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2023 Profile of the pharmaceutical industry and relevant sector aspects

Pharmaceutical market in Brazil

The Brazilian drug market has traded BRL 106,78 billion in 2022, equivalent to USD 20.70 billion [Canal Farmácia (Pharmacy Channel), net value - average discount of 37.58 %], according to surveys by consultancy company IQVIA. There was an increase of 16,95 % in BRL, compared to the previous year, representing approximately 2 % of the world market, being the 10th in revenue in the ranking of the 20 main economies. In Latin America, it is the main market, ahead of Mexico, Colombia and Argentina.

Industry profile

In 2022, the Brazilian drug market had 341 pharmaceutical companies, with prescription and nonprescription drug revenues starting at 50 thousand BRL/year according to consultancy company IQVIA. Of these companies, 95 (27.86%) were of international origin and 246 (72.14%) of Brazilian capital. At Canal Farmácia (Pharmacy Channel), multinational companies held 32.08% of the market in sales and 20.25% in boxes sold. Laboratories with Brazilian capital accounted for 67.92% of the market in revenue and 79.75% in boxes sold. The growing share of generic drugs gave companies in the industry important growth in units, expanding the Brazilian industrial park.

Tax burden

The recent approval in the Chamber of Deputies of the Proposal to Amend the Constitution (Constitutional Amendment) which deals with the reform of the Brazilian Tax System, corroborates Sindusfarma's historic claim regarding a differentiated taxation regime for medicines as well as for other goods and health products. The practice is applied by several countries.

This is an urgent and crucial measure given the notorious essentiality and importance of these products for individual and collective health and for the financial and operational balance of the public and private health systems in the country. Currently the tax burden on medicines for human use corresponds to 31.3%, on average, of the consumer price, one of the highest in the world.

Economic regulation

Economic regulation should serve as an instrument for improving the market, stimulating the search for innovative products and establishing an environment conducive to investments in general and protecting consumers by guaranteeing a sound market. A system of economic regulation in tune with the fundamentals of the economy does not support price control mechanisms such as those the country has been using for the pharmaceutical industry in recent decades. It is necessary to modernize the current prices regulation.

Price control

Unilaterally adopted and without a broad, articulated and long-term economic strategy, price controls in the past have disorganized the pharmaceutical chain and inhibited investments in factories and in the launch of drugs. The control must be selective and not comprehensive, being restricted to classes of drugs in which the market can be considered imperfect (of low competition). In 2019, CMED Resolution No. 02/2019 of the Drug Market Regulation Chamber (CMED, in Portuguese acronym) was published establishing procedures for the release of the Factory Price for Over-The-Counter (OTC). The OTC market has its prices free of control and this release has not brought any inflationary impact.

Price Adjustments

Since the end of 2000 the pharmaceutical industry has been subject to strict price controls. From January 2012 to March 2022 the average accumulated adjustment granted by the Drug Market Regulation Chamber (CMED) was 81.05% compared to an overall accumulated inflation of 87.90% in the same period in the country measured by the Brazilian Index of Broad Consumer Prices (IPCA) from Brazilian Institute of Geography and Statistics (IBGE).

Innovation

The Brazilian Innovation Law is a critical action for strengthening the pharmaceutical industry. The country lacks guidelines for the relationship between the private sector and public institutions such as university research centers. There is a need for greater subsidized public financing in this segment as the risk with research is great and the result is uncertain.

Incremental innovation

An important gap that needs to be addressed in the drug pricing rule in force in Brazil is the correct understanding of products based on incremental innovation. The current rule does not encourage companies interested in modernizing the so-called "old products", which are widely prescribed because of their proven effectiveness and which can be improved with important therapeutic gains such as lower dosages, reduced treatment time or less side effects in addition to possible cost reductions.

R&D and Clinical Research

Brazil has favorable conditions to become an advanced research center. Its biodiversity - the largest in the world - increases the country's potential to receive investments. To better take advantage of these resources it is necessary to have a policy that favors Innovation, encouraging investments, a more intense exchange between Brazilian and international researchers and, especially, a defined, stable regulatory framework that adequately protects intellectual property. Actions by the Ministry of Health to speed up the approval of Clinical Trials in Brazil have improved the local environment for this investment. Both National Commission of Ethics in Research (Conep) and National Health Surveillance Agency (Anvisa) have reduced the approval times for local Clinical Trials but there is a need to modernize regulatory frameworks and better define the individuals' rights in research. The Covid-19 pandemic has shown that more and better can be done with the same resources.

Patents

Despite defining as a priority the support for research, the development of drugs and the exploitation of biodiversity, the country has a lengthy process for analyzing and approving patents. This is due to the lack of structure of National Institute of Industrial Property (INPI), which would need to be strengthened to streamline the innovation network based on the international rules of compliance with intellectual property signed by Brazil.

Compulsory licensing

It is an illusion to think that the suspension of intellectual property rights for vaccines and drugs accelerates and expands the supply of these products, in addition to reducing prices. The so-called "patent breach" is ineffective because it disregards the complexity, investments and time required to absorb drug manufacturing know-how in its various scientific, technological, operational and financial aspects. There is only one effective way to incorporate technologies in the pharmaceutical area: the negotiation of technology transfer agreements complying with Brazilian and international legislation that regulates intellectual property.

Data protection

A complementary aspect to the granting of patents that needs to be guaranteed in the country, in accordance with international law, is the exclusivity period on information related to the security and efficacy tests of drugs provided to the regulatory agency by the pharmaceutical companies that hold products. The measure would create a strong additional stimulus to investments in incremental innovation by companies in the industry.

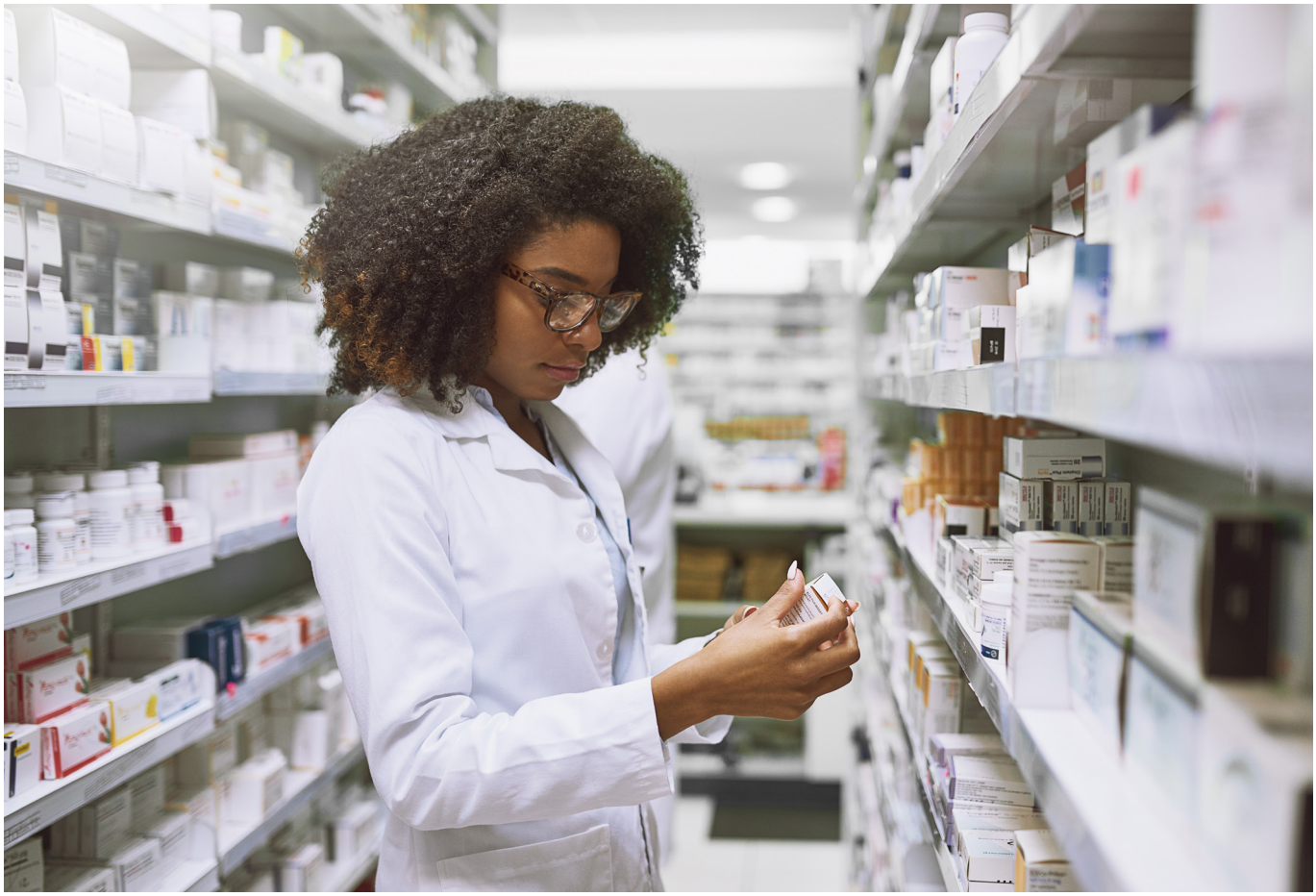
Generic drugs

In recent years, this segment has been gaining more and more market space. In 2022, generic drugs were responsible for 14.39% of revenue from drug sales in drugstores and 35.43 % of units sold (boxes).

Access to medicines

Despite price controls, the situation of access has changed little in the last decade, which shows that the main obstacle to expanding access to drugs is not price: it is, in fact, insufficient pharmaceutical assistance programs within the scope of the Unified Health System (SUS) and the Brazilian population's low average purchasing power. It is a fact that public funds for purchase and universal distribution of drugs have increased in recent years but the country still invests little in health: according to the WHO, Brazil spends 8.2% of its Gross Domestic Product (GDP) on health, of which 4.4% come from private spending and 3.8% from public spending.

Created in 2011, the National Commission for the Incorporation of Technologies in SUS (Conitec) analyses the claims from companies in the Health Productive Complex for the incorporation of drugs and other products to the public health system list. Periodic inclusion of modern drugs in the treatments offered by SUS is a critical action to offer the population cutting-edge products, in addition to encouraging pharmaceutical laboratories to invest in innovation.



Popular Pharmacy Program in Brazil

Created in 2004 and perfected in 2010, the Popular Pharmacy Program has represented an advance in the health system, in line with an old idea from the pharmaceutical industry according to which the pharmaceutical chain development must include the social function of expanding the market consumer of drugs (from which millions of Brazilians are excluded) without, however, disregarding the economic logic. The future of the pharmaceutical industry in the country depends on initiatives like this, which point to the desired situation of convergence of projects and synergy between government and private companies.

Until May 2023 the program had 27,461 accredited drugstores distributed in 4,127 municipalities where patients are offered different brands and presentations of 40 medicines. In the years 2020 and 2021, the Brazilian government spent approximately BRL 2.6 billion/year on the purchase of drugs for the program, granting over 14.1 billion pharmacotechnical units (tablets, ampoules, doses etc.) each year. Such amounts represent an 8.5% drop in the amounts paid compared to 2017 the year of greatest investment in the program.

Stimulating foreign trade

Expansion of the pharmaceutical industry in Brazil by means of conquering foreign markets depends on a modernization of tariffs, which includes, among other measures, the revision of import tariffs and the removal of barriers to exports. Some Brazilian companies are in the midst of an internationalization process. Recent initiatives to implement risk management activities have considerably reduced the deadlines for releasing products imported into Brazil.

Balance of trade

In 2022 pharmaceutical industry exports were US$ 713 million, which represented a high growth of 45.7% compared to the previous year. Imports of finished products, semifinished products, vaccines, blood products and other pharmaceutical products reached USD 7.1 billion - a drop of 11.9% compared to the previous year.

The drug and pharmaceutical products sector has been presenting a trade balance deficit of between US$ 3 and 4 billion in recent years but in 2021 and 2022 this deficit jumped to US$ 6 to 7 billion. According to the Ministry of Economy the significant increase in the deficit is due to some factors such as the exchange rate and the disorganization that the pharmaceutical sector presented in its production chain during the pandemic, with the consequent high costs of inputs and the cost of freight.

Jobs

The Brazilian pharmaceutical industry maintains just over 91,000 direct jobs in companies that manufacture medicines for human use, according to the most recent official data available from RAIS (Annual List of Social Information, a report of socioeconomic information requested from legal entities and other employers annually), from the Ministry of Economy. These direct jobs generate around 800,000 indirect jobs.

Industrial policy

The pillar of a successful industrial policy for the pharmaceutical industry is long-term financing with subsidized interest. A small advance has occurred with the creation of the so-called Profarma Programs by Brazilian Bank for Economic and Social Development (BNDES), whose financial contributions are insufficient to meet the industry's demand, especially in relation to research and development. Other aspects should be part of a technological innovation policy with a stable and defined regulatory framework which should include the industry's development. The industrial policy needs clear and perennial rules. There is no industrial policy without legal certainty.

Development of the sector

The pharmaceutical industry development should be based on the following equation: stimulating local production, stimulating innovation, an environment conducive to conducting clinical research in the country and adopting public policies on access to drugs.

Health regulation

Health regulation should be an instrument to guarantee drugs quality and security and to protect consumers without creating unnecessary limitations on the industry. To achieve this goal, regulatory bodies need to be equipped with sufficient personnel and infrastructure to perform their role comprehensively and effectively. Today, the National Health Surveillance Agency (Anvisa) is recognized as one of the best health agencies in the world. Brazilian Law 13.411/2016 established deadlines for approval of registrations and post-registrations in Brazil, granting predictability to pharmaceutical companies located in the country.

Updating Good Manufacturing Practices

In 2020 National Health Surveillance Agency (Anvisa) was accepted as a member of the Pharmaceutical Inspection Cooperation Scheme (PIC/S). This international entity concentrates requirements for Good Manufacturing Practices and Inspections in pharmaceutical industries. Being a member of PIC/S brings wide advantages to the country. First, by equating the Brazilian regulatory system with that of the most developed countries. Second, by streamlining and facilitating drugs export and import among the countries with which Brazil has an exchange of drugs in view of similar requirements.

Reverse Logistics of Household Drugs

In the beginning of 2021, in a partnership with the Brazilian Ministry of the Environment and state sanitation agencies, 17 entities representing the pharmaceutical industry started the implementation of the Brazilian Reverse Logistics System for Expired or Unused Household Medications for Human Use and their Packaging (MDVD) based on the National Policy on Solid Waste (PNRS) (Law 12.305/2010) and Federal Decree 10.388/2020. The System provides for the disposal of MDVDs by consumers in drugstores and pharmacies and their shipment to the places of treatment and environmentally appropriate final disposal with the participation of manufacturers, importers, distributors and retailers. In the first two years, the System should cover the 27 state capitals and cities with more than 500 thousand inhabitants. There are already approximately five thousand collection points for the correct destination of household medication waste.

State laboratories

Production of drugs by state laboratories must meet strategic objectives of public health policy in the country such as the manufacture of essential products for which there is no sustainable market. It is not the State's role to compete with private laboratories in the production of drugs that the private sector is able to produce at lower prices for consumers. These laboratories have had government incentives in recent years to absorb technologies by means of PDPs (Partnership for Productive Development). Currently, the PDPs framework is being reevaluated.

Sindusfarma, aiming to make the above topics come true, actively participates in the following groups:

- **CONITEC (National Commission for the Incorporation of Technologies in SUS)** – Incorporation of new technologies in the Brazilian Unified Public Health System (SUS) is important for the development of access and industry in Brazil.
- **CNS (Brazilian Health Council)** – This council determines the country's health policies and Sindusfarma advocates the valorization of the pharmaceutical industry established in Brazil.
- **COPIN (CNI's Industrial Policy and Technological Development Council)** – At the Brazilian Industry Confederation (CNI) Sindusfarma advocates public and private policies for the development of the pharmaceutical industry installed in Brazil, regardless of the origin of the company's capital.
- **COMSAÚDE FIESP** – ComSaúde, acronym for Health Committee, has been created by FIESP (Federation of Industries of the State of São Paulo) to support entities in the health, biotechnology and nanotechnology production chain. ComSaúde seeks to establish an impartial communication with the entire health sector, encouraging the discussion of agendas and aiming to foster dialogues among all parties involved.

To leverage the topics above, in addition to Sindusfarma's participation in the aforementioned bodies, we hold several seminars, workshops, work groups, strategic commissions, bringing universities, government and industries together, aiming at conveying knowledge and making dialogue possible among all.

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