

The pharmaceutical industry in Brazil

*Market overview
and trends*



Overview of the Brazilian market

For almost two decades, Brazil has experienced an important cycle of economic and political stability which has generated a positive effect on the country's economic development. It is important to point out, however, that this expansion has not been continuous and, at certain times, growth rates have been lower than those observed in other emerging countries.

Brazil was one of the last countries to enter the global financial crisis in 2009 and one of the first to overcome this negative period. However, particularly in the last two years, it can be noted that the Brazilian economy is still strongly tied to the global economic environment, and shows a close connection to the performance of emerging economies, principally to economic activity in China, but also related to developed markets: Brazil was significantly impacted by the economic slowdown in the United States and Europe. Even so, the business environment in Brazil is favorable and particularly in relation to the performance and development of the pharmaceutical industry in general, although there are still significant challenges which need to be addressed and overcome by the Brazilian market.

Socioeconomic aspects

Fifth largest country in terms of both land area and population, with 8.51 million square kilometers and close to 200 million inhabitants, in 2012 Brazil recorded a Gross Domestic Product (GDP) of US\$ 2.2 trillion, the world's seventh largest. Market estimates point to the possibility that the country could already become the world's fifth largest economy in this

decade. For this to happen, however, it will have to address important internal challenges, especially the greater availability of more efficient and less costly infrastructure, particularly for transportation and logistics channels, but also in sectors such as telecommunications and energy, in addition to promoting fiscal adjustments to make the state more efficient and allow for improvements in the domestic tax regime, which is considered as complex, costly to comply with and which represents one of the world's highest tax burdens. Another front which the country needs to address is education, recognized as being of poor quality and a key element in holding back local productivity.

The recent Brazilian economic expansion has also been accompanied by the social class improvements: it is estimated that more than 40 million Brazilians joined the middle class and entered the consumer market in less than six years. In 2012, domestic consumption of Brazilians represented 61% of the country's GDP and, even though it was a year in which the world was still recovering from the effects of the global financial crisis, most heavily felt in Europe, Brazil was the principal recipient of foreign direct investment in Latin America, receiving a total of US\$ 65.3 billion.

This development affected the labor market as a whole. For over two years the national unemployment rate has hovered around 5% of the Economically Active Population, which is deemed to represent full employment, in the opinion of several specialists. On the other hand, it is important to stress that the demand

for labor began to stabilize in 2013 and started to lose some of its vigor and there is a feeling among specialists that the market will tend towards a rise in unemployment.

Therefore, some reduction in salary levels can be expected in the local market, also to accommodate the strong increase in recent years. The growth in gross income contributed to the increased consumption, a fact made possible by a government policy strongly supporting the increase in available consumer credit together with reduction in interest rates and lower tax rates on durable goods, namely household appliances, cars and civil construction. In 2013, this set of factors, together with the worldwide trend of dollar revaluation and the devaluation of the Brazilian Real, raised fears of increased inflation, which led the Brazilian Central Bank to resume increasing basic interest rates in the economy. Nonetheless, there is currently no sign of any lack of control over inflation in Brazil, with the intervention of the monetary authorities only necessary to keep rates "on track".

Other factors regarding the Brazilian economy can also be highlighted as follows:

- Second largest agricultural producer in the world;
- Self-sufficient in petroleum with significant offshore oil and gas reserves (pre-salt layer);
- Largest global supplier of mineral commodities;
- Robust and highly qualified financial system;
- Diversified industrial base; and
- Excellent geographical location for trade with all South American countries.

In addition to the economic aspects, another factor inducing Brazil's development lies in its demographic profile. For the first time, the country surpassed the 200 million inhabitants mark in 2013, 10.8% of whom are senior citizens (age 60 and up) and 35.26% whom are young people up to age 14. The economically active population, therefore, is 53.93% of the total. In other words, every group of 100 inhabitants is supported by the work of just 54 people.

The so-called "demographic bonus", the period in which the working age population exceeds that of non-working age should last until 2041, when the proportion of inactive people will finally surpass that of the working age population, reaching 50.15% of the forecasted population of 228 million at that time. The Brazilian Government's statistical agency *Instituto Brasileiro de Geografia e Estatística (IBGE)* estimates that the total number of senior citizens will grow faster while the number of young people will decrease by 2037 when senior citizens will represent 24.15% of the population and young people, 23.76%. In 2041, the elderly population will represent 27.0% of the total and young people, 23.08%.

This transformation is the result of important Brazilian achievements, such as the sharp drop in infant mortality in recent years, which decreased from 23.5 deaths for every 1000 births in the period from 2005 to 2010, to close to 19 deaths for every 1,000 births from 2010. Life expectancy in Brazil also increased over the same period: from 72.2 between 2005 and 2010, to 74 as of 2010 and should reach 75.1 in the period between 2015 and 2020, according to data from the United Nations (UN) and the World Bank.

Health care in Brazil

Therefore, considering the abovementioned data, the health care industry in Brazil is undergoing profound transformations and experiencing new business dynamics, making the domestic market one of the most promising and attractive in the world, despite being extremely complex.

One striking aspect is the fact that the country is the only one in the world to have a universal and free public health care system- in other words, taxes paid by Brazilians cover all kinds of services and treatments offered by the national health system ("*Sistema Único de Saúde (SUS)*") without charging any additional amounts to the user. At the same time, Brazil has higher expenditures in the private health system than in the government system. In 2010, health care expenditures in Brazil totalled US\$ 193.09 billion, according to the World Bank and the World Health Organization (WHO). Of this total, 47% of the revenues came from the public sector, through SUS, and the other 53% from the private sector.

SUS's share of industry expenditures, which include Federal, State and Municipal governments, has grown over the years. These have grown from 41.7% in 2006, to the current level of 47%. In addition, starting in 2013, the country has determined that at least 12% of state and 15% of municipal resources available for investment be applied to health care.

Another form of financing and expanding public health services already operating in Brazil is the implementation of Public Private Partnerships (PPPs), which has significantly grown recently. These contracts are currently concentrated in hospital construction and operation and outpatient service facilities.

SUS is a vital structure for health care in Brazil, as a significant portion of the Brazilian population is unable to access the private health system. However, with the growth in income and expansion of the labor market, more and more people have joined private health plans as they believe the services offered are of higher quality than those provided by the government system.

Participation rates in health plans in Brazil are still relatively low compared to the total population. According to data from the *Agência Nacional de Saúde Suplementar (ANS)*, the government organ responsible for regulating private health plans, close to 48 million Brazilians, or less than 25% of the population, had health plans at the end of 2012.

Dynamics of the pharmaceutical industry

The pharmaceutical industry has shown significant progress in the country, benefitting from the growth in health care expenditures as a whole, and specifically by the increase in household income. From 2007 to 2011, retail drug sales increased 82.2%, from R\$ 23.6 billion to R\$ 43 billion according to an Interfarma report based on IMS Health data.

According to another study performed by Scrip Insights, of the total retail pharmaceutical sales of US\$ 25.8 billion in 2011, US\$ 18.3 billion represented prescription drugs and US\$ 7.5 billion over the counter. In the group of prescription drugs, 25.2% of the prescriptions were for generic products, a 42.5% increase over the previous year. Similar products accounted for 18.8% of prescription drug sales, a 33.8% increase. Although leading the prescription market with 40.8% of sales, brand name medication showed a smaller growth rate, 7.6% in 2011, over the prior year.

Despite having increased over the past few years, the Brazilian population's purchasing power is still relatively low. This factor, together with the popularity of generic and similar drugs, ensures a leadership position for local manufacturers in drug sales.

On the list of the best-selling medication in Brazil are those to reduce cholesterol and control high blood pressure, in addition to a significant portion of drugs not requiring prescriptions and others related to lifestyle, such as Cialis and Viagra, for example. Close to 80% of medication expenditures are for low-cost products, which is a phenomenon related to the low purchasing power of the local population as compared with developed markets. In addition, although the profile of illnesses in Brazil is getting closer to that found in more developed countries, like the United States, diseases common in underdeveloped countries are still prevalent, such as dengue fever, yellow fever and Chagas disease.

From 2007 to 2011 retail drug sales increased by

82.2%

The so-called "demographic bonus" will last until

2025

Of the US\$ 25.8 billion in pharmaceutical retail sales in 2011

US\$ 18.3 billion

refer to prescription drugs

Marketing and sales

The drug market in Brazil is also characterized by an important set of peculiarities. For example, there is price control, a regime administered by the *Câmara de Regulação do Mercado de Medicamentos (CMED)* (the “Drug Market Regulation Chamber”). It is CMED’s responsibility to define maximum product prices, define the annual price adjustments and ensure that the pharmaceutical industry complies with these determinations.

Prices of new drugs are defined based on overall reference values. The cost in Brazil may not exceed the lowest price charged in nine different markets (United States, New Zealand, Australia, Greece, Portugal, Italy, Spain, France, Canada, and, possibly, the country where the drug comes from). In this case, the price control and freeze system applies for one year. It is the pharmaceutical industry’s responsibility to negotiate discounts with the retail trade.

An important challenge in Brazil is related to the generic drug industry. With tighter margins, many companies have revised their aggressive discount policies, which in many cases went as high as 90%. The increased product costs and resultant reduced margins have led some companies to lessen discounts granted on medication. By law, generic drugs are 35% cheaper than the corresponding reference drug. But average discounts on these products exceed 50%.

An important aspect in the domestic market is the high market concentration in the hands of a few regional and national companies: between 65% and 75% of medication is delivered by local distributors,

while only 25-35% goes directly to retailers. Retail chains also have started to attract interest from domestic and foreign companies aiming to consolidate the industry. In August 2011, Drogasil and Droga Raia announced a merger of their operations followed, in the same month by a similar transaction between the Drogaria SP and Drogaria Pacheco chains. In February 2013, the American group CVS bought the operations of the Onofre drugstore chain.

SUS is also responsible for the sale and distribution of medication in Brazil, especially those requiring continuous use and for low income consumers. There are three national programs for the sale and distribution of medication, but these drugs must appear on the *Relação Nacional de Medicamentos Essenciais (Rename)* (“National List of Essential Drugs”). For purchases made by SUS, continuous use drugs must include a 35% price discount, which is the result of applying a “price adjustment coefficient”. This includes, for example, drugs used for several kinds of cancer treatment, HIV infection and chronic diseases, such as schizophrenia, rheumatism and arthritis.

Another government drug distribution initiative is the *Programa Farmácia Popular*, (the “Popular Pharmacy Program”) aimed essentially at supplying low cost generic and similar drugs to the low income population. This attempt, however, has not succeeded due to the difficulty people have in accessing this system: less than 10% of the market is supplied by this program.

At the same time, there has been an increase in the number of claims by SUS patients and medical plan

beneficiaries to obtain access to innovative and higher cost medication which, are still not offered by the public health system nor have they been included on the list of mandatory medication provided by the private health system. The large number of legal actions to obtain medication and treatments is known in the market as “Judicialization of Health Care”, one of the chief risks to the country’s health care system.

Regulation and investments

The regulatory agenda is another point which has deserved attention from the government and concerns companies operating in the local market. Although Brazil has made some important adjustments in recent years, there are still fragilities which need to be addressed.

This is the case, for example, of the long period required for the approval of new drugs by the *Agência Nacional de Vigilância Sanitária (Anvisa)* (“National Sanitary Vigilance Agency”) and recognition of intellectual property on some new drugs. Making this situation worse, there is also a dispute between Anvisa and the *Instituto Nacional de Propriedade Intelectual (INPI)* (“National Intellectual Property Institute”) as to which of the two organs is responsible for recognizing drug patents.

Frequently there is also concern about potential risks related to brand protection and an environment which combines excessive bureaucracy and a complex tax regime. These adversities are obviously reflected in Research and Development (R&D) expenditures: local pharma labs received only US\$ 140 million of the US\$ 40 billion invested worldwide in this area in 2009.

Despite these challenges, there is no question that Brazil appears as an emerging market and a key one for pharmaceutical companies interested in offsetting the slowdown in sales in developed markets. Thus, many multinationals have chosen to acquire local companies as a strategy to enter the Brazilian market. In 2009, according to IMS Health, the local industry had 378 players controlled by 45 laboratories who received 91.7% of total industry sales.

The local pharmaceutical industry is dynamic and growing and there are a large number of initiatives aimed at developing biotechnology projects. Additionally, the government has attracted new investment in the area through its program to support the development of a Health Care Industrial Complex (Profarma), of the National Economic and Social Development Bank (BNDES). The main objective is to substitute imports with local products and form partnerships between foreign and domestic companies. Thus, several organizations have strengthened their presence in Brazil through mergers and acquisitions, expansion of operations and new product launches.

In 2009, the Brazilian company Hypermarcas acquired Neo Química, a local generic drug manufacturer. Eurofarma, a Brazilian company concentrated in the generic drug segment, has expressed its intention to expand regionally by taking control of Laboratórios Gautier, with facilities in Uruguay, Paraguay and Bolivia.



Foreign companies, instead of deactivating operations which they have done in developed markets, are making important investments to expand activities in Brazil. In April 2009, Sanofi acquired Medley for US\$ 680 million. Novartis invested US\$ 500 million in its operations to establish a vaccine plant close to Recife, while the Japanese company Takeda announced in February 2010, that it was investing in a new subsidiary in Brazil, based in São Paulo. This is the company's first incursion into Latin America. In October 2011, Takeda announced a merger with the Swiss company Nycomed, creating the world's 12th largest pharma laboratory. In March 2012, the group assumed control of Multilab, a local generic drug

manufacturer, and, in May 2012, UCB acquired Meizler, another local player, just to mention some examples of industry transactions.

Also in this context, several state and municipal governments in Brazil are promoting incentive programs for investment in the pharmaceutical industry, in order to construct industrial manufacturing centers. These special regimes have ensured improvements in infrastructure as well as manpower training, two factors which are still deficient in Brazil. Many of the projects also include special fiscal and tax regimes to stimulate new investment in the industry.

Principal trends of the industry in Brazil

Even though there have been momentary variations in the performance of the Gross Domestic Product (GDP), the Brazilian health care market has shown itself to be robust and strongly resilient, even in periods of lower economic activity.

A large part of this phenomenon can be explained by the strong cycle of expansion of the middle class, the result of the income growth and a labor market still technically considered to be at ‘full employment’. In this case there is a strong connection between the domestic labor market and supplemental health care plans, as most of the industry’s contracts are collective corporate plans and this represents one of the benefits most valued by employees.

Therefore, as long as the country is able to maintain economic stability and, chiefly, the level current of employment, continued new contracts for health plans and maintenance of current plans can be expected. In addition, the local news media has given wide coverage to the fact that the Federal Government is studying, together with health plan operators, a possible financial subsidy, in addition to tax benefits, to create health plans at lower cost and, consequently, become more accessible to the low income population.

The expected growth in the supplementary health market also makes these activities attractive for investors, especially foreign investors. In the short term, there is great expectation of new acquisitions of health plan operators by foreign companies, similar to the operation led by UnitedHealth when purchasing Amil, an almost R\$ 10 billion deal, which took place in 2012. With the entrance of this new management, an environment of greater competition is expected in the supplementary health care industry, in addition to effective economies of scale and greater productivity among the companies involved.

This combination of actions becomes a very relevant aspect to be considered by the pharmaceutical industry. This is true because recently, the *Agência Nacional de Saúde Suplementar (ANS)*, (“National Supplementary Health Care Agency”), the regulatory agency covering health plans published a standard allowing operators to sell health plans which also include coverage for medication. However, the standard, announced in 2012, has not yet affected the market to the point of making this type of plan available or changing existing plans.

Precisely for this reason, many professional, especially among health plan operators and health insurance companies, believe that, in the near future, coverage of medication will be made mandatory by the ANS for all health plan contracts, new or old. Some signs to support this belief have already been given, such as, for example, the recent ANS resolution which determined that certain oral medication used in cancer treatments be covered by health care operators at no cost to plan beneficiaries.

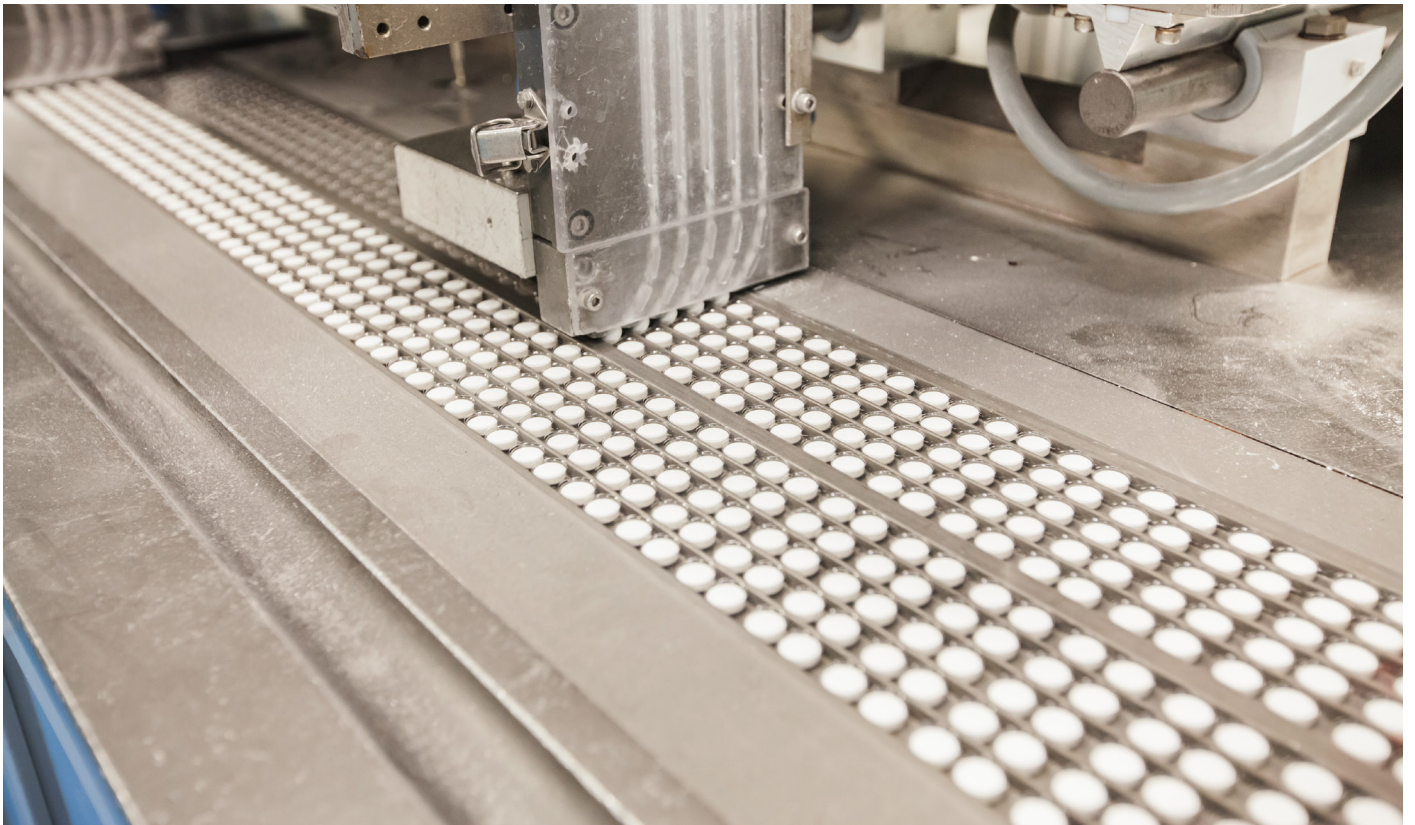
If this is confirmed, it would not be a surprise if the new format of the market makes health plans a relevant source of drug purchases in Brazil, surpassing the government and disputing leadership with retail chains. Even so, the pharmaceutical retail trade remains the fundamental market entry point. With mergers among major companies and the recent entrance of the American company CVS into the Onofre chain, further consolidation of operations as a result of the strong growth in drug sales is expected.

This whole debate takes place in an environment of high health care costs with no signs of reduction or, even, slower rates of increase. Some stopgap measures have been implemented by the federal government to reduce this cost pressure.

Recently, a new electricity pricing policy was implemented to reduce the costs of this input. On another front, the BNDES launched a program to grant financing for new projects and ventures in the health care area, also including the pharmaceutical industry. This initiative is expected to result in a reduction of input and drug imports in the medium or long term, which will result in lower costs in the domestic market. On the other hand, in the search for innovation and facing the need to cut expenses, a market niche of bio similar drugs has begun to evolve, and will tend to grow more in the coming years. With the support of the BNDES and financing from the National Council of Scientific and Technological Development (CNPq), the intention is to develop the production of bio similar products, taking advantage of countless current initiatives throughout the country in the field of biotechnology and maintain the governmental focus on producing “essential drugs” locally”.

In April 2011, through the state-owned laboratory *Instituto Vital Brasil*, the Brazilian government announced an agreement with PharmaPraxis, a Brazilian pharmaceutical conglomerate to develop a biosimilar version of Humira (adalimumab, Abbott Laboratories). The purpose is to reduce the impact of the cost of this medication in *Sistema Único de Saúde (SUS)* purchases. Abbott, for its part, denies reaching any agreement with the Brazilian government, but, as the Humira patent is protected in Brazil until 2016, it is not clear at this moment if the biosimilar version of the product will enter the Brazilian market before 2016, which would represent breaking Abbott’s patent. In addition to Humira, SUS has included another 25 drugs on the list which could be produced locally in the coming years.

While, on one hand, the government is trying to contain and stimulate competition in the health care area and, by extension, also in the pharmaceutical industry, there is clear recognition of the need to increase SUS funding. Since the beginning of 2013, the state and municipal governments increased budget allocations earmarked for health care expenses. It is expected that, with the current growth in government expenditure in this area, very soon public expenditure will equal those in the private health care market in Brazil.



Much of this impact also comes from the end of the so-called “demographic bonus” and, as of 2020, the aging of the Brazilian population, which is expected to peak in 2030, when the country will have more senior citizens than the Working-Age Population (citizens between ages 15 and 64). In addition to the growing demand for medication brought about by aging, it should also be considered that public and private administrators have given greater emphasis to programs which promote good health, in order to increase population longevity promoting a better quality of life. The significant increase in obesity registered in the Brazilian population in the past few years is also of concern. Greater demand for medication related to people’s lifestyles and the promotion of greater well-being among the population can be expected.

In the case of Brazil, some regulatory risks still persist which should be overcome after further interactions between government and industry. There is a clear priority from the government on this subject. In 2012, within the scope of the Productive Development Partnership Program (PDP), the Health Ministry signed 20 new partnerships with private- and state-owned laboratories, in addition to scientific institutions, with the objective of transferring technology and establishing local production of medication and vaccines to be offered by SUS. Estimated investment is in the order of R\$ 5.7 billion, promoting savings on drug purchases of up to US\$ 2.7 billion in 2014. It is expected that 30 million doses will be supplied to SUS by next year. The government also guarantees exclusivity for the purchase of medication at prices lower than those quoted on the global market for five years.

As already indicated in some editions of the series “Pharma 2020”, published by PwC, it is estimated that, by 2020, companies will become more dependent on emerging markets, where between 30% and 55% of their revenues will be generated. In the case of Brazil, revenue on the sale of patent medication will be less than that of generics: US\$ 8.8 billion vs. US\$ 15.3 billion.

This situation, like the rest of the production and market structure in Brazil, represents a paradox for pharmaceutical companies. The market potential is large, but obtaining a return is difficult, and the dispute between competitors is very strong. Operating in this market can represent risks, whether or not the corresponding share of company revenues is material. Each company, therefore, has the challenge of deciding whether or not to invest in emerging markets, to what extent, where it plans to apply funds and which strategies to use.

How we can help

We are a global network of firms with over 180,000 professionals in 158 countries. We have close to 9,000 specialists in the health care area alone who are integrated with our other areas of excellence, always focused on generating value and tangible and sustainable results for our clients.

We have a multidisciplinary team, with a broad experience in large hospitals and health care operators, expertise in negotiations with current and potential suppliers, credibility with financial institutions and good relations with industry regulatory entities.

Every day we are involved in solving strategic problems and looking for unique solutions for our clients' problems based on a combination of knowledge of the pharmaceutical industry, technical training, proven methodology and experience in the many diverse areas we deal with, both in Brazil and all over the world.

We work, together with our clients to develop winning business strategies

- Clients hire us to solve strategic and operational issues.
- Through our international network of experts, supported by our deep knowledge of industry issues and best practices, we offer unique solutions that bring concrete benefits to each clients' challenges.
- Our goal is to support our clients in designing, managing and executing beneficial and sustainable changes.

1.
Building efficient organizations

2.
Innovation

3.
Cost reduction

4.
Technology

5.
Leveraging talents

6.
Managing crisis, risks and regulation

7.
Strategic growth

8.
Business management

9.
Compliance

Our principal services are:

Auditing

We audit local financial statements and standardized formats for the purpose of group consolidation, in accordance with the professional and ethical standards related to independent audits applicable in Brazil and with the International Auditing and Assurance Standards Board (IAASB). We also review HR, purchasing, legal department, controllership, technical provisions, treasury and commercial processes, as well as process mapping, tests, identification of control deficiencies, alignment of recommendations, support in defining action plans and follow-up of the implementation of these plans, in addition to designing and implementing the budget management system.

Included among the principal audit activities are:

- Statutory financial statement audits.
- IFRS financial statement audits.
- US GAAP financial statement audits.
- Consolidation package audits.
- Internal controls audits (US-SOX, J-SOX, etc.).
- Systems audits.

Consulting

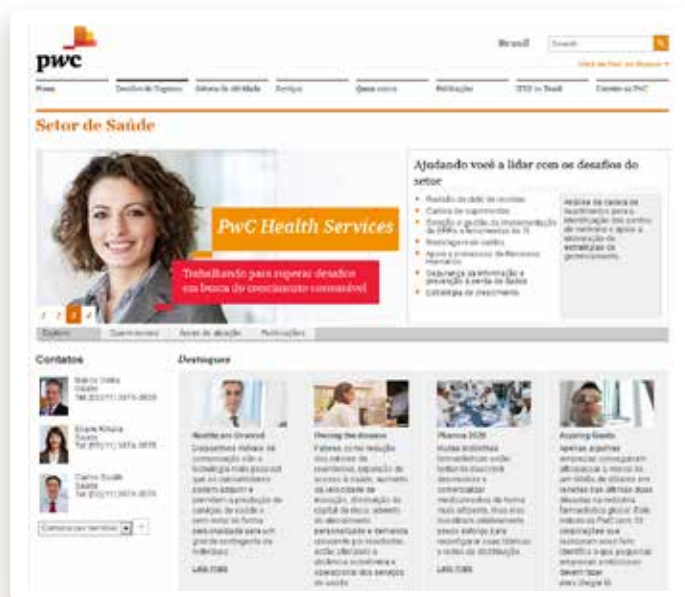
We offer support all the way from the preparation of a plan to enter the Brazilian Market to expansion to other regions. Among other services, we also assist in defining plant locations and structuring business plans, tax consulting, strategic management and process restructuring focussed on gaining in efficiency.

Our principal Consulting activities include:

- Tax compliance.
- Tax planning.
- Strategic planning.
- Implementation of “go to market” strategies.
- Budget planning.
- Evaluation and improvement of the finance function.
- Structuring of shared service consolidation.
- Merger, acquisition, sale and restructuring processes.
- Post-merger integration.
- Governance, Risks and Compliance (GRC).
- Market regulation.
- Development of risk management models.
- Compliance monitoring programs.
- Due Diligences including the FCPA.
- Technology.
- Outsourcing.
- Human resources.
- Organizational development.
- Efficiency and cost reduction.
- Supply chain.
- Sustainability.

Knowledge generation

In addition to having an exclusive website dedicated to health care, which represents one more communication channel open to clients on a full-time basis, PwC works to generate constantly in generating knowledge by performing relevant research and studies annually for the pharmaceutical industry and the health care area as a whole. These studies address issues such as accounting, tax legislation, risks, regulations, sustainability, strategy and growth, governance, operations, innovation and technology, talent and changes.



An example of this work is “*Pharma 2020: which path will you take?*”, a series of publications exploring fundamental questions for the future of pharmaceutical companies, such as productivity, R&D, marketing and sales, supply chain management and tax planning, amongst other topics.

To make this work possible, PwC has three centers of excellence:

- **PwC Health Policy Economics (HPE)**
A unit specialized in applying economic analysis and statistics to a broad group of issues related to health care. Using quantitative analysis and focused research, the HPE helps clients to study and become acquainted with the impact of changes in legislation and regulations on organizations and the other stakeholders in the value chain.
- **PwC Global Best Practices (GBP)**
This center offers the best market practices and sources for benchmarking to help companies evaluate their performance, mitigate risks and learn new ways to perfect their processes. The GBP data base is continually updated with proven practices by leaders in each segment and provides clients with detailed information on a variety of business processes which can make all the difference for the success of your operation.
- **PwC Health Research Institute (HRI)**
This institute develops relevant and innovative publications, in addition to research for our clients on important problems in the pharmaceutical industry and health care sector as a whole. The HRI is part of a major PwC initiative in industries related to the health care area which brings together experience and resources to allow for collaboration among all actors in the market, to provide intelligence and analyses on the industry.

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