



BRAZIL HEALTH CARE SYSTEM

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Market Brief: Brazil Health Care System

Overview

The healthcare market in South America has room for strong and steady growth. The continent's growing middle-class can afford good healthcare, but the region is still marked by profound national and social inequalities. South America's governments have been making strenuous efforts to curb their rising healthcare bills, where two trends are particularly clear: the decentralization of healthcare management and the growing participation of the private sector. Many of those countries have been introducing mandatory generic prescribes and capped drug prices. Intellectual property regime is still working weakly on the area.

With the 12th largest economy in the world, Brazil's GDP for 2006 is estimated at near US\$ 1 trillion, with a per capita income is of \$8,400 (PPP) and a population of nearly 190 million people. The local currency is the Brazilian Real, which has appreciated by near 44% against the U.S. Dollar in the last three years, as seen below:

- R\$3.50 : US\$1
- Today - R\$1.95 : US\$1 (approximately)

Brazil is the world's 10th largest market for drugs and second largest in Latin America after Mexico. The Brazilian market for health care has great potential, due to the fact that 9% of the Brazilian population is currently over sixty years of age, a demographic segment that consumes significantly more health care services than other age groups

Government Action

Today, the Brazilian government and its citizens are combating the high prevalence of deadly and costly diseases, including HIV/AIDS, tuberculosis and diabetes. Regrettably, the investment in healthcare is not enough to meet the challenges they pose.

Fiocruz (Oswaldo Cruz Foundation) recently released data comparing Brazil's per person public health expenditures with those of other South American countries. In Argentina and Uruguay, the amount spent per citizen is US\$ 362 and US\$ 304, respectively. In Brazil, the amount is just US\$ 212 per citizen. This is approximately 10% of what is spent per year, per citizen, for public health in Europe, Japan and Canada.

According to data from the Brazilian Ministry of Health, an estimated 600,000 Brazilians live with HIV today. The mortality rate in 2003, the last year for which statistics are available, was 2% higher than in 2002, and the incidence is increasing among women.

Today, all Brazilian citizens can have access to monitoring tests and therapeutic medication, supplied by the government. They go to the public services and, according to clinical criteria, receive the necessary treatment. This is not sufficient.

The Brazilian STD/AIDS Program is prepared to assist approximately 200,000 people, according to the last AIDS Epidemic Update by UNAIDS in December 2005. The government touts the program as a model for other developing countries, and while it has taken a tremendous step toward reducing the number of deaths, there is still a considerable way to go. Specifically, the program could place more focus on prevention.

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A highly prevalent disease, tuberculosis has infected an estimated 50 million Brazilians, with approximately 100,000 new cases and 6,000 deaths occurring each year. Significantly, 25.5% of Brazilian patients with HIV/AIDS are co-infected with tuberculosis, which often goes undiagnosed.

Brazil, in line with the international community, aims to detect 70% of tuberculosis cases and achieve an 85% cure rate. To achieve this goal, the government supplies diagnostic tests and medication. Today, Brazil ranks 15th among the 22 countries responsible for 80% of the total TB cases worldwide.

As with HIV/AIDS and tuberculosis, effective management of diabetes can only be achieved with timely patient access to appropriate diagnostic tests and monitoring technologies.

Brazil has joined 191 other countries in signing the Millennium Declaration, approved by the United Nations in September 2000. Three of the Declaration's eight major development goals are healthcare-related: reducing child mortality; improving maternal health; and combating HIV/AIDS, malaria and other diseases. We have an opportunity to focus on these problems and implement policies that stimulate productivity. By studying the impact of disease on national health in comparison with other countries, we will have an opportunity to better understand the linkage between early detection of disease, timely delivery of quality healthcare, and the competitiveness of our people and nation.

Privatization, deregulation, and removal of barriers to competition have led multinational companies to dominate the pharmaceutical industry with a 70% share, while domestic companies generally concentrate on selling generic medicines. The factors that prevent the market from progressing are the high prices of the drugs, interest rate fluctuations, and increased R&D costs.

The SUS program – *Serviço Unico da Saude* – provides free universal health coverage to all Brazilians. It is largely decentralized, with over 90% of the Brazilian municipalities partially managing their own networks and the remaining 10% having complete autonomy. Three-quarters of the population relies exclusively on the SUS and the remainder uses the “supplemental” medical care system. Despite the government's far-reaching and free health coverage, the United Nations estimates that 50% of the population is still unable to meet its medication needs. Government efforts consist of developing new programs to reach the poorest, but none has proven largely effective until now. Currently, there are more than 7,800 hospitals in the country to serve the needs of its entire population. To meet the growing demand for healthcare, investment in both public and private sectors has been increasing.

Hospitals:

- Total: 7,800
 - Public: 2,500
 - Philanthropic: 1,800
 - Private: 600
 - Universities: 200
 - HMO: 2,600

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- Approximately 810,000 beds

About 30% of the hospital equipment and medical devices are imported from Japan, Germany, and the United States. Numerous medical devices – plastic tubes used for special applications, surgical gloves, syringes, etc. – have been exempted from import duties. Telemedicine and home healthcare sectors are other emerging sectors in the healthcare industry.

The Government is the largest buyer of healthcare goods and services, with a budget of approximately \$5.2B (2005). Selling to the government is possible, but it is quite challenging without a local partner or significant in-country presence.

Although the government has been criticized for being unable to bring about socio-economic development, President Lula has shown commitment to bringing about reforms. This has helped in keeping consumer and business expectation indices on the positive side. The new macroeconomic reforms have gone a long way in making Brazil a preferred market. Privatization, deregulation, and removal of many types of barriers to competition have led to many multinational companies setting up a base through Greenfield projects and acquisitions. Trade and investment policies are favorable to private investments and certain capital goods are exempt from custom tariffs and other forms of taxes and duties. Brazil is a member of the Southern Cone Common Market (MERCOSUR), and has greater access to other countries in the region such as Argentina, Paraguay, and Uruguay. Since the inception of the MERCOSUR, not only has Brazil experienced increased investment, but it has also reduced tariff rates on several items. Patience and financial resources are necessary to respond to frequent legal challenges and bureaucratic delays. However, it's clear that the opportunities presented by Brazil's market can outweigh the risks.

ANVISA (the National Agency of Sanitary Surveillance), an agency of the Ministry of Health, is the Brazilian equivalent to the US FDA. Any US firm seeking to enter the Brazilian market must register its products with ANVISA. Registration takes 3 to 18 months, and a local presence or partner is needed. For controls registration, commercialization and price, the ANVISA has a website at www.anvisa.gov.br/eng/drugs/registration.htm.

Different approaches can be taken to access the Brazilian market. If a foreign company decides to establish a local presence, adequate preparation must be made. The option of having a local representative presents the advantages of an intimate knowledge of the local environment, regulatory, medical, and cultural issues. A company can also pursue exclusive distribution, but it is essential to consult a local lawyer or adviser before signing a contract – which lasts for a minimum five years – with any agent-distributor. Other options such as joint ventures or even a company's sales office are good possibilities. The Latin American business culture is largely based on personal relationships. One can also find very sophisticated business environments, such as in the state of Sao Paulo. It is vital to visit the market and current trade shows and to attend one-on-one meetings.

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Import Taxes

One should note that the taxes applied on imports in Brazil are high. Cascading tax (tax over tax) method applies on manufactured goods in Brazil; if the import duties go from 0 to 20%, the tax burden could reach up to 60% FOB.

Drugs & Pharmaceuticals

Brazil's pharmaceutical market is the 14th largest in the world, the second largest in Latin America, and is among the top five countries in units sold. An expansion of Generic Drugs is expected from 0% to 15% in 6 years (estimated to reach 40%), with prices 35% to 55% lower than branded drugs. Local generic drug manufacturers operate at world-class levels. Good opportunities are presented on exporting raw materials to Brazil (85% used in the production of generic drugs are imported). Also, foreign companies supply 70% of the market (not direct sales to government). A major demand for equipment and services associated with the construction of pharmaceutical manufacturing plants is remarked. The market for medicines is approximately US\$ 9.3 billion. Imports represent a large share of the market: US\$ 2.4 billion, with 20% (\$480 million) being imports from the United States.

Significant import opportunities include:

- Equipment
- Raw-material
- Active ingredients for Generic Drugs
- Chronic Disease Treatment Drugs
- Modern Life drugs

Price is controlled once a year and patents can have a delay of 7 years. The government's HIV/AIDS program provides its patients with a free drug cocktail of 14 medications, four of which are imported.

All taxes applied are expected to decrease, in order to make drugs more affordable for the population, causing this market to likely increase dramatically. The current imports portfolio consists of:

- Medical equipment and devices
- Dental equipment and products
- Radiological and diagnostic imaging equipment
- Laboratory equipment

Products & Services:

US\$ millions	2004	2005 est*	2006 est*
Market Size	\$1.810	\$2,172	\$2,389

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Local Production	\$1,148	\$1,604	\$1,964
Exports	\$317	\$382	\$475
Imports (Global)	\$979	\$950	\$900
Imports from U.S.	\$412	\$400	\$380

The market size for equipment is estimated at \$1.8B, where imports represent \$1.05B. The U.S. represents 50% of that number. Import possibilities include home health care support products, high technology products, dental products, x-ray, scanners, pacemakers, artificial kidneys, tomographers and others.

Natural Products

Brazil has the world's largest reserve of biodiversity, a very promising source of material for the discovery of new medicines. The market has been increasing at a rate of 20% per year, with good possibilities for natural supplements, vitamins and herbs. (Note: even natural products must be registered with ANVISA).

Trade Shows

Hospitalar Trade Show

The event takes place annually in June in São Paulo.

Expo Center Norte

São Paulo, SP - Brazil

www.hospitalar.com

Hospitalar is an annual International Trade Show for products, equipment, services & technology for hospitals, health clinics & laboratories. It is the largest and most important medical trade show in Latin America and provides a unique opportunity to become acquainted with new products, medical devices, healthcare technologies and services for hospitals, health clinics and laboratories. The trade show features products from leading state-of-the-art medical technology to practical equipment, with a wide variety of solutions in quality and price. Hospitalar showcases hundreds of Brazilian and international exhibitors, aiming to launch products/services and meet potential new clients and partners. On its last edition, it featured over 1,000 exhibitors from over 32 countries and attracted 70,000 visitors from more than 51 nations.

Four thematically related trade fairs are held concurrently within Hospitalar:

- Diagnóstica 2008 (Clinical Analysis and Pathology),
- Hospfarma 2008 (Pharmacy and Drugstores),

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- Reabilitação 2008 (Assistive Devices)
- OdontoBrasil 2008 (Dentistry).

FCE Pharma Trade Show

The event takes place annually in May in São Paulo.

Expo Center Norte

São Paulo, SP - Brazil

www.fcepharma.com.br

The FCE Pharma and Cosmetique is the only exclusive event of technology for the pharmaceutical industry in Latin America. It has broken through as the most important meeting point among the industry. With the industry pole focus on São Paulo and Rio de Janeiro / Brazil, FCE Pharma is the opportunity to expand sales, to change the market and to do new business in Latin America. Moreover, with the appreciation of the Brazilian currency against USA Dollars and EURO, all foreign products became much more competitive. Stimulated by this great opportunity, international companies are considering Brazil as a very important market worldwide. FCE Pharma is considered by the whole industry to be the biggest development platform for new products. On display: raw materials, packing, equipment, outsourcing and services.

What We Can Do for Massachusetts Companies:

Massachusetts companies interested in entering South American markets or attending/visiting local trade shows, please contact the Massachusetts South America Office in Brazil at massbrazil@massbrazil.com.br.

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Resources

- Anvisa: National Agency of Sanitary Surveillance - www.anvisa.org.br
- USCS: Trade Reports www.focusbrazil.org.br
- Brazilian Ministry of Health: www.saude.gov.br