

The Life Sciences Industry in Brazil

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IMPRESSUM

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1. Introduction

Being one of the fastest growing's economies, part of the BRIC's group, and experiencing unprecedented political and social stability, Brazil is nowadays seen as a true land of opportunities for European and American businesses aiming to diversify their activities and avoid recession and stagnation in their national markets.

Brazil is not only a BRIC country, it is also the most stable one with an established democracy that has successfully and significantly improved living standard and reduced income inequality during the last two decades. Furthermore, the Brazilian government has been fostering the development of new industrial clusters, renewable sources of energy and actively promoting the transfer of technology.

It is namely in this context that this report aims to present an analysis of the life sciences industry in Brazil. The following chapters will introduce this sector, describing its major aspects and developments, and provide guidance for business and investment opportunities.

This report is organized in five chapters apart from this initial introduction. The second chapter comprises an introduction to Brazil, presenting its major economic and social indicators, and providing an economic outlook for the next two years. The third chapter introduces the life sciences sector in Brazil. This part is divided in three topics, each addressing one of the main sub-sectors that form the life sciences industry. Hence, these three topics introduce the pharmaceuticals, medical equipment and biotechnology sectors, describing each area economic performance and current development, and presenting the opportunities for investment and technology transfer that lay ahead.

On the fourth chapter the Brazilian technology park network is presented, describing the location of its main infrastructures, expansion projects, and its importance for knowledge and science.

The fifth chapter introduces main public investment support policies and identifies the most important funding programmes available for the life sciences sector.

Finally, a short conclusion overviewing major market trends and potential is presented.

2. The Brazilian Market

2.1 WHY BRAZIL?

Brazil is the largest country and economy in South America. It is simply too big to be ignored. With an area of 8.5 million km2 and a population of approximately 190 million, it hosts 49.7% of the entire region population and produces 57.4% of its GDP. Also, Brazil has considerable oil and scarce raw materials reserves, the world's largest reserves of tropical forest, biodiversity and flows of fresh water (25%), a developed industrial base, high standards in scientific research and considerable human capital.

During the past fifteen years Brazil has experienced unprecedented political stability and economic growth. The Plano Real economic reforms that were introduced in the last decade of the 20th century allowed the country's economy to successfully take off during the last ten years. In 2010 national GDP grew by 7.5%.

This economic boom, together with federal government social policies, led to low unemployment rates and great social development in recent years. The fact that governments were able to successfully redistribute wealth allowed a growing number of Brazilians to increase their income, hence improving their quality of life and allowing them to move up in the social scale.

This new scenario is creating a whole new middle class with higher purchase power, thus enabling great growth potential in many market sectors. Furthermore, Brazil has a strong science and industrial base, and is considered to be a keen promoter of technology transfer, hence presenting great opportunities for foreign companies who are willing to invest time, money and effort in order to diversify their activity and profit from a new and fast growing market.

The following topics of this chapter will introduce the most important economic and social indicators of Brazil, aiming to provide a broad but accurate picture of the country. On the last topic an outlook over 2012 and 2013 major economic prospects is provided.

"The 5th largest country in the world; 5th largest area, 5th largest population, 5th largest economy."



2.2 ECONOMIC AND SOCIAL INDICATORS

To understand Brazil's current economic, political and social environment it is important to analyze its recent history and the changes that allowed the South American nation to become one of world's fastest growing economies and a regional power with growing importance in global political and economic institutions.

Continuous political instability undermined the potential of Brazil and diminished its regional and international role until the mid-1990's. During the post-war golden age of western economies, Brazil struggled to develop and to cope with social inequalities. During this period, the greatest threat to development was the volatility of national currency, which accumulated an inflation of 1.1 quadrillion percent between 1965 and 1994, historically comparable only to the German inflation in the 1920's.

In order to face this economic challenge and slash inflation, in 1994 the federal government launched the Plano Real. This was one of the most successful battles against inflation in history, representing a decisive milestone that allowed the Brazilian economy to stabilize and to have a steady growth since then.

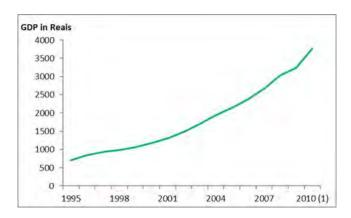


Chart 1 – Brazilian GDP evolution 1994-2010 (in Reais)

The results of Plano Real where remarkable and could be felt as early as three months after the deployment of its first measures, when monthly inflation had already decreased from 46% to less than 2%. Furthermore, between 1993 and 1995 the implementation of the plan allowed the reduction of extremely poor population by almost 20%.

In the longer term, the contractionary fiscal and monetary policies enacted by Plano Real, not only introduced a new currency, which controlled inflation and stabilized the economy, but also paved the way for a long and remarkable cycle of growth. The economy grew from US\$ 0.8Tn in 1995 to more than US\$ 2Tn in 2010.

This new scenario enabled the South American country to overtake the UK and France in 2011, becoming the world's 5th largest economy. Moreover, international institutions forecast that this strong growth rates will be maintained, expecting the GDP to increase from USD (PPP) 2.25Tn in 2011 to USD (PPP) 3.35Tn by 2021. For 2013, the IMF estimates the economy to expand more than 4%.

Nonetheless, inflation and interest rates are still high when compared with developed economies. The National Bank reference interest rate is now 9.5% and inflation has been around 5-6% during the past decade. However, interests have been consistently decreasing during this period, achieving a one digit rate for the first time early in 2012. Also, inflation can be considered normal for a country with Brazil's development stage and growth rates, and has been kept between the targeted values (2.5% to 6.5%).

"The Brazilian gross domestic product rose up to US\$ 2Tn in 2010. 15 years ago the country produced US\$ 0.8Tn, approximately 60% less than today.

GDP is expected to rise up to US\$ 3Tn by 2015."

The remarkable evolution of the Brazilian economy during recent years is shown on the first chart. This shows an average growth of 4.6% per year between 2006 and 2010. Recent year's inflation is displayed on the second chart.

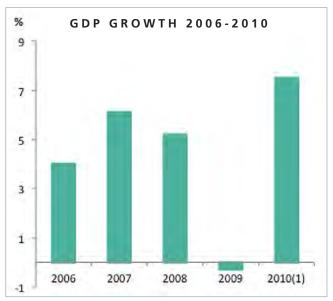
As mentioned above, for the next few years growth is expected to continue. Its largest contributor will be domestic demand, mostly due to the expected increase on families' income. Investment will also significantly contribute to this forecasted outcome due to the need of increasing industrial and services production in order to respond to domestic consumption needs.

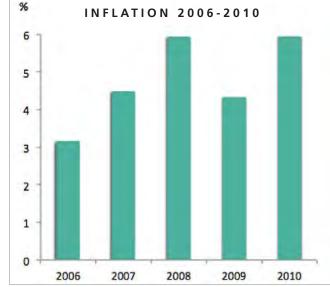
However, economic growth was not the only achievement of modern Brazil. More than being able to generate sustained economic growth, the government has been able to significantly reduce social inequality. The social policies employed during the last decade by former president Lula da Silva allowed not only to sustain the economic growth enabled by Plano Real, but also helped millions of Brazilian's to significantly improve their living standards.

Estimates show that, between 2004 and 2009, more than 26 million Brazilians were able to move up in the social scale and become part of the country's middle class. During this period, poor and extremely poor population was also reduced from more than 43 million to about 27 million. Also, average income increased by 28% and income inequality was reduced by almost 6% during this five year period.

These numbers show that social policies had a great positive impact in the improvement of Brazilians living standards. Nonetheless, the fact that 9 million people are still considered to be extremely poor shows that a lot of work still has to be done.

"30% poverty reduction During the past decade, former
president Lula da Silva social policies
reduced by almost 30% the number
of poor families, enabling these
people to be part of Brazil's middle
class."





2.3 OUTLOOK FOR 2012/2013

The achievements of economic stability and progress in social inclusion point Brazil's development model to be in the right track and to able to maintain its successful record in the years to come. Nevertheless, a lot of work has to be done in order to sustain growth, continue the reduction of social inequalities and make Brazilian institutions less bureaucratic, more transparent and increasingly efficient in order to improve business environment.

According to the World Bank, in 2011 the business environment in Brazil was ranked 120 amongst 183 countries. The country's general ranking position was penalized by the complexity in property registration and construction permits. On the other hand, credit concession and investment protection were considered to be strong.

Regardless the deceleration in the last quarters of 2011, which resulted from the global economy slowdown due to Europe's weaker growth and to the deceleration in emerging economies (which had the lowest growth rate since the 2008 crisis), 2012 is expected to be a promising year for the Brazilian economy and for its investors.

Whereas growth in Europe is likely to be kept weak, global demand is expected to grow in 2012. In Brazil, after stagnating in the end of 2011, the economic activity is expected to accelerate over 2012, speeding up the GDP grow to 3.2% this year and to more than 4% in 2013.

Also, due to the slowdown of GDP grow in the last quarter of 2011, meeting public budget goals will be challenging due to lower revenues, higher salaries and investment needs. However, a primarily surplus is likely to be achieved. Inflationary pressures are expected to remain strong in 2012 and 2013, though within the government and national bank targets. Hence, the reference interest rate is likely to be maintained, after it was reduced to 9 % in April 2012. Overall, a positive outlook can be drawn for the Brazilian economy over the next years. With a successful track both in wealth redistribution and general economic growth, these numbers show that the Brazilian economy will continue to offer great opportunities for companies aiming to diversify their activities and invest in new, promising and fast growing markets.

	2010	2011	2012	2013
GDP (% y/y)	7.5	2.8	3.2	4.3
Inflation (% y/y)	5.0	6.5	5.4	5.6
Interest Rate (%)	10.0	11.0	9.5	9.5
Private Consumption (% y/y)	7.0	3.9	3.1	4.4
Government Consumption (% y/y)	3.3	2.2	2.4	2.8
Investment (% y/y)	22.0	5.1	6.3	8.0

Table 1 – Main economic indicators 2010-2013

KEY FACTS

LOCATION / AREA South America / 8.5 million km²

POPULATION (2010) 191 million

CAPITAL Brasília (2.5 million)

LARGEST CITIES São Paulo (11.2 million), Rio de Janeiro (6.3 million)

LANGUAGE Portuguese

INDEPENDENCE / CONSTITUTION 07/09/1822 (From Portugal) / 05/10/1988

GOVERNEMNT TYPE Federative Republic (27 States)

WORKING FORCE 101.7 million

LITERACY / LIFE EXPECTANCY 90.3% / 73.1 years

GDP (NER/PPP) US\$ 2.5Tn / US\$ 2.3Tn

Per Capita GDP (NER/PPP) US\$ 12.917 / US\$ 11.845

GDP % (AGRICULTURE/INDUSTRY/SERVICES) 6% / 28% / 66%

EXPORTS / IMPORTS / TRADE BALANCE

US\$ 202Bn / US\$ 182Bn / US\$ 20Bn

INTEREST RATE (BNB – April 2012) 9%

GDP GROWTH 7.5% (2010) / 3.8% (2011 est.)

INFLATION 6% (2010) / 6.5% (2011 est.)

EXPECTED GDP GROWTH 3.2% (2012) / 4.3% (2013)

3. The Life Sciences Industry in Brazil

3.1 INTRODUCTION

Brazil is considered the Americas' most attractive emerging life sciences market, with its potential underpinned by a combination of economic, political and demographic factors. Governmental commitment to the development of local pharmaceutical, medical equipment and biotechnology industries is also highly responsible for this scenario.

The South American country has also structural and current situational characteristics able to sustain and provide future development for a strong life sciences industry. These include the existence of abundant natural resources, a strong scientific base and a deep interest in knowledge and technology transfer, a leading agribusiness and biofuel industry, an aging population and a growing middle class able to boost health care services demand in the next years and decades.

Nowadays, the Brazilian life sciences sector already comprises more than 1.000 companies, most of which located in the state of São Paulo. Other states in the South and Southeast, such as Rio de Janeiro, Minas Gerais and Rio Grande do Sul also host a significant number of companies. Smaller but important clusters can be found in the Northeast and Centre-West.

Furthermore, the Brazilian life sciences sector experienced considerable growth during the last decade. From 2003 to September 2009 new investments from foreign companies accounted for more than US\$ 1.5bn. Also, latest economic figures from different life sciences subsectors show a remarkable growth of this industry in Brazil, sustaining optimist forecasts for the next few years.

According to the Brazilian Trade and Investment Promotion Agency (APEX), last year's pharmaceutical sector revenues increased by 8.4%; from R\$ 36.85bn (US\$ 20.95bn) in 2010 to R\$ 39.94bn (US\$ 25.60bn) in 2011. The healthcare and medical devices sectors achieved even higher growth rates with 10.5% and 10.3% expansions. Healthcare revenues increased from R\$ 314.77bn (US\$ 178.98bn) in 2010 to R\$ 347.72bn (US\$ 222.90bn) in 2011, and medical devices sales grew up to R\$ 7.30bn (US\$ 4.68bn) in 2011 from R\$ 6.62bn (US\$ 3.76bn) in the previous year.

These figures result both from a fast growing market for health care products and from significant investments in research and development. Combined, Brazil's skilled workforce, technology parks network, and financial incentives are responsible for this solid and sustained growth.

More important, investment in the life science sector is likely to increase in years to come, boosted both by the private and public sectors. The PROCIS public program, conducted by the Health Ministry, will invest R\$ 2bn until 2014 in order to establish partnerships with the private sector for technological development and to support the construction of scientific laboratories. In the private sector, Brazil Pharma, the largest pharmaceutical retailer in Brazil, recently secured R\$ 414mn through the launch of its initial public offering (IPO) on the Brazilian Stock Exchange in order to carry out new acquisitions and invest in new retail stores.

On the other hand, whereas great private investment took place in manufacturing in recent years, life sciences research is still highly concentrated in Universities and public research centres. Although a considerable increase in the level of interaction between Universities and industries has taken place in the last five years, a lot of work still has to be done in order to further promote this interaction and to boost private research.

With this objective, Brazilian federal and state governments are funding the construction of a wide network of technology parks across the country. These are intended to host large corporations and to support small entrepreneurial projects in order to develop a strong national cluster in the life sciences sector as well as in other technological areas. Due to its importance, this topic is introduced in the next sections and further developed on a separated chapter, dedicated to present and explore the opportunities of this technology parks network.

However, before introducing this topic and following the facts presented above, an overview of the main life sciences subsectors (Pharmaceuticals, Medical Equipment and Biotechnology) is presented next in order to provide a deeper understanding of the whole sector in Brazil.

"The life sciences sector received more than US\$ 1.5bn from foreign investment between 2003 and 2009.

These numbers are expected to increase in the next decade."



3.2 PHARMACEUTICALS

The pharmaceuticals sector is characterized by heavy investments in R&D with the rights to sell a product issued by the concession of patents. These assure to the company who develops a medicine the monopoly over that product for a period of 20 years.

In 2011, 25 medicine patents expired, thus representing a loss of US\$ 500mn for patent owners, only in the Brazilian market. This results from the fact that generic's producers are now allowed to manufacture and sell these drugs to consumers, hence increasing competition and reducing multinational companies' profits. Consequently, in order to cope with market requirements and sustain profits, pharmaceutical companies need to innovate both in terms of R&D and market positioning.

For these reasons, Brazil's high skilled labour in this field and public support to research based organizations willing to establish in the country turn it into a very attractive location for pharmaceutical businesses. Moreover, Brazil is an emerging pharmaceutical consumption market that will offer great revenues over the next decades.

During the last ten years national demand for pharmaceutical products has grown approximately 10% per year, sustained by public social programmes and better income distribution. In 2011, the whole pharmaceutical market rose up to almost R\$ 38bn.

However, this growth trend in not evenly distributed. Even though brand medicines sales had a significant increase, the generic's market is growing considerably faster. As shown on Chart 5, generic medicines grew around 20% per year for the last five years, thus increasing this segment market share up to 20% in 2010. By 2013, IMS Health expects generics market share to reach 23%.

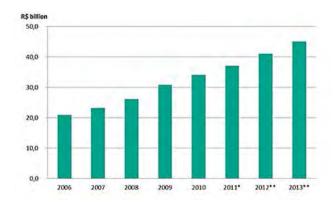


Chart 4 – Brazilian pharmaceutical market value.

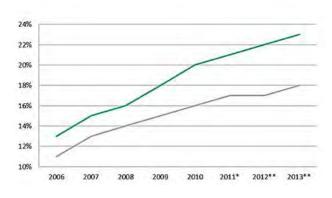


Chart 5 – Generic medicines market share. (green)

As a result of this growth trend, in recent years pharmaceutical companies have significantly increased their investments in Brazil, targeting the development of both manufacturing and R&D. In 2009, pharmaceutical companies invested R\$ 3.4bn in new manufacturing plants, research and marketing.

Furthermore, both large and smaller players expect to increase their investment in research, distribution, and production capacity over the next decade. Nycomed Pharma has recently announced US\$300mn investments on acquisitions over the next five years and Sanofi-Aventis plans to start building new manufacturing facilities in 2012.

These investments aim to enable companies to respond towards expected consumer's health soaring demand, which largest share is obtained in the retail market.

In fact, the retail market represents more than 70% of overall revenues, most of which come from the wealthiest regions of Brazil. The Southeast region represents 56% of the market and the South accounts for 17%.

COMPANIES AND GEOGRAPHY

The Brazilian pharmaceutical industry comprises several types of organizations, with different goals and size. Whereas large multinational companies that locally produce their brand-name products are important players, large national companies hold a significant share of the market. In 2011 there were more than 600 organizations operating in the Brazilian pharmaceuticals market.

Table 2 shows the largest players in the Brazilian pharmaceutical market. The market share values displayed on this table show that there is significant competition in the Brazilian market.

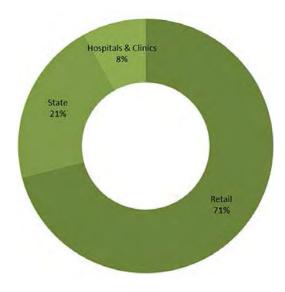


Chart 6 – Pharmaceutical market in Brazil.

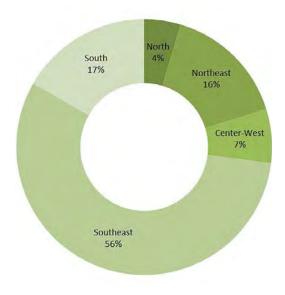


Chart 7 - Pharmaceutical regional market share.

	RETAIL MARKET		NON-RETAIL MARKET		GENERICS (RETAIL)	
1	EMS PHARMA ^{Bra}	6.7%	ROCHE	11.8%	MEDLEY ^{Bra}	29%
2	SANOFI-AVENTIS	6.0%	NOVARTIS	9.7%	EMS PHARMA ^{Bra}	26.1%
3	ACHE ^{Bra}	5.7%	ASTRAZENECA	7.5%	ACHE ^{Bra}	8.2%
4	MEDLEYBra	5.2%	CRISTÁLIA ^{Bra}	6.1%	EUROPHARMA ^{Bra}	8.0%
5	EUROFARMA ^{Bra}	4.2%	BERGAMO ^{Bra}	5.9%	SANDOZ	5.5%
6	NOVARTIS	4.0%	ABBOTT	5.6%	GERMED PHARMA ^{Bra}	4.1%
7	PFIZER	3.5%	SANOFI-AVENTIS	5.5%	RANBAXY	3.9%
8	BAYER SCHERING	2.6%	EUROFARMA ^{Bra}	5.2%	TEUTO BRASILEIRO ^{Bra}	2.7%
9	ASTRAZENECA	2.5%	CELLOFARM	5.0%	SANOFI-AVENTIS	2.2%
10	BOEHRINGER ING	2.1%	PFIZER	5.0%	MERCK	1.7%

Table 2 – Retail market share of the largest pharmaceutical companies.

SOURCE: IMS HEALTH; BRA - BRAZILIAN COMPANY

A higher market concentration on the generics market is noticeable on table 2, since the two largest players account for 55% of the whole market. Furthermore, these data show that the generics retail market is controlled mostly by Brazilian companies, which hold more than 70% of this market.

Geographically, the distribution of pharmaceutical industries is very similar to that of the retail market, with most companies concentrated in the Southeast. The state of São Paulo accounts for nearly 39% of the whole industry and Rio de Janeiro state for almost 12%. The state of Góias (Center-West) also represents a significant share of Brazil's pharmaceutical industry (6%), due to the existence of a strong pharmaceutical cluster in the city of Anapólis. The entire Northeast region accounts for 10% and the South for 18% of the total number of companies in the country.



Figure 1 – Geographical distribution of pharmaceutical companies in Brazil.

GOVERNMENT POLICIES AND REGULATIONS

Following the trend of other sectors considered to have an economic or social strategic importance by the government, the state has an important role in the pharmaceutical industry. The presence of a large number of public laboratories in the market, developing and manufacturing vaccines and generic medicines, is a good example of this strategic positioning.

Also, the government has a strong influence in this sector through the establishment of strong regulations. The most important governmental institutions are ANVISA (National Health Surveillance Agency) and INPI (National Institute of Industrial Property).

INPI is a signatory of the Patent Cooperation Treaty, hence assuring that companies willing to sell their products in Brazil can extend their rights to the country. However, to guarantee patents protection in Brazil, companies cannot automatically extend registration rights from abroad. Instead, they need to register the international patents and trademarks with INPI. ANVISA is an autonomous agency linked to the Ministry of Health. It is responsible for all regulations and controls over the management, imports, storage, distribution and retail of health products and services in Brazil.

ANVISA has adopted national guidelines for good manufacturing and laboratory practices, following OECD standards. These actions promoted the quality of medicines, which can now be exported without adaptation.

However, as chart 9 shows, pharmaceuticals international trade deficit is still significant, since only recently large investments were deployed in order to build a strong exporting cluster.

Nevertheless, aiming to change this scenario and boost exports, the government is also deploying large sums of public funding to support the construction of new technology parks and to the development of small and medium size enterprises. These initiatives comprise important federal and state programmes that will be further developed in the next chapters.

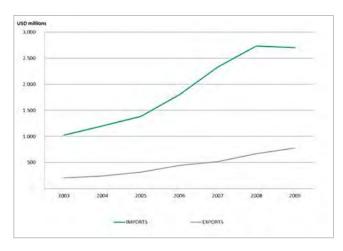


Chart 8 – Brazil pharmaceuticals international trade.

OPPORTUNITIES

Due to the expected market expansion in the next few years, the Brazilian market offers great business opportunities to pharmaceutical companies.

However, following a strategy based on local production rather than imports has significant advantages. This is related with the fact that, even though the federal government excludes medicines from the payment of the main taxes, the total amount of taxes on imported medicines is still high. This results from a combination of federal and state taxes that often almost double imported medicines costs when compared with local produced ones. Also, ANVISA regulations now oblige importers to have their own quality control laboratories, hence making it more competitive to produce locally.

Another great advantage of producing medicines in Brazil is related with production costs. Accordingly to IMS-Health, Brazil production costs are 4.8 times lower than those in the United States, thus making it very competitive to produce in Brazil, especially for exporting companies. Also, producing pharmaceuticals for the Brazilian internal market is also a very interesting business, since prices to consumers are only 2.8 times lower than in the US, thus indicating that profit margins can be higher than in developed countries.

Other activities that do not involve the direct production of medicines also place interesting business opportunities in this industry. The increase on medicines sales will also boost the transportation and machinery for manufacturing businesses. The demand for pharmaceutical production machines is estimated in the range from US\$ 50mn to US\$ 100mn per year, during the next five years.

Nowadays, almost all process equipment is imported, thus creating business opportunities for companies willing to export this equipment. However, greater opportunities also lay ahead for companies willing to invest in Brazil and locally produce this machinery.

For smaller R&D based companies willing to establish in Brazil, the government also provides important funding. This financial support, together with Brazil's high skilled labour force in these field and lower labour costs also make this a very promising market for investors.

3.3 MEDICAL EQUIPMENT

Brazil has the largest medical equipment market in South America. In 2011, the Brazilian medical market was valued at US\$ 4.4bn. Also, the industry is well established in the country, comprising local and multinational companies. According to the Brazilian Association of Medical, Dental, Hospital and Laboratory Articles and Equipment (ABIMO), which currently has 320 associates, the local market can be divided in five areas where most companies can be included: implants and consumption material, electronic equipment's, odontology, radiology and laboratories.

However, many companies operating in other sectors also develop and sell products for this market. These include companies like Renault, which produces an adapted van model for ambulances in Curitiba. Other companies also manufacture components or parts of medical equipment, such as special INOX and Corian counters for industrial kitchens, surgery rooms and odontology offices.

Worldwide, the medical equipment sector represents more than US\$100 billion and had an average annual growth of 2.5% over the last few years. In Brazil, this sector has been growing considerably faster. Between 2003 and 2008 the medical industry grew more than 150%.

The largest contribution for this remarkable growth came from internal demand, with 90% of revenues obtained in the domestic market. Furthermore, international trade data shows that the country is not only unable to exports its medical devices yet but also that it is still highly dependent on imports. According to ABIMO, in 2008 exports accounted for US\$ 581 million whether imports rose up to US\$2.74 billion.

Chart 9 displays the share of revenues achieved in each sector by Brazilian medical equipment manufacturers.

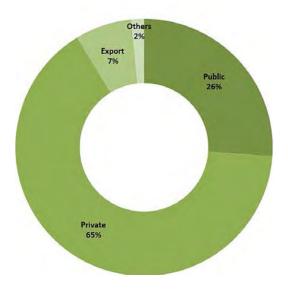


Chart 9 – Medical equipment sales distribution.

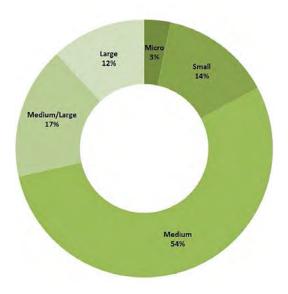


Chart 10 – Distribution of companies by size.



Even though the Brazilian medical equipment industry is still highly focused on the internal market, its players cover a wide range of specialities. Brazilian companies are able to manufacture 90-95% of the devices needed to equip a modern hospital.

Also, the Brazilian medical equipment sector is considered to be quite innovative, regarding the high demand for high-tech products and the development of new technologies in different sectors, such as electronics, IT, and precision mechanics. Moreover, the development of these new technologies comprises a considerable mix of different products and involves both multinationals and small specialized companies.

Some of the largest multinationals like Siemens and GE are amongst the most important companies in Brazil's medical equipment sector, importing and locally producing highly specialized equipment for hospitals. On the other hand, less complex equipment, such as odontology tools or chairs, are mostly manufactured by Brazilian organisations. However, since the Brazilian medical equipment industry is still on an early development stage, its share on the Brazilian economy is still small. Also, economic indicators are difficult to find for this sector.

ABIMO and SINAEMO associations claim that there are 449 companies operating in this sector in Brazil. According to these data-bases, most of those companies are medium size enterprises (54%). Micro and small enterprises account for 17%, medium large for 17% and large corporations for only 12%. Together, these companies have more than 31.000 employees and sustain more than 72.000 indirect jobs.

Geographically, medical equipment manufacturers are mostly located in Sao Paulo (68%). The region of Ribeirão Preto (SP) is the main centre for commercial medical equipment activities, hosting the largest Brazilian cluster in this sector.

Other regions, such as the South (17%) and Rio de Janeiro (6%) are also important medical production areas.

Likewise for the pharmaceutical sector, ANVISA is also the regulating institution for the medical equipment sector. The latest legislation was released in 2011 in the Compêndio da Legislação Sanitária de Dispositivos Médicos and displays a set of technical regulations and certification requirements based on ISO standards.

Furthermore, this legislation also set property registration rules and specific procedures for the certification of imported devices, often involving several bureaucratic steps that may delay return on investments if not carefully planned.



Figure 2 – Geographical distribution of medical equipment companies in Brazil.

OPPORTUNITIES

The expansion of the healthcare sector in Brazil offers great growth potential for medical device companies doing business or willing to expand to the South American country. Opportunities in this market arise as a consequence of higher and better income distribution, increase in public healthcare spending and aging population.

Moreover, the expansion of the private sector and the implementation on higher healthcare standards, have significantly increased demand for cutting-edge and top quality healthcare services and technology in recent years. Also, together with private investments, large public spending in new hospitals and health centres, aiming to provide better healthcare to the entire population, will drive demand increase in the next decade.

This scenario opens great opportunities both for large and small foreign companies willing to invest in Brazil.

Furthermore, by investing in Brazil companies can not only take advantage of the large domestic market but also avoid high tariffs on imports and benefit from fiscal incentives, provided by the government to foreign investors willing to manufacture their products in the country. Additionally, companies can benefit from Brazilian skilled though cheaper labour force in order to export and increase profit margins.

For smaller companies great opportunities lay on the establishment of partnerships with Brazilian SME in order to promote technology transfer.

These opportunities are focused on the of know-how of small and medium size European companies that can be transferred to small Brazilian companies in order to increase local production. Following this approach, European organisations can benefit from the large potential of the Brazilian market, avoiding high import tariffs and taking advantage of public technology transfer incentives provided by the Brazilian government.

3.4 BIOTECHNOLOGY

Brazil has the greatest biodiversity in the world. This abundance of natural resources represents a major strategic advantage to the development of a strong national biotechnology industry; hence enabling the South American country to become an important global biosciences centre.

Also, the biotechnology industry has experienced rapid growth during the last few years and presents great opportunities for future social and economic development. However, excluding agricultural and biofuels areas, the biotechnology sector is relatively recent in the country. Hence, in order to boost this potential the right strategic decisions must be taken.

So far, Brazil has conquered a leading position in agriculture biotech. It is now the world's second largest producer of plant biotech crops. Moreover, biotech crops area is estimated to increase by 16% in 2012 from the previous year. These figures are highly related with the increase of biotech plantations, which result from recent approval of new legislation and higher availability of subsidized credit to farmers.

However, even though agriculture represents a significant part of the Brazilian biotech market and has future expansion perspectives, the most promising businesses rely in other sectors, such as human health, animal health, and environment and bioenergy.

In these areas, most companies are micro and small size organizations, most of which are still relying on public funding. According to the Brazilian Association of Biotechnology (BRBIOTEC), there were more than 230 companies operating in the Brazilian biotech market by the second quarter of 2011. Most of those (60%) were founded after 2000, and 45% after 2005. Also, 20% of those

companies employ no more than 5 people and up to 45% have no more than 10 workers.

The largest companies are focused on the agriculture market, which is partly controlled by multinational corporations. Hence, although this sector represents a significant share of revenues, it comprises only 10% of biotech companies operating in Brazil.

Also according to BRBIOTEC, most of the smaller firms centre their business in the human health sector (about 40%). Animal health, and environment and bioenergy are also important business fields, each representing around 15% of companies in the market.

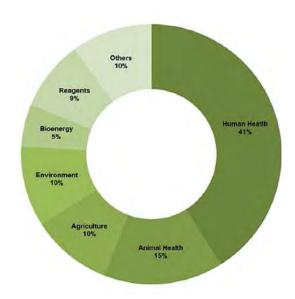


Chart 11 – Distribution of companies across different biotechnology sub-sectors in Brazil.

These different sectors manufacture and develop a great diversity of products. The human health sector includes companies performing drug development, recombinant proteins, cell therapy and vaccines. The animal health sector also produces drugs and vaccines for animals, and works on genetic improvement and animal reproduction. The environment sector is focused on waste management and recovery of degraded areas, and the reagents industry develops bioactive molecules and enzymes.

Similarly to the agriculture sector, which is focused on the development of transgenic seeds and biological pest control, the bioenergy sector is a leading industry in Brazil.

In this specific sector, foreign companies willing to establish partnership's with bioenergy Brazilian firms can benefit both from the large revenues of the Brazilian biofuels market and from the Brazilian know-how in this area.

Geographically, and following the trend of the life sciences subsectors presented before, biotechnology companies are highly concentrated in the Southeast of Brazil, namely in the states of São Paulo, Minas Gerais and Rio de Janeiro. Furthermore, as shown on chart 12,95% of companies are located in only 6 out of the 27 states.

The state of São Paulo alone, host 40% of Brazil's biotech companies. This high concentration of bio businesses is sustained by a large network of Universities and public research organizations which develop partnerships and provide funding to small and medium size private organizations.

"Leader in the biotechnology sector, the state of São Paulo host 40% of national biosciences companies."

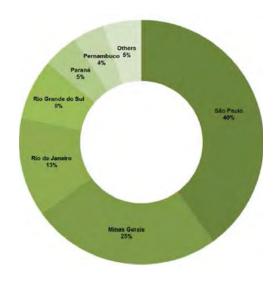


Chart 12 - Percentage of companies per state.



Figure 3 – Geographical distribution of biotechnology companies in Brazil.

THE IMPORTANCE OF UNIVERSITIES AND BUSINESS INCUBATORS

As mentioned above, the large concentration of biotech companies in the region of São Paulo is highly related with the existence of a strong network that includes not only other private companies but also public organizations, such as universities and research centres.

Likewise other life sciences sectors, such as pharmaceuticals, to which the biotechnology sector is strongly related, scientific research have a vital importance to this industry and is often promoted and supported by technology parks and business incubators. For that reason, the Brazilian technology parks network and its importance to the life sciences sector will be further discussed on the next chapter.

According to research performed by BRBIOTECH and BIOMI-NAS associations, up to 95% of biotech companies do have a relationship with universities or research institutes. The main objectives of these partnerships are the co-development of products or processes and the share of infrastructures.

However, the dependence of biotech firms on public institutions is highly related with small investment from private funding mechanisms, such as venture capital. This lack of funding does not enable companies to hire more highly skilled people (the large majority of MSc and PhD still work in universities), to invest in R&D, and to expand production.

Another outcome of current capital shortage is the low contribution of exports for global revenues. Since small organizations do not have the money to develop and grow, only one quarter of companies are able to sell their products abroad. On the other hand, these companies are highly dependent on imports to supply their needs for reagents and equipment.

GOVERNMENT POLICIES AND FUNDING

The approval of several kinds of genetic modified seeds and plants by the government, and the existence of significant subsidies and funding programmes has supported the emergence of strong national biotech clusters in the fields of agriculture and biofuels.

Important funding programmes focusing on technological innovation have also an important role on the development of other biotechnology sub-sectors, supporting research funding needs of almost 80% of the companies. A good example of these funding mechanisms is the "Programa de Pesquisas em Caracterização, Conservação e Uso Sustentável da Biodiversidade do Estado de São Paulo - Biota-Fapesp" (Programme in Characterization, Conservation and Sustainable Use of Biodiversity of São Paulo state). Other programmes, such as "Fundo Setorial de Biotecnologia" and "Capital Semente", supported by FINEP and BNDES, also play an important role on the emergence and expansion of these firms.

Due to the importance of these funding programmes to companies aiming to enter or to establish partnerships in the Brazilian market, further information is provided in a separate chapter of this report (chapter 5).

"Public funding is essential for the development of the Brazilian biotech private sector: almost 80% of the companies rely on this funding to run their projects."

OPPORTUNITIES

The previous topic showed that there is a strong political commitment in Brazil towards the development of a national biotech cluster. Also, biotechnology companies operating in Brazil are likely to achieve significant growth within the next few years by taking advantage of the country's richest biodiversity and considerable market growth.

Hence, Brazil should be considered as a serious candidate for foreign companies looking forward to expand business and invest in new markets.

In order to take advantage of local natural resources and market potential, these investments can either take the form of direct investment and local production or through the establishment of partnerships with local companies.

The establishment of partnerships with local companies can be achieved by promoting technology transfer or through funding high potential small companies. By investing in Brazilian SME and start-ups, foreign companies can support this companies that are still significantly dependent on public funds and path the way to benefit from the large revenues and growth that the Brazilian biotech market is expected to deliver in the next decades.

4. The Importance of Technology Parks

According to the International Association of Science and Technology Parks (IASP), these infrastructures can be described as "organization managed by specialized professionals, whose main aim is to increase the wealth of its community by promoting the culture of innovation and the competitiveness of its associated businesses and knowledge-based institutions".

Since the concept was created in the 1950's, technology parks have played an important role in technological capacity building and development.

Aiming to narrow the gap between companies and research institutions, technology parks bring together in the same location organisations such as, manufacturing companies, testing and analytical laboratories, technology and business incubators, financing institutions, and industrial services. With a proven track of success in scientific and economic development in many knowledge based societies, technology parks became widely spread in recent years. Also, these centres now offer a complete range of services able to foster its main purpose: the share and development of knowledge and ideas.

Modern technology parks offer the most advanced business, IT and communication tools in order to provide a physical environment needed for the development and flourishing of scientific innovations. These objectives are achieved by economies of scale that allow the reduction of investment in infrastructures as well as in operational costs. Furthermore, by bringing the right people together, they promote the technology transfer between firms established within the park.

As stated before, the development of technology parks is a wide spread phenomenon in today's technology era. Hence, following the results achieved by some of the most advanced economies, developing nations like Brazil are now deploying significant public and private funds to the development of strong and efficient technology parks networks.

THE BRAZILIAN NETWORK

The Brazilian network of technology parks is still small for a country with its size. Until recently, only 25 technology and innovation parks were operating all over the country. Also, most of these organisations are located in the South and Southeast regions. The state of São Paulo alone, host 10 technology parks.

Nevertheless, the results achieved by this small network were remarkable. The contribution of technology parks to the economic development of local communities, by promoting innovation and supporting the emergence of new high value economic activities, has been significant.

One of the best examples that show the great positive role of technology parks for local development is the Florianópolis Park in Santa Catarina. This infrastructure allowed regional GDP to take off; IT companies now account for 45% of the entire city GDP and made it known as the South American Silicon Valley.

Though there are no magic formulas, governmental incentives to support innovation and entrepreneurship proven to be a major tool to encourage the creation and development of new technology parks. Consequently, this experience led the government to create an ambitious plan to expand this network.

This expansion plan includes a total of 47 new technology parks, 17 of which are now under construction or ready to open. Another 30 are also planned.

Considering that the 25 parks operating today include 520 companies and generate annual revenues over €1 billion, the new projects can significantly increase the contribution of high technology to national income.



Figure 4 – Geographical distribution of the 25 existing parks in Brazil.

The 74 planned parks cover a wide range of industries and research sectors, including IT, nanotechnology, pharmaceuticals, medical equipment, renewable energies, environment and biotechnology. Also, these institutions are built upon strong bounds with local governments, universities, and private companies; hence fostering the development of truly successful clusters.

The role of public institutions is essential, since Municipal, State or Federal governments are considered as crucial partners to promote and to provide funding to these organisations. So far, local, state and federal governments accounted for 55% of all the investments in these parks.

THE LIFE SCIENCES INDUSTRY

As previously stated, the development of technology parks is still a new trend in Brazil. Hence, in most cases parks are not dedicated to a single research/industrial sector. However, higher specialization in certain fields can be found in almost all of them.

The life sciences sector is spread all over the country, with companies located in a large number of technology parks as well as other locations. However, certain areas can be identified as important centres for each of the three scientific areas presented on this report.

The technology park of Ribeirão Preto (SP) is the most advanced centre of research and production on the medical equipment sector. On the biotechnology field, Bio Rio (RJ) park plays a significant role, and the state of Goiás (Centre-West) has one of the most advanced research and industrial areas in the pharmaceuticals sector.

Nevertheless, it is important to highlight that the area of São Paulo, due to its size in terms of population and economic strength is a major centre for all these activities. Cities of Porto Alegre (RS) and Belo Horizonte (MG) are also important life sciences polo's, with technology parks that concentrate a considerable number of companies operating in the life sciences sector.

5. Funding Programmes and Public Support

Likewise other high technology sectors, the greatest challenges faced by life sciences organizations are associated to long development cycles and large capital needs. In order to cope with these requirements and handle fierce foreign competition, Brazilian companies require a favourable business environment which stimulates private investment, fosters innovation, and strengths its competitive advantages.

The previous topics showed that this favourable environment is already partly in place due to the Brazilian life science market attractiveness and expansion prospects. However, government support is also essential to build and sustain this favourable atmosphere. Moreover, just as important as having support and incentive tools is their continuity and the establishment of long-term policies.

Brazilian public authorities are responsible for a considerable number of important initiatives, ranging from technology transfer support and infrastructures construction to funding and financing special programmes. Nevertheless, some weak points can be found in this strategy, namely, the effectiveness of long-term support and, often, the absence of an overall chain view.

Regardless the fact that improvements between different spheres of federal, state and local government could be achieved, in order to enhance regulatory frameworks and stimulate this sector, a significant number of important public programmes can already be used by companies aiming to establish and develop their business in the Brazilian life science sector.

One of the best examples of governmental support is the deployment in recent year's of considerable investments in

the improvement and expansion of the technology parks network, as described in the previous chapter.

Even though the demand for specialised infrastructures is still an important bottleneck for the development of this industry, new projects now under construction are likely to improve this scenario.

Regarding the support of technology transfer, great progress was obtained with the recently approved Federal Innovation Law, which, by giving special treatment to the interaction between universities and companies, as well as between national and foreign organizations, now strengthened the technological base and innovative potential of the life science sector, also making it more attractive for foreign companies willing to establish in Brazil or to develop partnerships with local institutions.

THE IMPORTANCE OF CAPITAL

According to the description presented on the previous chapters, most companies operating in the Brazilian life sciences industry are small and medium size organisations. Moreover, most of those are still highly focused on research, hence being unable to independently generate enough revenues. For these companies funding supply, either from public or private investors, is essential.

Main government funding contributions are related to support of seed and venture capital funds which invest in the life sciences sector. These funding mechanisms offer attractive lines of credit or non-reimbursable funds to supply companies' capital requirements.

The National Bank of Social and Economic Development (BN-DES) and FINEP, a research and innovation projects financing agency, linked to the Ministry of Science and Technology, are the most important public funding institutions in Brazil.

Aiming to support and develop the federal government policy of promoting the emergence of a national and globally competitive life science industry, these institutions have implemented programmes that specifically target this sector.

These programmes can significantly improve credit availability to small and medium size companies, due to its favourable conditions. For example, BNDES provides funding charging a 3% interest rate, which is considerably lower when compared to Bank of Brazil reference rate (9%); hence making money much cheaper for companies.

As mentioned before, the number of companies in the life sciences sector aiming to access these funds is considerable. Accordingly to several Brazilian life sciences associations, such as BIOMINAS and BRBIOTEC most biotech companies (70%) expect to raise funding from Federal funding programs, with most of them willing to apply these funds primarily in R&D (80%) and secondly in the establishment and expansion of infrastructure (60%).

Amongst the public programmes offered by public agencies such as FAPESP, CNPq, as well as BNDES and FINEP, one of the most important programmes is Profarma, which specifically target the pharmaceuticals industry.

Profarma is supported by BNDES and during its first phase (2004 – 2007) it leveraged investments of R\$2bn. Major spending's addressed manufacturing improvement (supporting the construction, expansion and modernisation of production capacity), innovation, by supporting the promotion of radical or incremental products and processes

innovation, and the empowerment of national companies, by supporting them on acquisitioning and merging processes.

The second phase of this programme, which was launched in 2007 and is still running, aims to provide R\$ 3bn funding to the Brazilian life science sector.

FINEP, on the other hand, is mostly focused on providing non-reimbursable funds for research in order to support both profit and non-profit organisations on every stage of the scientific and technological development cycle.

One of the most important FINEP programmes, considered to be one of its priorities, is the Health Industry Complex programme, to which the agency provided more than R\$ 600 between 2002 and 2009.

Other federal programmes mentioned on the previous chapter, such as PROCIS, Fundo Sectorial de Biotecnologia and Capital Semente also represent important funding resources.

All the programmes supported by these public organisations provide funding for national and foreign companies willing to invest in Brazil, hence representing great financing mechanisms for foreign companies aiming to expand production to Brazil or promote technology transfer to the South American country.

"Profarma programmes provides
R\$600mn annual funding for
the pharmaceutical
and biotechnology sectors"

6. Market Trends and Potential

The previous chapters disclosed Brazil's life science sector remarkable and sustained development trend over the last decade. Also, the data introduced and analysed in this report shows that these results were built upon a strong bid towards innovation, education, and social development, rather than relying on other Brazilian competitive advantages, such as lower salaries.

Furthermore, government's support to the development of high-tech and high add value industries, together with wealth redistribution policies, is creating a virtuous circle of prosperity, which is likely to foster a multiplier factor in the growth of many economic sectors.

The life science sector is not an exception to this rule. In fact, the preceding topics displayed significant growth rates across different sub-sectors of this industry over the last few years. As mention on the second chapter, Brazilian and international organizations forecast current economic growth to be sustained over the next decade. Social inequalities reduction is also likely to continue and, likewise most developed nations, the percentage of elderly people is expected to increase.

These scenario arises great business opportunities for the pharmaceuticals and medical equipment industries, since it is likely to boost demand for its products.

Considering the biotechnology sector, impacts are also expected to be significant, mostly due to the importance of the human health sub-sector, but also to the emergence and development of other areas. These include the expected growing demand for genetic modified seeds, animal health products and biofuels.

Moreover, public investment in the construction of new hospitals and health centres, as well as specific programmes targeted to support companies willing to establish and invest in Brazil are also major reasons for companies to consider Brazil as a serious expansion market.

Henceforth, for foreign companies looking for new and innovative markets to expand, Brazil can offer great opportunities both for technology transfer and direct investment.

FAIRS & EVENTS

CPHI SOUTH AMERICA – 21-23 AUGUST 2012

Pharmaceuticals fair. http://www.cphi-sa.com

IMPORTANT LINKS

APEX BRAZIL (BRAZILIAN TRADE AND INVESTMENT PROMOTION AGENCY)

http://www.apexbrasil.com.br

BNDES (NATIONAL ECONOMIC AND SOCIAL DEVELOPMENT BANK)

http://inter.bndes.gov.br

FINEP (PROJECT FINANCING AGENCY)

http://www.finep.gov.br

MINISTRY OF DEVELOPMENT, INDUSTRY AND EXTERNAL TRADE

http://www.desenvolvimento.gov.br/sitio

MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION

http://www.mcti.gov.br

ANVISA (SANITARY SURVEILLANCE NATIONAL AGENCY)

http://portal.anvisa.gov.br/wps/portal/anvisa/home

INTERFARMA (PHARMACEUTICAL ASSOCIATION)

http://www.interfarma.org.br

ABIMO (MEDICAL EQUIPMENT ASSOCIATION)

http://www.abimo.org.br

BIOMINAS (BIOTECHNOLOGY ASSOCIATION)

http://www.biominas.org.br

BRBIOTEC (BIOTECHNOLOGY ASSOCIATION)

http://www.brbiotec.org.br

