical market**: Demand for pharmaceutical products grows about 10% per year. Thanks to better income distribution and social programs, more and more of Brazil's 191 million people are getting access to health services and medicines.
- **There are 270 private and 20 state-owned pharmaceutical laboratories in business.** Multinational companies (including Novartis and Roche) are using Brazil as a production platform, exporting to Latin America, North America, and Europe. At the same time, the domestic laboratories, both private (EMS, Aché, Eurofarma) and public (Fiocruz and Butantan), have gained sophistication and market share in recent years.
- The rise of domestic laboratories was mainly driven by three factors: **the Brazilian government's industrial policy, new regulations, and the introduction of generics**.
- **The development of a national "health industry complex" is a priority for the government. It supports investments and exports by providing special credits ($300 million per year),** through the Profarma program, operated by the national development bank BNDES. It also stimulates innovation through subsidies and a solid IP protection.
- **Regulations and technical standards enforced by the national health surveillance agency (ANVISA) keep the industry under pressure** to adjust their plants in Brazil to the state of the art and thus to improve its competitiveness.
- **Growing demand for generics offered another growth opportunity for domestic laboratories over the past decade.** They came to dominate this market segment and are expanding and modernizing production capacities.
- **The pharmaceutical industry in Brazil has increased its production by 50% within the last five years.** While overall capacity usage stands at 74% (2009), foreign and state-owned laboratories present relatively high levels of idle capacity, as some of their production lines are outdated. They sometimes resort to manufacture outsourcing.
- **The demand for pharmaceutical production machines is estimated in the range from $50 million to $100 million per year.** Almost all process equipment is imported; packaging machines, however, are manufactured in the country.
- **Brazil still relies on foreign raw materials and imports more than $2 billion worth of active pharmaceutical ingredients per year, since there are only a few local producers.** It is a net exporter of excipients, though.
- Research and innovation are concentrated at public institutions. **There are more than 100 small biotech companies, most of them located in clusters linked to public universities and research centers.** Private laboratories spend a small (6%), but growing part of revenue on R&D. They still lack infrastructure for preclinical tests. Certain toxicology studies and special chemical tests are not available in Brazil yet.

Source: Osec Business Network Switzerland. For more information, visit osec.ch.