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Brazil: Big Dancer Takes the Floor

With its huge market of 186 million people; its current position as the largest pharma market in Latin America, with strong growth projected; the influx of foreign and local investment into its pharma market; its reputation for conducting high-quality clinical research; and its incredible biological diversity, Brazil seems poised to become pharma's next giant. However, Brazil must overcome several challenges to assume this mantle.

Credit: Antonio Scorza/AFP/Getty Images ©



Bel Noronha, great-granddaughter of Helio da Silva Costa, designer of the famous statue Christ the Redeemer poses in front of representations of the monument.

“ Between our business and our health, we are going to take care of our health.”

Reelected President Lula da Silva, long an outspoken advocate for the welfare of Brazil's marginalized citizens, spoke unambiguously this spring about one of the most vexing problems facing his country: lack of access to healthcare and medicines for most citizens.

According to his predecessor, former President Fernando Henrique Cardoso, “Brazil is not a poor country, it is an uneven

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49% of the population has no access to medicines and another 36% only have limited access

country.” Indeed, Brazil ranks tenth among the world's leading economies but 74th in terms of social development. The main reason for this discrepancy is the concentration of wealth in the hands of a small percent of the population: “This discrepancy is what is making us lag behind. Brazil needs to improve its income distribution and its healthcare system,” says Luiz Eduardo Violland, country manager for Nycomed Pharma. A whopping 49 percent of the population have no access to medicines and another 36 percent have only limited access to pharmaceuticals. “These numbers are the evidence that we need to improve our healthcare system and put together a new healthcare model. Although these figures are not, what we could call, very motivating, the recent positive aspect is that our new Minister of Health, Jose Gomes Temporão, is very willing to work hard and improve the situation. He has already presented 22 projects aimed at reforming the healthcare system, and this really encourages us,” Violland added.



Jose Gomes Temporão, Minister of Health

The Plea for a Universal Health System

Although Brazil's constitution guarantees access to health care for all citizens, thus any patient today can go to court and ask a judge to legally force the government to pay for a certain treatment or product. But in fact this process is very inefficient in its application, inadequate from a public healthcare point of view, and probably subject to abuse. “Our industry and the Ministry

of Health are working on a more efficient process to include new technologies, new products in the government's existing access programs. By doing so, we will hopefully avoid patients having to go to court in order to obtain their treatments,” says Philippe Crettex, CEO of Pfizer in Brazil. “The dialog between the authorities and our industry is not always easy but I think that at the end we both have the same objective, to improve healthcare for all,” he added.

Wealthy individuals with purchasing power in cities like Sao Paulo, Rio de Janeiro, and other major urban centers may be interested in innovative products but the rest of the population craves basic medicines. “There is so much need for basic medicines that this overshadows any selling of innovation in this country,” Volker Bargon, general director of Boehringer Ingelheim Brazil commented. “It is nice to have innovation, but we still have high infant mortality. I think we are, quite honestly, a bit disconnected from the market reality, being innovators and being solely focused on innovation.”

Controlling the indiscriminate dispensing of all types of medicines at the country's more than 56,000 pharmacies is also a great challenge for Brazil's healthcare system. In response, Anvisa (Brazil's FDA) has launched a program called Farmacias Notificadas and Hospital Sentinela. It also announced plans to conduct a survey of the country's 56,000 plus pharmacies and drug stores to deal with the sale of “black label” controlled substances and cut down on illicit trafficking. The move is significant as it represents a major effort to exert control over Brazil's sprawling retail pharmacy industry and could put poorly run players out of business. In the long run, instilling greater order in this sector would not only make statistics on sales more reliable but also help deter the illegal and unregulated trade that presently distorts the market.

DEFINITIONS

"Reference" drugs	These are usually innovative drugs whose effectiveness, safety and quality have been proven scientifically at the time of their registration with the Ministry of Health. They are drugs that generally have been a long time on the market and which carry a well known brand name.
Generic (non-branded generics) drugs	A generic drug is one which contains the same active substance in the same dose and pharmaceutical form, and is administered in the same way and with the same therapeutic dosage as the reference drug. A generic can be totally interchangeable with the latter. Generic drugs display on the package “Generic Drug - Law 9.787/99” and are identified with a large letter “G” in blue, printed over a yellow emblem.
"Similares" or branded generics	Similar drugs are those that contain the same active agent, the same concentration and pharmaceutical form, and are administered in the same way and with the same dosage and have the same therapeutic result as the reference (or branded drug), but which do not have the same bioequivalence as the proven reference drugs.

Source Anvisa



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In 2001 the Brazilian government reimposed a strict price control policy for prescription drugs

Government Price Controls

From 1994 until 2001, government price controls for pharmaceuticals were lifted. Then in 2001 the government reimposed a strict policy of price controls for prescription drugs. Prices are revised every year, usually with insignificant increases, by the Chamber of Drug Market Regulation or CMED. This new regulatory body, which falls under Anvisa, was established in October 2003 to regulate prices and establish regulatory guidelines for the pharmaceutical industry. This development followed a change in the law in June 2003 when the Ministry of Health and Anvisa took over full responsibility for drug pricing and

industry regulation from the Ministry of Justice. The first annual price adjustment occurred in March 2004; in calculating the price adjustment, the government considered the competitive climate and prices in the domestic sector.

According to Luiz Milton, president of Cmed, from 1992 to 2000 as price controls were lifted, drug prices increased 250% in real terms. Consequently, drug sales dropped and production declined considerably. During the same period imports skyrocketed from around US\$100 million to US\$2.6 billion. "Such measures had an important role in monitoring the price increases and limiting the prices of new technologies arriving in the country considering that Brazil has strong issues with access to medication", Milton says.

Pharma companies maintain that price controls are not the way to increase access to medicines. "I believe that prices should be something that we need to agree with in respect to the market conditions," says Gaetano Crupi, president and general manager of Eli Lilly do Brasil. "Regarding our own experience with the diabetes care business, we have learnt that, in a place where price controls are not in existence, competition and the market place dynamic by its own will dictate prices. Therefore, when the government talks about price controls and free market, what we need to understand is that you must allow the dynamic of the market-

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place to play a role. You are going to have a better price if you have a higher volume."

"I believe that price control is maybe the most delicate and difficult issue," Ernest Egli, president of Roche Brazil added. We always argue that the government should be more flexible, giving us better prices for the private market, because if we have reasonable prices on the private market then we can give bigger discounts to the government sector." Some important developments have taken place, though. For instance, Government purchases, are now tax-free. And, in the OTC market, which is accounts for about 15% to 20% of the total market, there is not 100 percent price control. "Nevertheless, the government argues that four years ago, when they started to give us free prices for OTC products, some companies increased their prices by 60% to 70% so this created a difficult situation. These kinds of practices by some companies make it more difficult to gain the trust of government. No doubt, the economic stability of Brazil would favor a more generous pricing policy," he notes.

The Market : 186 Million Strong

Despite the country's structural constraints including lack of API manufacturing, governmental price control, administrative red tape and ever-changing regulations, Brazil is the place to be for the pharmaceutical industry these days. "There is one fact about Brazil that you can never deny; we are big. 186 million people make up a huge country, and it is a huge market. That is the bottom line. No company in the world, on an international basis, can afford not to be in Brazil," says Lilly's Crupi. For him, the Brazilian pharmaceutical industry's number-one asset is its people. "We have talented people at work and to circumvent all of the country's challenges. What amazes me is how committed and resilient the Brazilian professionals at Lilly Brazil and also those elsewhere in the industry are."

Despite tough competition from Mexico, the Brazilian pharmaceuticals market is now the largest in Latin America, valued at US\$9.2bn in 2005. In recent months, growth in US dollar terms has been strong, largely due to favorable currency rates and rising consumer demand. IMS Health's May 2006 retail market data puts the year-to-year growth rates of the Brazilian pharmaceutical industry at about 42%; however, industry sources estimate the current

expansion rate at about 10.8% annually in local currency terms. The market is presently dominated by "similares" or branded generics, which continue to account for almost 89% of pharmaceutical sales, by value, despite strenuous government efforts to promote the use of non-branded generics. "Today, we have 15 companies competing in the same segment, and the



Ernest Egli



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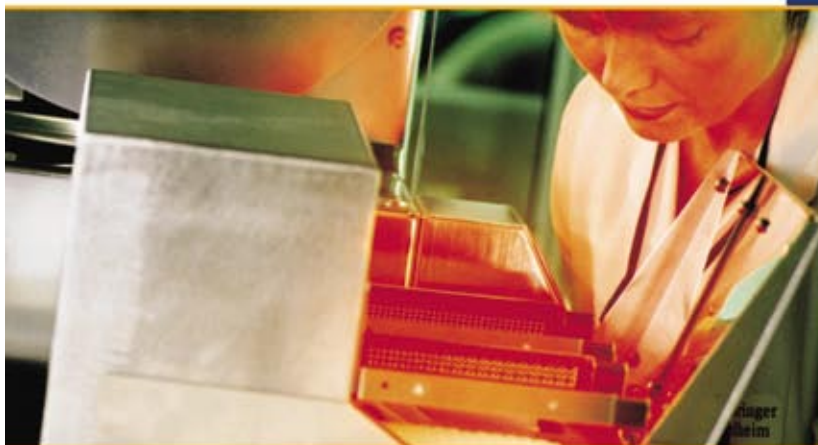
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Brazil Report

The Brazilian pharmaceutical industry is organised around three main categories of players: multinational companies, local companies that manufacture branded generics or “similares” and local companies that produce generics.

only differentiation between them is the price of their products,” notes Nilton Paletta, country manager of IMS Brazil. Paletta adds: “Nowadays, the larger companies, such as EMS and Medley, have very large portfolios and have therefore been able to meet our clients' needs. Smaller companies have not been able to compete, price wise, due to the discounts and commercial situation of the larger organizations. In Brazil, there is no incentive to buy large amount of prescription drugs, due to the availability of cheap generics brands.”

The Industry and Consolidation

The Brazilian pharmaceutical industry is organized around three main categories of players: multinational corporations (MNCs), often innovators; local companies that manufacture “similares” or branded generics; and local companies that produce non-branded generics. The country also has 11 state owned laboratories-most of which are obsolete, with old manufacturing facilities and small production capacity. Five of these labs produce most of the government's drug supply; the two leading state-owned labs are FURP and Farmanguinhos.

In Brazil government purchases comprise a significant portion of overall pharmaceutical purchases. Anti-AIDS is a major area for government purchases; the government has procured these drugs for free distribution to the public, which has led to a decrease in the number of AIDS-related deaths over the last three years. Other top therapeutic areas for product sales include cardiovascular, CNS, analgesics, anti-diabetic, hypertension, and anti-cancer.

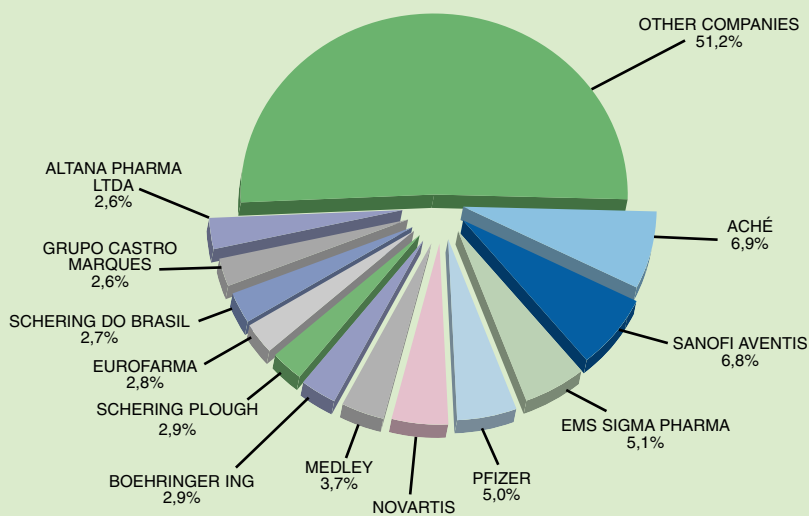
Although operational conditions remain challenging, foreign direct investment is increasing. Brazil is thus becoming an attractive regional base for multina-

tionals, including, most recently, US manufacturer Bristol-Myers Squibb. MNC investments in Brazil are aimed at minimizing their exposure to smaller, less well-regulated markets in the region, while also developing the country's potential as an export base. Meanwhile, Brazil's indigenous pharmaceutical industry is consolidating with the encouragement of the country's economic development agencies, and the nation's private sector is reportedly investing heavily in drug marketing and product development. Nevertheless, risks remain for those investing in Brazil's pharma research sector. Although this sector is clearly a priority for foreign investment, the country's healthcare reform initiatives are focused not on innovation but on providing affordable medicines to low-income citizens through the use of government price controls on prescription drugs and some OTC products. Meanwhile, foreign firms continue to complain that the government is changing regulations too abruptly and too often.

A Complex Regulatory System

When describing the regulatory system in Brazil, many sum it up in one word: unpredictable. “Regulations change from one day to

Private Pharmaceutical Market in 2005



Source: IMS Health



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Volker Bargon

the other," Crupi says. "Hence, the cost of doing business is very high." He mainly blames the structure of the country's tax system, with its many layers and taxes. In addition, he cites Brazil's complex labor laws and the Brazilian legal system, one of the world's most complex. "I spent five years as president of Eli Lilly in Canada and I don't recall having as many labor- and tax-related cases that I needed to deal with as I have had in one year here!"

"Well, you have surprises everyday," adds Volker Bargon, director general of Boehringer Ingelheim Brazil. "The working environment changes rapidly, and you can wake up and have a new legislation on the table. Then you need to understand where this comes from and why it was promulgated. In Brazil, there is no real story line you may anticipate. Things change from one

day to the other, which is something you will not see in well-established markets."

Ciro Mortella, president of the Brazilian Pharmaceutical Industry Federation (Febrafarma), concurs: "The Brazilian industry is very moody. It could be extremely good or extremely bad." Among its several missions, Febrafarma closely watches issues relating to the production and consumption of medicines; tries to increase access to medicines within the country; seeks fair drug prices and taxes to stabilize the country's economy; and attempts to stimulate R&D while protecting intellectual property. Mortella adds: "Brazil is a very



Ciro Mortella



Lauro Morretto

aggressive pharmaceutical

market and therefore companies have to learn how to thrive in a market of low growth. A real issue is that Brazil does not know where it wants to be when it grows up. There is a saying: 'Brazil is the country of the future and it will always be like that.' But the future is now and there is a lack of strategic vision for the country and its health system."

Sindusfarma, another industry association, works to improve conditions for both workers and manufacturers. Its executive vice-president, Professor Lauro Moretto, who is also director of Febrafarma responsible for the good manufacturing practices (GMP) and quality regulations, has a different view: "We have moved upward to a considerably higher level. The most important reason for such changes was a new GMP standard issued by World Health Organisation (WHO) in 1992 and implemented in Brazil in 1995." Moretto believes Brazil's regulations are in line with those of some of the most developed countries in the world. In fact, many manufacturing facilities in Brazil have been inspected by reliable regulatory agencies from other countries.

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Generics on the Go

Despite the traditional consumer preference for branded and branded generics products, and the key role played by doctors as market gatekeepers, the non-branded generics sector remains the market's fastest-growing segment. The generics sector's share of the Brazilian market reached 10.26% in the 12 months ending May 2006, with annually adjusted growth estimated at 31.3%. The government has launched a number of high-profile initiatives to promote off-patent, bioequivalent medicines in recent years—not all of which have been successful, largely due to the continued presence of so-called 'similar' medicines (non-equivalent copies of local origin).

The Hegemony of "Similares"

Indeed, despite government efforts and the growth of the generics segment, sales of similares still top those of branded drugs and branded generics. "Similares" sales represent almost 90% of the total market for locally manufactured drugs. Meanwhile, the branded market witnessed negative growth in 2002 but has experienced slow growth over the last few years.

Brazil's generic market is exceptionally concentrated with 80% of the market dominated by only four players.

Branded pharmaceuticals continue to benefit from being the first choice of medical professionals but in recent years generics manufacturers' targeting of pharmacies has affected branded pharmaceutical sales to some extent. Similares manufacturers claim that generics manufacturers use unfair competition policies that are hurting the similares industry.

Brazilian law requires generics prices to be at least 35% lower than reference drug prices, and the prices must be preapproved



Odinir Finotti

by CMED. However, due to market competition, generics price reductions are in fact higher—45% on average and reaching 70-80% in some cases. Such price reductions have been an important driver for consumer purchases; it's estimated that generics were responsible for saving US\$1.3bn for Brazilian consumers over the last five years. A noteworthy achievement, especially considering how most of the country's low-income population doesn't receive any reimbursements for medicine purchases. Generics have started to impact access to medicines in Brazil, especially in

the treatment of chronic diseases. Market data show that the total sales for substances such as atenolol, metformin and simvastatin—for hypertension, diabetes, and cholesterol control—have increased up to 150% over a four-year period.

"The generics business is a very exciting one," says Odinir Finotti, president of Pro Genericos. "I just regret that the Government is not doing enough work to promote it." He says that the government had done good work in promoting generics

use in earlier years but not of late. "The government should advertise more to the public as to make them understand generics are cheaper and as efficient as branded products," Finotti notes.

According to Carlos Alexandre Geyer, president of Alanac, Brazil's oldest state-owned pharmaceutical company, and a strong supporter of "similares," drug counterfeiting and falsification had become serious issues by the end of the 1990s, resulting in the establishment of the Federal Parliamentary Investigative Committee. The committee has had a two-fold effect; on the one hand, it has helped to identify and solve these critical problems and on the other hand, it helped draft a generics legislation.



Carlos Alexandre Geyer

"Nevertheless, the path chosen by the government was a wrong one. It decided to discourage the use of copy medicines (similares) in order to promote generics," Geyer notes. "Hence, the strong Brazilian campaign for generics created a discomfort about copies." In Geyer's view, there is no future in Brazil for small and medium-sized companies that produce non-branded generics: "The Brazilian scale is very big and demands big companies. The only way for smaller companies to survive would be to consolidate a brand. The same phenomenon occurs in sophisticated markets where smaller companies look for business niches."

Generics: the Players

Brazil's generics market is exceptionally concentrated, with 10 companies accounting for 98% of the market. And 80% of the market is dominated by only four players: EMS, Eurofarma, Medley, and Ache Biosintetica.

EMS, generics pioneer. The distinction

between generics and branded medicines is of no real consequence to EMS, Brazil's number-one pharmaceutical company. "I believe that there are no issues in acting in both segments because we have bioequivalence, which proves that we produce safe and quality drugs.

Generics are very new in Brazil. At the beginning, it was difficult to position generics because there were a meaningful number of doctors that didn't want to prescribe generics. Today, resistance to prescribing generics has diminished but, still, branded generics or similares medicines are far much stronger than generics," says Telma Salles, international affairs manager of EMS. Although generics have helped EMS achieve its position in the marketplace, their branded products have been highly successful as well.

The choice of generics, if it helped achieving this outstanding progression of EMS, was not the only key for its success. EMS is indeed increasing in both segments. One of the highlights of EMS's brand portfolio is its line of branded products from the Sigma Pharma lab, which ranks sixth in doctor preferences; in all, EMS offers a portfolio of 1,500 medicines that are very popular among doctors.

Moreover, the company is considered the leading pioneer of the generics market; EMS's state-of-the-art R&D center employs approximately 200 scientists who are constantly working on drug development and allow EMS to launch five new products per month. "We bet on our position of pioneers in the generics segment. As you know, in the generic segment, to be the first in is essential for success," says Salles.

In 2007, President Lula da Silva inaugurated EMS's new facility; EMS invested US\$50 million in the facility. "This new extension gives us the possibility to considerably increase our production capacity. As the market grows and EMS continues its healthy performance, we will have the production capacity to supply the national demands and other markets," Salles says. The technology we use to manufacture our products is exactly the same that is used in



President Lula da Silva (left) visiting EMS' plant in May 2007

developed countries such as the US and Germany. We are able to demonstrate that our products are safe and efficient."

Medley, a reliable partner. One company that may be able to challenge EMS's market dominance is Medley. Medley has jumped from 28 in 2000 to third place in



Thelma Salles

2006, has grown an average 25 to 30 percent annually, and has beaten production records in the generics sector. "We have a very good production capacity, an excellent portfolio and sales team. All these factors put together make us a successful company," notes Jairo Yamamoto, CEO of Medley. "As for our last year's performance, we had very good results thanks to Sibutramine. We launched this product six

months before the patent expired since we had an agreement with Abbott, and this launch was an absolute success and helped us achieve fantastic results."

The company has just secured a comarketing agreement with Bayer to launch Vivanza, highlighting its status as a reliable partner for MNCs. Yamamoto explains: "Even though we are in the generics business, we absolutely respect patents. In our case we believe that we do a very good job at comarketing innovative products, and, at the same time, we can also perform very well in the generics segment. Being in both businesses shouldn't be a conflict. Large pharma companies like Sandoz are recognizing that there is room for both products in the same house, and that is exactly what we are doing here."

While Medley is currently focusing on the Brazilian market, it also seeks to penetrate other Latin American markets. For example, the company exports its products to Mexico, where some are licensed to local partners who market them there?; Medley is following the same strategy in Peru. Regarding its future development, Yamamoto emphasizes the company's core values: "In our industry, it is very important to build a good image because we are

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EMS. The company that reinvents the pharmaceutical market.

Leader in sales and holder of the most varied product portfolio in the sector, EMS is the first Brazilian laboratory to be inspected by Infarmed and to be granted approval to export medicines to Europe. Currently, EMS exports its products to over 15 countries, among them Portugal, a market supplied by its subsidiary Germed, which is responsible for the distribution of EMS products throughout Europe. In a world where many laboratories compete with each other by offering a great range of products, only those working with enterprise, excellence, simplicity and responsibility are the ones to survive. Based on these four pillars, EMS reaffirms its mission and commitment to continuously seek development of novel products directed to its ample public.

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Leader in sales, according to IMS Health, May/2007. EMS exports medicines to Europe (Portugal, Spain and Italy).

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looking after the health of the people. We want to grow but at the same time, we want to be sustainable. Being sustainable summarizes our motto 'Proudly Medley'.

for the same indication. Billi says, "We see generics as a necessity. Our company needs to be present in the generics segment and do all the necessary efforts to be competitive. Nevertheless it is very important for us to be present in the branded generics segment. Our principal focus is to market our branded products to doctors."

you will certainly lag behind. Our position is to emphasize developing products with aggregated value, and we want to offer differentiated products."



Maurizio Billi

Eurofarma started in 1972 by producing drugs for both local and multinational companies. Then, it bought a small lab and started to produce and sell drugs.

According to Maurizio Billi, president of Eurofarma: "The generics law was very beneficial for local producers like us because it forced the companies to improve the quality standards. It made us learn how to develop quality products. Moreover, the Brazilian generics law is very rigorous, therefore the companies that wanted to succeed in this segment had to force themselves to upgrade and get equipped to make generics. This was a big learning step."

Determined to continue forging ahead, Eurofarma is also building a new industrial complex in Sao Paulo that is expected to be one of the most modern facilities of its kind in Latin America. Billi believes the new state-of-the-art facility will enable the company to have both a production and export hub within Brazil. And to further their research capabilities, Eurofarma has partnered with Biolab to establish a new company, Incrementa. "We had three main objectives: join our capacities to develop new products, divide costs, and in the future get stronger," Billi explains.

Grupo Castro Marques (Biolab).

Cleiton de Castro Marques, CEO of Biolab has this take on his company's partnership with Eurofarma: "This deal was a great idea because, with this company Incrementa, we are fully focused on constant research and development. This focus has given results, and over the one-year period of time since its establishment, we have already registered three products to undergo clinical trials and we are looking forward to their approval in the near future. From 2008 onwards, we will be able to launch around 15 products per year, always improving."

Marques believes innovation is the key to success: "We believe R&D is a must to keep our growing pace because if you are not able to invest in R&D and offer the market products with aggregated value,

you will certainly lag behind. Our position is to emphasize developing products with aggregated value, and we want to offer differentiated products."

Ache Biosintetica. Number-three ranking Ache holds the distinction of having the only 100-percent-made-in-Brazil drug product, Achelan, which is made out of herbal ingredients. Ache, like Biolab, is more focused on similars than generics; however, the company bought Biosintetica in 2002 to enhance its generics business. "The success story of the company has been built through acquisitions. Now that we are going listed, we are planning to buy more companies here in Brazil and really consolidate our success in the country," explains Jose Ricardo, president of Ache. In Ache's case, consolidation efforts do not exclude international expansion through partnerships. Ache now ranks number one company in Mercosur (an economic community that includes Brazil, Argentina, Paraguay and Uruguay). "We have just partnered with Mexican Silanes for R&D synergies. We also have as a partner the biggest company in Argentina and one in Venezuela. We will soon try to enter the European and the US markets, always through partners," he adds.

Germany's **Merck** may be the only multinational to date to have succeeded in Brazil's competitive generics field. In 2002, the company decided to introduce its generics portfolio in Brazil, which proved to be a good decision. "We are very pleased at our results because today we rank seven among the overall industry, and the most important thing is that we managed to position ourselves in the generics market despite the fact the four main players are national. Our seventh position is not bad at all in a market where national players are getting very strong," notes Gerd Bauer, president of Merck Brazil.

EVOLUTION OF THE GENERIC MARKET

	UNITS		
	05/2005	05/2006	05/2007
Generic Market	135.855.862	170.961.819	212.109.452
Market Share	10,12 %	12,23 %	14,45 %

	DOLLARS		
	05/2005	05/2006	05/2007
Generic Market	527.166.173	851.274.798	1.220.919.710
Market Share	8,13 %	9,54 %	11,60 %

Source: IMS Health

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enviable leadership that is extensive to the antidepressant sales sector. Eurofarma has an extended experience in international partnering ventures, being fully capable to manage pharmaceutical products licensing, meet regulatory requirements and establish pricing policies, the whole crowned with an outstanding expertise in the marketing and sales areas. We are actively engaged in P&D both individually as well as through Incrementa PD&I, in partnership with another Brazilian pharmaceutical company. Eurofarma has a unique manufacturing capacity - 80 thousand sq.mt. of installed plant facilities meeting every standard from the major world health organizations. **In other words: We can be your entrance gate to Brazil. Welcome to Eurofarma.**

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The Cost of Innovation

Another challenge to Brazil's pharmaceutical industry is the lack of R&D activities and the low expenditures that companies currently designate for R&D. Companies need to enhance their R&D but at the same time are under pressure to reduce costs.

"Innovation is very important, the Brazilian people like innovation," says Gabriel Tannus, executive president of Interfarma, the association representing pharma research-based companies. "Usually, people look at the concept of nominal price. Sometimes, you will have a product that appears to be more expensive, but if you reduce the time of treatment it has its advantages. If you look at the case of AntiRetroViral/ HIV drugs, they used to be a lot cheaper in the past compared to what you have nowadays. However, if you reduce the length of treatment in hospitals and you reduce the use of other products like antibiotics, you will increase the life expectancy of the patient with these new products," Tannus adds.

The Technological Innovation Bill was approved by Brazil's Congress in 2004 to promote partnerships between universities and enterprises for the development of new products and processes, and to divert more resources from the private sector into R&D. It also aims to increase patent registrations. The legislation is viewed by most industry players as a key policy instrument for fostering the transfer and dissemination of knowledge. According to Sergio Rezende, Minister of Science and Technology of the Federal Republic of Brazil: "The changes in the world economy throughout the 20th Century demanded a continuing reorganization of the Brazilian Science, Technology and Innovation Policy (S,T&I), having in mind the necessity of the country's insertion into a more competitive international economic pattern. Such adaptations have been gradually achieved with the evolution of the Brazilian Science and Technology System."



Sergio Machado Rezende
Minister of Science and Technology

A Strong Biotechnology Policy

This February, the government of Luiz Ignacio Lula de Silva cited biotechnology as one of the most important development areas for the country. Brazil's biotechnology policy for the next 10 years is aimed at developing pharmaceuticals, renewable

energy, and foods from the country's hugely diverse ecological base. Under current plans, the initiative will be majority (60%) backed by the state, and funding will be channeled through the Brazilian Development Bank (Bndes) and managed by the National Committee on Biotechnology (CNB). The program reflects the government's desire to develop advanced biotechnology-based indigenous industries: "This program aims at stimulating the generation and control of technologies focused on the Brazilian production of strategic human health products in order to competitively place the national bioindustry in the international biotechnological community," Minister Rezende notes.

In February the government of Lula da Silva cited biotechnology as one of the most important development areas for the country.

"Since 2004, the industry is really moving to be innovative. Today, we finance 47 programs, most of them dedicated to incremental innovation. It will be indeed very difficult to make radical innovation but if India did it, why wouldn't Brazil?" commented Pedro Palmeira, chief of pharmaceuticals and chemicals department of BNDES.

Different programs have been implemented to strengthen local companies; enhance production, research and development; and promote mergers and acquisitions. "We would like to be part of the success of seeing an emerging Brazilian pharmaceutical giant," Palmeira added.

"The future of the pharmaceutical industry is in biotechnology and, definitely, Brazil has the potential to make it happen. Brazil is the most advanced country in Latin America regarding biologics legislation, and this is very positive for the future growth of

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our industry,” says Ernest Egli, president of Roche Brazil. And Egli describes Roche’s ambitions for the biotechnology sector: “We are contemplating that if all goes in the right direction, Roche might be interested to produce a biological product here in Brazil in 2011 or 2012. We have all the technological capabilities, the lyophilization equipment, so we could easily produce it here; now let’s see how the law is going to be enforced. Investment today basically goes either into biotechnology or to Asia; therefore, as a Latin American subsidiary, we have to fight for our place and we can make it in the biotechnology segment.” In addition to increasing Brazilians’ access to medicines, Roche is focused on encouraging clinical research in the country, despite all the country’s hurdles for getting protocols approved. This year, the company is investing some US\$15 to 20 million to conduct trials in Brazil. “Brazil has always had the reputation of conducting very high quality clinical research and very rapid enrollment because there are a considerable number of naïve drug patients, so we have always managed to deliver quality and quantity at reasonable price. We foresee that in the next couple of years we will maintain this 20 to 25 percent increase in investment in clinical research, which will basically be focused on our key areas, such as oncology, anemia, diabetes, and virology,” Egli notes.

Roche is not the only company to see the potential of biotechnology in Brazil. Genzyme, the first biopharmaceutical company to establish a presence in Brazil, has been in the country for 10 years. “Since our origins, we have been conducting R&D to come out with drugs that make a difference for a few people and where no other pharmaceutical companies have been interested to invest in. We are focused on developing innovative solutions to provide people with rare diseases products that will allow them to improve their quality of life, survive, and interact in society,” explains Devaney Baccarin, general manager of Genzyme Brazil.

Genzyme first introduced Ceredase, then Cerezyme, and, in 2002, the company launched Renagel. A major milestone for the company was the inclusion of these two products on the Ministry of Health’s list of exceptional medicines. These events were key to Genzyme’s successful start in Brazil. The company has continued to add important launchings to their portfolio: Thyrogen for thyroid cancer in 2003 and several transplant-related products in 2004. Then in 2005, Genzyme registered Fabrazyme and Aldurazyme to treat Fabry and MPS I diseases, respectively. “It is important to point out that the only possibility for the patients



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to get these treatments are through the government access and reimbursement programs, since they are chronic treatments for life. Having said that, it is fundamental to include these products on the formulary of exceptional medicines," says Baccarin.

With its acquisition of Serono, Merck has become the number-one biotech company in Europe. "With Serono, we have a great pipeline in biotech and this represents great opportunities for the future growth of our Brazilian subsidiary," notes Merck's Bauer. Merck, the oldest pharma company in the world, was established in 1668 at which time drugs were mostly based on natural products. "I can say the inception of this company has its base in natural products. Since then, we have continued the tradition of working with natural products although in the 1980's the production of natural products was discontinued in Germany. Despite the production stop in Germany, we continued production in Brazil and today this is the only country where we produce our natural products," Bauer adds. As an innovator company, Merck relies significantly on its introduction of new products. Last

"For a country like Brazil phyto pharmaceuticals is huge because it will not only take less time to do R&D but also because it is far more economical to do research in plant than in synthetic molecules"



Henrique da Silva

August, the company introduced several oncology products; Merck hopes this new line will prove to be an important growth driver.

The Phyto Golden Mine

With one of the most biologically diverse environments in the world, and good infrastructure and human resources, Brazil has the potential to become one of the world's best phyto producers. "We have immense opportunities for developing and enhancing R&D in this type of product," asserts Josimar Henrique da Silva, president of Hebron and president of the Council at

Great partners reach great conquests

Apsen is a Brazilian Company which has been acting on the Ethical Pharmaceutical Market in the main medical specialties for about 4 decades. It has been growing in a sustainable way, conquering expressive results.

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Carlos Paris

“Brazilian companies for three or four decades were just focused on developing similar products to be sold in the Brazilian market because the cost of manufacturing was low.”

Febrafarma. “For a country with an emerging status like Brazil, the possibilities to develop phyto pharmaceuticals is huge because it will not only take less time to do R&D in phyto medicines but also it is far more economical to conduct research in plants than in synthetic molecules,” Da Silva adds. According to Da Silva, Hebron has broken ground in three areas: first, focusing on phytopharmaceuticals; second, creating close relationships with universities; and third, convincing doctors that phyto therapies are as effective as chemical drugs. “The Brazilian doctors today see phytotherapies as serious treatments that have a scientific base and curative power. These three pillars make us the pioneers of phyto pharmaceuticals in this country,” Da Silva says.

“The potential is great and it is sad to see that most of the phytotherapeutics we have in Brazil are foreign,” notes Carlos Paris, CEO of Apsen. “Apart from us, two or three other companies are working with phytotherapies, and today in Brazil, this segment represents only four to five percent of the market. We hope that in 10 years, these percentages will double. We believe that in the future this growth will not be able to happen in the synthetic market, so we are on the right track. The booming of the phytomedicine market has yet to occur, and we have all the possibilities to further succeed because we know the

market very well and we have the expertise to tackle this niche.” Paris believes that exports will fuel future growth. Today, Apsen has the ability to export Postec, an innovative topical treatment that avoids the need for phimosis surgery, and other phytotherapeutics. Meanwhile, the company is developing key areas to enable them to export their other range of products, especially solids.”

Paris notes that developing exports is new to many companies: “Brazilian companies for three or four decades were just focused on developing similar products to be sold in the Brazilian market because the cost of manufacturing was low. The Brazilian industry followed this trend for a long time, and only now things

140,000 UNEXAMINED PATENT APPLICATIONS

“It is important to remember that we have as our common and main goal the patient, whose life is being improved through the innovation we bring to the market,” Gaetano Crupi, president and general manager of Eli Lilly says. “In order for us to develop new products and to keep on investing, we need a very strong patent law.”

According to many analysts, Brazil's patent law, enacted in 1996, has not been well enforced. For example, the Instituto Nacional da Propriedade Industrial (INPI) has a backlog of some 140,000 unexamined patent applications, and decisions can take 10 years or longer.

Ernest Egli, Roche's president, complains about those delays: “I believe Brazil really has a good patent law, the only complication that I found in it is the delay on the approvals and the fact that contrary to other countries where the Patent Institute will be the one to approve the patentability of a product, in Brazil, INPI, and, additionally, Anvisa (our FDA) have to approve a product whether it is in the innovation category or not.”

Anvisa, Brazil's pharmaceutical market regulator, was created eight years ago to control the increasing number of counterfeit drugs. Then, it started registering drugs, granting patents, and, today, mostly focuses on improving the drug registration process. Industry players criticize Anvisa for delays in the patent approval process. Dirceu Raposo de Mello, general director of Anvisa, responds to the criticism: “Anvisa is certainly trying to optimize and strip the red tape out of its procedures; nevertheless the institution's job is not to follow the needs of the industry but to make sure the consumers have a safe medication as soon as possible. Fifteen years ago, the approval process would take years, currently it takes months. I would like to emphasize that Anvisa is not against making the process faster for companies, but the institution is simply not cutting corners.”



credit: Centaflora

The future of Brazil's pharmaceutical industry?

have changed. We have to do our best efforts to change this comfortable position and try to innovate."

APIs Lag Behind

Unlike India, Brazil is building a strong generics sector with little innovation and almost nonexistent export activities. The country still lacks a strong API industry-most companies aren't vertically integrated so they have to depend on API imports, which mainly come from China, India, and Europe. "Brazil imports US\$200 million of API and they can produce 600 million," observes Jose Correia Silva, president of Abiquif, an association of APIs whose goal is to enhance exports. "Only 15 to 20 percent are destined for the export market," he adds. Silva notes that in Brazil most MNCs import their API from company headquarters. "API manufacturers in Brazil want to be similar to the ones produced in Italy or Korea and this will take about 10 years." "The Lula government is promoting today the manufacture of API and other fine chemistry products," adds Nelson Brasil de Oliveira, vice-president of Abifina, another association for APIs. Brazil has a vast opportunity to be a big API producer if the right policies are implemented. "Brazil today doesn't need money per se, we are aiming to attract companies to invest in infrastructure, technology, and innovation", he adds.

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Other companies are developing innovative products. "Rather than looking into generics, a company like Cristalia chose to develop innovative products," says Philippe Boutaud, CEO of Cristalia, which has developed the first Brazilian drug for erectile dysfunction, Helleva, which will be launched in a few months. Cristalia plans to export Helleva, mainly to the US and Europe. "Since our API is granted a patent by the pharmacopeia in the US, I think it will be easy to register it. Now, we are looking for a partner or to in-license this product to a company in these countries," Boutaud notes.

Innovating is also Libbs strategy according to Alcebiades de Mendonça Athayde, president of Libbs Farmaceutica: "At Libbs we have always invested in innovation. For us developing APIs was a question of strategy and principles." He recalls how the company had to become self-sufficient because there were several fundamental raw materials Libbs needed that couldn't be found or bought in other places. "I believe this was one of the cleverest decisions we made. Thanks to it, today we produce around 60 percent of our raw materials and we actually have the capacity to export to some markets in Europe and Latin America. In 2006, we were certified by the European Union so now we can export our APIs to this part of the world." To meet interna-

"We are the only company in Brazil that can do steroids biotransformation"

tional demand, Libbs constructed a new facility to produce APIs, mainly for hormones. "This investment made us have the most modern hormone-synthesis plant in Brazil, and we are the only company in the country that can do steroids biotransformation," Athayde notes. The company is present in several therapeutic areas, such as cardiovascular, gynecology, neurology, respiratory, and dermatology. Their best-selling drugs include Diminut, Ancoron, Cebrolat, Cebrolin, Naprix, Procimax, Libiam, and Siblisma.



Alcebiades de Mendonça Athayde

MNCs Hanging In There!

The Brazilian market is a hybrid of MNCs and local companies; the latter are currently undergoing consolidation. In the past, MNCs led the market. Today, it seems that generics and similars have pulled even with MNCs. Most MNCs in Brazil have manufacturing facilities within the country; most of these facilities are not operating at full capacity. Despite Brazil's potentially perfect location as the gateway to Latin America, the country hasn't yet managed to become the region's export and production hub. Nevertheless, top MNCs consider Brazil a center of excellence in several areas, including clinical research.

Growth Ahead

"For me the milestone is the fact that Novartis is the number one company among the multinational pharmaceutical companies with presence in Brazil. We are also attracting investments to become one of the largest drugs exporters in the country and we are a strong partner of the gov-

Despite Brazil's perfect location it hasn't yet managed to become the region's production and export hub.

ernment," says Alexandre Triebnigg, CEO of Novartis. "We are now growing market share, we have achieved the best launches of products in the industry such as Diovan that became the number one product of the entire pharmaceutical market of Brazil and Prexige that has achieved leadership of the

ant inflammatory market," he adds.

Brazil is quickly becoming a very important subsidiary for the group so that it has overtaken Canada and the UK in the worldwide ranking of Novartis subsidiaries. "Novartis Brazil is a powerhouse subsidiary and not perceived as a subsidiary in a developing country," Notes Triebnigg.

And with the companies latest investments he Triebnigg predicts steady growth for the coming years: "We have also attracted investments to expand the company's production plants in Resende (Rio de Janeiro) and Taboão da Serra (São Paulo). These plants will now supply other markets. With the expansion, production volume is expected to treble by 2012. The target is to become one of the largest drugs exporters



Alexandre Triebnigg

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in Brazil.”

Philippe Crettex, president of Pfizer in Brazil is also very positive about future prospects for the world's largest pharma company in Brazil: “One of the major drivers for healthcare markets is demography; Brazil is the 6th largest country in the world in terms of population. The age pyramid is such that in the coming 20 years, the population growth rate will be quite higher among the older generations. If the country can sustain a reasonable economic growth and achieve a better distribution of wealth, the prospect for growth of the healthcare market is very interesting,” he explains.

On the other hand, Pfizer's existing product range is facing tougher competition. “With Viagra a tremendous success in Brazil, we were the innovator and remained alone in the market for several years,” recalls Crettex. “There are, today, “me-too” products in this category and we now have to fight to maintain leadership.” Similarly, for a long time, Pfizer's Lipitor was unmatched in its efficacy in lowering cholesterol. Today, Pfizer's challenge is to



Philippe Crettex

differentiate Lipitor from its new competitors in this therapeutic area and explain its competitive advantages. “The general increase in competition forces us, as an organization, to become more sophisticated, more efficient, more customer oriented,” Crettex says.

According to him, Pfizer's challenge in Brazil is to develop new capabilities in

order to launch the many new products in their pipeline: “New capabilities will be necessary because the new products are very different from the ones that made our success in the past. We will launch, for instance, a new product for AIDS toward the end of this year, beginning of next year.” This is a new therapeutic category for them, and means new patients, new physicians, and a single customer -the national program against AIDS. “We also have several specialized products for the institutional sector, mostly for oncology and anti-infective,” Crettex adds.

In Brazil since 1956, Boehringer Ingelheim Brazil was actually Boehringer's first overseas subsidiary. Although Boehringer Ingelheim's main growth drivers remain its core products, such as Spiriva Micardis, Sifrol, and Secotex new launches should boost its sales. “We are also waiting for an international launch of Dabigatran, an oral thrombin inhibitor. We have good expectations for this new product. But then again, it will be very much limited to a patient sector, mainly targeted to the elderly, and in Brazil, we don't have a large population of

When Girls Take the Lead

Very few Brazilian pharmaceutical companies are managed by a woman. Dr. Varso Toppjian, general director of France's Servier Brazil for more than 20 years, really is an exception. After having fled Lebanon because of the war and headed the Near East region, Dr. Servier himself offered her to head the Brazilian branch. “It was a huge challenge when I arrived here 20 years ago because nobody believed in this country and the development of the subsidiary was very slow. But Dr. Servier believed in the potential of Brazil, so I took the challenge to make things happen, I didn't give up and here we are positioned in the top 50 pharmaceutical companies in the coun-

try with great expectations for growth.”

“This country is very important for our group not only because it is one of the biggest emerging markets in the world but also because it is a research center of excellence. In 2001, we established here one of our international centers for therapeutic research (ICTR), which will be one of the right hands of our research activities worldwide. The creation of this ICTR represents the commitment that Servier has to establish a stronger presence in Brazil and the Latin American region. Along with this ICTR, we have a state-of-the-art plant here in



Varso Toppjian

Jacarepaguá (inaugurated in 2006) that will become the export and production hub for Latin America.


Today I am glad to say Servier Brazil is the first subsidiary of Latin America and it will continue to be,” she concludes.



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Boehringer Ingelheim's plant

elderly if we take into consideration that more than 50% of the population is below 30," observes Boehringer's general director, Volker Bargon.

run a business in this country. Brazil is less international than I anticipated it would be. Another factor would be that the Brazilian market lacks of consolidation. In a scattered picture, if you look into the

As one of the few non-Brazilian CEOs based in Brazil (most multinational drug companies appoint Brazilians to the top spot at their Brazilian operations), Bargon had a bit of a learning curve. "First of all, I would say the language barrier because speaking just English is not enough to successfully manage and

area of doctors, retail and wholesalers, you can see numbers which we do not experience in any other markets, and this makes things more challenging. The last point would be from the perspective of managing a business. Business in Brazil is very much based on personal contacts, it is very much driven by 'who knows who' and 'what is your level of hierarchy'. You have to deal very personally with people and business, which for me can be translated and viewed as a still very informal and unstructured environment," he explains.

"It took me almost one year to understand the rules, to understand how the people think. They appear in some respects to be very American due to their education and they also appear in some other respects, to be very European, but if you listen very carefully and if you go a little bit behind the scenes, you find a very South American nature."

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MANUFACTURERS	RANKING			MARKET SHARE		
	05/2005	05/2006	05/2007	05/2005	05/2006	05/2007
EMS SIGMA PHARMA	4	3	1	4,54	5,60	6,64
SANOFI-AVENTIS	1	1	2	6,95	6,66	6,52
ACHE	2	2	3	6,83	6,45	5,70
MEDLEY	6	6	4	3,41	4,00	5,31
NOVARTIS	5	4	5	4,32	4,37	4,39
PFIZER	3	5	6	4,92	4,07	3,67
EUROFARMA	10	7	7	2,54	2,94	3,33
BOEHRINGER ING	7	8	8	2,96	2,83	2,72
SCHERING DO BRASIL	8	9	9	2,70	2,69	2,55
ALTANA PHARMA LTDA	13	11	10	2,44	2,47	2,48
JANSEEN CILAG	9	10	11	2,57	2,52	2,47
D M IND FTCA	16	13	13	2,22	2,33	2,25
ROCHE	12	12	12	2,45	2,37	2,25
MANTECORP I Q FARM	17	15	14	2,07	2,10	2,03
ASTRAZENECA BRASIL	22	19	15	1,67	1,78	1,98
BAYER	11	14	16	2,49	2,24	1,97
BIOLAB-SANUS FARMA	23	20	17	1,58	1,77	1,90
MERCK-SHARP DOHME	15	16	18	2,33	2,07	1,85
MERCK	21	23	19	1,69	1,62	1,74
BRISTOL MYER SQUIB	14	17	20	2,34	2,03	1,73
GLAXOSMITHKLINE	18	18	21	2,00	1,78	1,64
LIBBS	19	21	22	1,82	1,73	1,61
ABBOTT	20	22	23	1,76	1,67	1,55
LILLY	26	24	24	1,36	1,45	1,39
ALCON	27	26	25	1,28	1,33	1,34

Source IMS Health

The Spreading of Licensing Agreements

MNCs with manufacturing facilities within the country, as well as local companies, are looking to increase their use of third-party manufacturing and in-licensing agreements. "You have already heard about the generics penetration, so they eat from our table and as our products decline, we get more and more space in the facility which we can then fill up with opportunities. If that is growing fast and requires investments, and the cash flow allows us to do so, we will," says Volker Bargon, Boehringer's general director. The company chose to set up its facility for third parties in 2005; it has become a growing business. "I must admit we are already a little bit surprised to see how well it is going. We surely now have a good reputation in that market segment and we are picking up nice opportunities from mostly international companies to produce locally and package those products."

A Means to Improve Market Share

MNC Nycomed also acknowledges that the generics market is

gaining considerable market share and growing faster than the rest of the industry. Licensing is one means of responding to this situation and improving revenues. "As an innovative company, we need to launch products that make a real difference to patients and healthcare providers," explained Luiz Eduardo Violland, country manager of Nycomed Pharma. "Nevertheless, one of the strategies to put emphasis on is licensing. This explains why our local business-development team has been actively seeking opportunities and, through new partnerships, planning the future for our strategic areas. It is also open for contacts and opportunities in new therapeutic areas both for licensing and acquisitions, aiming to expand our current presence in the country and increase our position among research-based companies." Moreover, Nycomed is determined to take advantage of the fact they have one of the most modern plants in Latin America, certified by Anvisa, MERCOSUL, Invima, and the European Community. In addition, Nycomed produces synthetic and phytotherapeutic medicines in accordance with the highest standards. "The plant is qualified to produce personal hygiene

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products and some cosmetics. Taking advantage of this infrastructure, we believe Brazil can become our export and production hub in the continent,” Violland says. The 2007 merger between Nycomed and Altana globally should help reinforce Nycomed's position in Brazil as Altana traditionally held a strong position in Brazil.

Gaining trust might be the crucial factor in the in-licensing wars sinews of the war of in-licensing. Cifarma, a medium-sized company, agrees: “Our core mission was to gain the confidence of the medical community,” says Marinho Braga, president of Cifarma. “Today the medical community is looking to prescribe quality drugs that are safe, with affordable prices. If they are prescribing a Cifarma product, they are looking to a brand that has therapeutic success and which is economically viable for a significant number of patients. We are attending to the necessities of the Brazilian population.” This ‘new kid on the block’ believes licensing agreements are important for its future growth. “Despite our ‘young company’ status, we are now well established in the marketplace. For us, joint ventures and partnerships are relevant because in today's globalized world, it makes absolute sense to partner in order to share ideas and strategies.” Cifarma started operations in Belo Horizonte and recently moved some operations to a new industrial park in Goiania with three units: hormones, liquids, and semisolids and, soon, colirios collyrium (ophthalmologic products). The other units continue to operate in Belo Horizonte. The new facility covers an area of 100,000 square meters, and has great potential for expansion. “The concept of our facility is high productivity at low costs, for us this is the way toward competitiveness. Furthermore, all our facilities have state-of-the-art technology in compliance with international and GMP standards because this is the only way we can manage to be globally competitive and gain international partnerships,” Braga says.

Becoming a Partner of Choice

Farmoquímica (FQM), a medium-sized firm, also uses in-licensing and diversification to grow their business. “We decided to pay close attention to in-licensing agreements because we didn't want to depend 100% on branded generics. Indeed, until 2001, we were very dependent on them so we needed to diversify and license specialized, exclusive products. At the same time, we also started to develop new galenic



Eduardo Violland

formulations for our products in order to differentiate them from the rest of generics and branded generics,” notes Marcelo Geraldi, president of FQM. “We are an ethical company that has a strong image among doctors and wishes to be known as a mar-

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keting company. Therefore, if an international company has an excellent product in one of our specialties, we want to be the first and best option.” FQM wants to maintain their licensing activities and become the partner of choice for companies that have good products in the FQM's specialties. “As a 100 percent prescription-oriented company, we can show the market that we have as good performances as the generics companies, and this demonstrates that we can be the best alternative to in-licensing relevant products that can make a big impact in Brazil,” Geraldi says.

In order to strengthen its market position, in 2001 FQM met with Argentina's Roemmers Group that was present in all Latin America countries except Brazil. “They (Roemmers) bought a major share of FQM and invested in our expansion project. This new endeavor allowed us to hire 100 sales reps and enter the mentioned states in 2002. At that point, we had 220 sales reps and we assigned 80 just to focus on the State of Sao Paulo.” As part of its efforts to create the best work environment for its 600 employees, FQM offers its staff meditation classes.

David de Pinho Filho, general director of Farmasa is also very



credit FQM

Meditating to reach excellence

thankful to in-licensing. The company's dermatology line experienced a huge jump in market share after an in-licensing agreement was put into place. “It was nearly doubled! This is just one example but I can tell you that the performance is what usually happens with all our in-licensing agreements,” observes de

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* Source: PIB/M&S May, 2007 excluding generics.

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Pinho Filho. "What makes us strong is that we have a strong and consistent strategy, we focus on specific therapeutic areas where we can guarantee to our partners that we are far stronger than the competition."

In 2006, Farmasa acquired Rio de Janeiro-based Barrenne, which enables Farmasa to further its growth. Tamarine®, Barrenne's top product, is already the leader in its respective therapeutic class. "The synergies were enormous; consequently, we not only integrated the company very rapidly but we also

reduced costs and improved Farmasa's profitability," Pinho notes. In addition, the acquisition enhanced Farmasa's OTC portfolio, giving them an important critical mass in this market segment. "The efforts of all our collaborators have helped Farmasa to be recognized as one of the best pharmaceutical companies in the country, but the journey hasn't ended yet. With the implementation of our aggressive strategy, we will guarantee the continuity of the company's solid brands, our strong reputation among physicians, and the trust of the community."

ITALIAN SAMBA

After 17 years of partnership with the Schering-Plough, Gian Enrico Mantegazza, an Italian entrepreneur established for more than 30 years in Brazil, founded Mantecorp in 2006 when Schering decided to put an end to the joint venture. Mantegazza aim was to rip the benefits of his long experience working with MNCs: "The great expertise my father has from working in MNCs combined with the expertise we built during our former joint venture has transformed us into a very professional, business oriented and dynamic Brazilian company. All these characteristics position us as a partner of choice," explains Luca Mantegazza, vice president of Mantecorp and son of the founder.

Despite what many in the industry saw as total madness the Mantegazza family decided to keep the production facility running even after the break up: "Furthermore, as we keep the production facility, we will manage to capitalize on producing complex drugs. Having the factory will also allow us to have different licensing agreements that will allow us to fill the gaps of the production of specialty products that were returned to Schering-Plough," explains Mantegazza.

Mantecorp wants to build upon this experience to further their investment in the in-licensing area; hence, after a little more than a year they managed to secure an agreement with Amgen: "It is a very important recognition because it means that due to the company's history, we managed to convert ourselves into a hybrid of



Mantecorp's plant in Rio de Janeiro

local and multinational companies, which definitely puts us ahead of other local companies, Mantegazza says, adding: I believe that what Amgen found was not only a company that has the know how in the specialty drugs and which knows extremely well the Brazilian market, but also an enterprise that speaks the same language in corporate management, which has the spirit of always bringing innovative drugs and treatments into the Brazilian market."

About their past partnership with Schering, Mantegazza explains: "I'd rather say that the partnership did not really come to an end but that it was restructured. In fact we still perform some services, such as retailing, distribution, and manufacturing, for some of Schering's products. We still have a very amicable relation with Schering-Plough and we intend to remain having a good cooperation because apart from speaking the same language, there are good business opportunities for both companies ahead."

MANTECORP IS A BRAZILIAN OWNED PHARMACEUTICAL INDUSTRY WITH MORE THAN 17 YEARS OF EXPERIENCE IN INTERNATIONAL PARTNERSHIPS. IT IS THE FIFTH LARGEST DOMESTIC PHARMACEUTICAL COMPANY IN REVENUES AND FOURTH IN UNITS.

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The company reaches over 95,000 physicians generating approximately 100,000 contacts a month. Mantecorp manufactures many market leading products in the Primary Care, Specialty Care and Consumer Products segments. Our products can be found in every single one of the today's 55.000 existing pharmacies in Brazil. Brazil is a country of opportunities. Mantecorp's mission is to offer innovative solutions in health.



Mantecorp

Distribution: the Constant Miracle

I believe Brazil has one of the highest number of pharmacies in the world. The distributor is therefore seen in Brazil as a very important player. As a country larger than the continental US,



Luciana Dias

Athouguia Dias, president of Athos Farma and president of Abrafarma (the associa-

tion for Pharma distributors and wholesalers). As an independent distributor, Athos Farma makes large investments in logistics and personnel; the company has to be very competitive in terms of delivery times. "For instance, Athos' operations in Rio de Janeiro make up to three daily deliveries to our clients and this is a very advanced system that you see in very few countries in the world. In fact, I think you can just see this in Brazil," Dias observes.

The Highest Number of Pharmacies

In a country larger than the continental US with several problems regarding infrastructure getting the drugs where they are needed is an everyday fight

At present, an estimated 56,000-plus pharmacies are involved in the distribution of pharmaceuticals. Almost 80% of the drug stores are small, with low sales, so distributors act as banks, giving loans and long-term payments terms to the pharmacies. Brazil's distribution system used to be very regional but it has been experiencing consolidation lately, with four local

SUCCESS IN A BOTTLE

Wheaton Brasil Vidrios, part of the Wheaton Group, is one of the most important glass companies in the country and supplies various industries like food, cosmetics, and pharmaceuticals. According to Peter Gottshalk, CEO of Wheaton do Brasil: "The importance of the pharmaceutical industry for our business is very considerable because all our production and packaging systems as well as marketing activities are very linked and directed to the pharmaceutical industry. I would say that the pharmaceutical business represents 50 percent of our overall operations." For nine years in a row, Wheaton has received

Febrafarma's award as the best provider of "glass bottles". Wheaton is indeed one of the few companies that has all the different types of packaging needed to pack pharmaceutical products. Moreover, they consider themselves experts in servicing the cosmetic industry, and able to translate such expertise to develop customized and detailed presentations for their pharmaceutical clients. "I also believe that the industry perceives us as an innovative company," Gottshalk adds. Wheaton is not a common provider. We are a company that is positioned to deliver services that other providers can't afford to do so."

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glass packaging



Brazil Report

players now comprising around 95 percent of the market. The main challenges for all four are to weather the consolidation process, find solutions and strategies to maintain their leads, and offer the best services to the industry.

Athos's Dias observes: "The Brazilian distribution market is very hard, competitive, but it is also very promising. We see ourselves as a service provider, not just a wholesaler. In my vision, I do not just sell medicines but provide services and solutions to the healthcare industry. Athos focuses on the level of services, where we guarantee speed, punctuality on our deliveries and add value in terms of sales consultancy." Sales are done on-line, which leverages their sales representatives to be key elements in adding value to clients' performance. "This vision was designed in 2003 and four years later we are very happy to see that it has worked out very well. Today, we are seeing the results as we are one of the fastest-growing distribu-

tors in the country," Dias says.

Independent distributors may be affected by the recent arrival of large pharmacy chains and supermarkets like Pao de Azucar, Wal Mart, and Carrefour. These entities, which buy their drugs directly from pharma manufacturers, intend to increase their pharmaceutical sales and market share.

Competition and the Big Chains

Alexandre Panarello, CEO of the distributor Panarello, is confident of his company's ability to compete with the big chains and generate growth. "These big chains don't have an expertise in distributing pharmaceutical products as we do. The country has very few pharmacies with a national perspective and regional businesses still prevail. It would make sense to be worried in terms of prices, but a lower price pressure on manufacturers could also have a favorable impact for us. Panarello



Alexandre Panarello

outlines the company's history and growth trajectory: "At the time Panarello was created, back in 1976, the dream of our founder was to initiate an expansion throughout the whole country. We started in Minas Gerais, and every two years, we would open a representative office in a new state. It was very bold for that time and only 20 years later the competition started to follow. Currently, we are the only company to reach the whole country."

With the opening of subsidiaries and com-



Award – Febrafarma – Brazilian Federation of Pharmaceutical Companies



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Francisco Megale

mercialization points in Brazil's major cities, Panarello has expanded its client base and market share considerably. As the competition started to follow Panarello's strategy, the company decided to acquire another distributor, Sudestefarma, located in a region where there were no other strong competitors. "The major strategy today is to enhance the opportunities for Sudestefarma and increase the complementarities between the two businesses. If we combine the number of pharmacies from both companies, the figure reaches around 33,000 clients. On the one hand, the company needs to increase the participation of current clients while on the other hand reaching the left-out ones. At Panarello, we will keep up our efforts to be at the forefront and always go forward in time and quality as well as to put all our efforts into further consolidating our brand in the Brazilian territory. Our vision is that Panarello will continue to be the biggest and best distributor in the country," says Panarello.

Gilberto Mayer, president of distributor Santa Cruz, one of the country's top-three distributors, shares Panarello's confidence about competing with supermarkets and

big pharmacies chains. Mayer believes that these entities actually present opportunities for independent distributors like Santa Cruz because in his opinion Brazil will always have room for neighborhood pharmacies. He differentiates his company from competitors like Panarello who have expanding their operations to new areas; instead, Santa Cruz wants to be number-one in the states in which they already operate. "Our great challenge is to take advantage of the consolidation process that the distribution business is facing. Security is another big issue considering the high number of trucks that get robbed and the great amount of counterfeit drugs in the market. We have developed a program to track their trucks and they also, most importantly, always track all the products that go out of their centers. We have invested a lot of money in IT in order to make this happen," Mayer says.

Also ranked in the top-three, distributor Profarma has been in business for 45 years. Profarma is also the only company in the sector listed on the stock exchange. "The great advantage of this is that it makes us very transparent," explains Sammy Bismaker, CEO of Profarma. "Today, we are looking forward to further consolidate in the Brazilian market and attract more investors." Bismaker predicts their shares will grow by 50 percent over the next five months. Today, Profarma's priority is the domestic market but in two to three years the company plans to enter the marketplace outside Brazil. "We are the only distributor to have the capacity to succeed in this endeavor," Bismaker asserts.

Offering Customised Logistics Solutions

Logistics and transport companies view distributors as agents that buy and sell goods, while they instead provide differentiated services to their clients. Some of these companies work with distributors since most distributors, with the exception of Panarello, outsource their trucks and some logistics services from them.

In 2006, Atlas, a 100-percent-Brazilian-

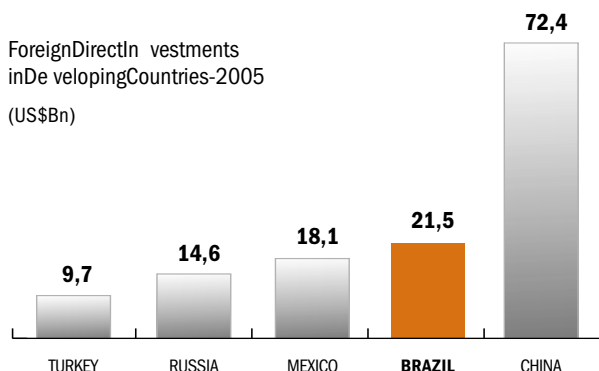
family-owned company, in business for 55 years, won the Febrafarma award for best service company. Since its establishment, the company has experienced great growth, with 40 branches throughout the country. "Atlas is at the front of the transportation business because we managed to implement a strategy which is wholly focused to guarantee an excellent level of service to our clients. We managed to offer customised logistics solutions to our clients. Atlas offers the best level of quality to our clients, which is back up with our ISO 9001:2000 certification," notes Francisco Megale, president of Atlas Brazil. The pharmaceutical industry is a very important industry sector for Atlas. Hence, the company has invested heavily to comply with all industry requirements, such as the GMP norms and Anvisa regulations. "Atlas has become a specialist in serving the pharmaceutical sector and we are committed to invest to better serve this industry since it has an immense potential for growth," Megale says. He expects to see 20 to 25% growth annually in transportation services for the pharmaceutical sector. As a result, Atlas has added to its service portfolio a logistics CD dedicated 100 percent to servicing the pharmaceutical industry, with the objective of better integrating the producer within the value chain.

Specialization has been the key to success for Bomi, Atlas's main competitor in Brazil. "Health is a market which needs a lot specialization, and that is why we know logistics in the health sector, and not in other fields," says Jose Corrales, president of Bomi. "In fact, the majority of our collaborators come from the pharmaceutical industry so we speak the same language the pharmaceutical executives do." For Corrales, the main difference between a classic transportation company and Bomi is they resolve logistics problems. "We will take care of the stock, take care of tax paperwork, and deliver the products. As logistics companies, we integrate the value chain to make things more efficient and cut costs. This is our great difference and one of our keys to success," Corrales asserts. Bomi applies "customer relationship management" to service their current clients while working hard to gain new clients.

WHY THE BRAZILIAN PHARMACEUTICAL MARKET?

TOP 2 IN FOREIGN DIRECT INVESTMENTS...

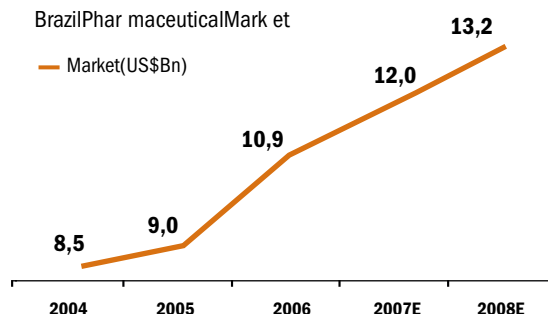
Foreign Direct Investments
in Developing Countries-2005
(US\$Bn)



TOP 2 PHARMACEUTICAL GROWTH MARKET IN THE WORLD

Brazil Pharmaceutical Market

Market (US\$Bn)



WHY ATHOS FARMA AS YOUR BRAZILIAN WHOLESALER CHOICE?

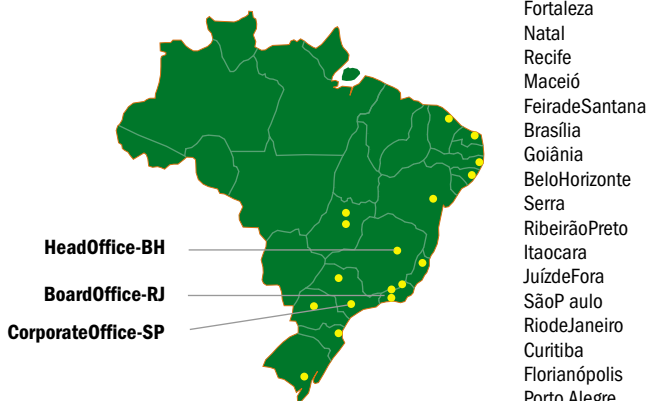
#1 NATIONAL PLAYER WITH THE MOST HORIZONTAL SALES...

100% BRAZILIAN COVERAGE WITH NATIONAL SALES FORCE

ATHOS: 26 STATES - 17 WHAREHOUSES

ATHOS FARMA IN NUMBERS

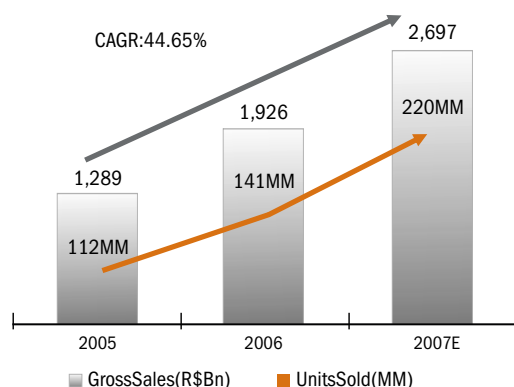
Market Experience:	45 years
Turnover 2007E:	R\$2,7Bi
Units Sold 2007E:	220MM
Warehouses:	17
Employees:	2.000
Sales Representatives:	489
Call Center Attendants:	359
Call Center Order Share:	48%
Electronic Orders Share:	52%
Pharmacies Served:	25.000
Suppliers:	227
Vehicles:	841
Km driven/month:	5,900,000km



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