The Brazilian pharmaceutical industry: actors, institutions and policies

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Abstract

The Brazilian pharmaceutical market is the largest in Latin America and the Caribbean and the 7th largest globally. The sector has a concentrated structure, with the ten largest companies responsible for 41.2% of the products registered with the Brazilian Health Regulatory Agency (ANVISA). Since the 1990s, several important institutional developments have changed this structure, which caused different responses from companies. This paper aims to characterise the main actors in the Brazilian pharmaceutical industry – national companies, foreign companies and public laboratories – and analyse how they were affected and how they reacted to these institutional framework changes. The results show that national companies have been gaining prominence in the Brazilian pharmaceutical market with their internationalisation movement and their strengthening of innovation strategies. On the other hand, foreign companies have drastically reduced their local production of medicines in Brazil. They keep the technological efforts within their headquarters and only import innovations launched to Brazil. Public laboratories have a smaller market share, since they can only sell to the Unified Health System (SUS). They produce mature products, and their budgets are unstable, but they are vital in the local production of vaccines, as seen in the production of the COVID-19 vaccines.

Keywords: Pharmaceutical industry, development policies, institutional framework, Brazil

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Introduction

Brazil comprises the main pharmaceutical market in Latin America and ranks 7th in the world, right behind the United States, China, Japan, Germany, France and Italy, representing around 2.6% of the total global pharmaceutical market in 2018 (SINDUSFARMA 2020). The Brazilian pharmaceutical market has a concentrated market structure, as well as the world pharmaceutical markets. The ten largest companies are responsible for almost half (41.2%) of the products registered with the Brazilian Health Regulatory Agency (ANVISA) for commercialisation. In 2017, 214 pharmaceutical companies were operating in the Brazilian market, earning USD 13.9 billion (BRL 70 billion)[i] and selling more than 6,500 products in 458 therapeutic subclasses (ANVISA 2018).

There was an increase in the volume of manufactured products (36.9%) and in the number of employees (53.6%), but a reduction in the number of production facilities (-47.4%), denoting a relative rise of medium and large firms (29% to 47%) from 2003 to 2020 (ME/ST 2020; IBGE 2021). In 2019, the sector employed 94,283 people, 95% in pharmaceuticals and 5% in pharmochemicals (ME/ST 2020).

Despite this relevant growth in the production and in the size of companies, the production in terms of transformative value shows a negative trend. The average annual growth of the pharmaceutical industrial transformative value (value-added proxy) was 2.4% from 2007 to 2020. The share of value-added in gross output fell by 9 pp (65% to 56%) in the pharmaceutical industry and almost 20 pp (62% to 43%) in the pharmochemical industry (IBGE 2020a). As a result, the trade deficit of Brazil's pharmaceutical industry has increased by 10.6% since the 1990s and has become a structural problem, reaching USD 5.7 billion in 2019. Most of the country's imports consist of finished products, including medicines. Even though active pharmaceutical ingredients (APIs)[ii] imports increased by 252% between 2003 and 2019, amounting to around USD 2 billion per year (ME 2020).

The pharmaceutical sector's performance demonstrates its low capacity to add value to production, which has been replaced by imported inputs in domestic production – about 45% in 2018 (CNI 2018). On the other hand, the export coefficient rose from 4% to almost 12% between 2003 and 2018 (CNI 2018) and Brazil became the largest Latin-American exporter of pharmaceutical products in the region between 2018 and 2020 (CEPAL 2021). Furthermore, between January and September 2022, the pharmaceutical industry represented 27% of Brazil's high technology industry total exports (IEDI 2022).

The Brazilian pharmaceutical industry comprises public and private national companies and foreign companies. In the early 2000s, only one company with national capital was among the ten largest (Hasenclever, Fialho, et al. 2010). In recent decades, national companies have gained prominence in the domestic market share, especially in generic medicines. Foreign companies have been drastically reducing their production activities in Brazil, focusing on commercialising new medicines developed abroad. The public laboratories have a smaller share of the market, since they can only sell to the Unified Health System (SUS), but they are vital in the local production of vaccines, especially in the production of the COVID-19 vaccines (Paranhos and Perin 2021; Paranhos, Mercadante, and Hasenclever 2020; Radaelli 2012; Hasenclever et al. 2018; Oliveira et al. 2004).

The paper aims to characterise the three groups of actors in the Brazilian pharmaceutical sector – public and private national companies and foreign companies – and to discuss the institutional framework changes and the policies implemented from 1990 to 2020 that promoted stimuli and obstacles to the development of those companies. The research question is: What lessons were

learnt, and what future directions are needed for developing and strengthening the Brazilian pharmaceutical industry? Are these lessons relevant to Latin American countries?

The methodology is descriptive and exploratory, comprising a survey of secondary public data and an analysis of scientific literature, newspapers and official documents. The main official datasets used are the Brazilian Institute of Geography and Statistics (IBGE), the Secretariat of Labour of the Ministry of Economy (ME/ST) and the ANVISA.

Institutional framework and development policies (1990-2020)

In 30 years, the institutional framework and development policies have significantly changed in Brazil, but the intensity and direction of the changes varied over time. This section presents the policies and institutional changes related to the pharmaceutical sector, in Brazil, from 1990 to 2020. The period is divided into three distinct cycles. First, between 1990 and 2002, when the alignment to the Washington Consensus and its liberal propositions took place. Second, the explicit industrial policy on the Brazilian government's agenda was resumption between 2003 and 2015 with a continuous focus on the pharmaceutical industry and/or the Brazilian Health Industrial Complex (CIS). Finally, between 2016 and 2020, when some significant moves for the industry development were disjointed and driven mainly by a health emergency agenda at the end of the cycle.

The first cycle is defined by four relevant institutional changes: the trade liberalisation (1992), the TRIPS Agreement (1994), the Intellectual Property Law (1996), and the creation of the generic drugs market and the ANVISA (1999). In the 1990s, Fernando Collor and Fernando Henrique Cardoso took over the Brazilian government, intending to integrate domestic production into the Global Value Chain. The sudden economic opening in the early 1990s ended the market reserve that benefited national companies and imposed the reduction of tariff and non-tariff barriers to imports. As a result of the trade and price liberalisation without support for national companies (less competitive in the global market), the participation of foreign pharmaceutical companies in the Brazilian market grew significantly over two decades, complemented by imports that have gradually replaced the local production of inputs and medicines (Caliari and Ruiz 2014).

The post-1990 period is also characterised by the movement towards harmonisation of international regulatory levels, particularly in health and intellectual property. Brazil carried out an accelerated harmonisation with TRIPS and introduced, with the Intellectual Property Law (no. 9,279/1996), some elements beyond the obligations of TRIPS. Some of the additional rules defined as TRIPS-plus are: the use of only one year of the transition period, the definition of a minimum period of validity[iii] of 10 years after the granting of invention patents and seven years for utility models, and the concession of pipeline patents that had already been granted abroad, without technical examination by the local authority (the Brazilian Institute of Industrial Property – INPI) (Oliveira et al. 2004; Hasenclever, Lopes, et al. 2010; Sampat and Shadlen 2015; Mercadante and Paranhos 2022; Shadlen 2017).

In the late 1990s, ANVISA[iv] (Law no. 9,782/1999) and the generic drug segment (Law no. 9,787/1999) were created. The latter has instituted mandatory bioequivalence and bioavailability tests[v] to register generic drugs. Drug price regulation was reassumed[vi] in 2003 (Law no. 10,742/2003), when the Drug Market Regulation Chamber (CMED) was created, with the role of defining the regulatory norms for the pharmaceutical sector (Kornis et al. 2011; Hasenclever, Fialho, et al. 2010).

The second cycle started in 2003, with Luiz Inácio Lula da Silva assuming office, followed by Dilma Rousseff's government. This cycle was characterised by the return of explicit industrial and science, technology, and innovation (STI) policies to the government agenda to improve local companies' capabilities to participate in the global market. It included the implementation of three industrial policies – the Industrial, Technological and Foreign Trade Policy; the Productive Development Policy; and the Brazil Mayor Plan, under the responsibility of the Ministry of Development of Industry and Foreign Trade (MDIC 2005; 2008; 2011). It also included two STI policies – the Science and Technology Growth Acceleration Programme and the National Science, Technology and Innovation Strategy, under the responsibility of the Ministry of Science, Technology and Innovation (MCT 2007; MCTI 2011).

Within the scope of the Ministry of Health (MoH), the National Policy on Science, Technology and Innovation in Health (PNCTIS) was implemented in 2008 to articulate the production and innovation policies with the health policies (MS/SCTIE 2008). Furthermore, the link between policies and institutions from different government areas was facilitated by the Executive Group of the Industrial Health Complex (GECIS), created in the same year by Decree DNN no. 11,578/2008. GECIS comprised 14 public institutions under the coordination of the MoH and the MDIC executive secretariat and was assisted by a permanent forum for articulation with civil society. The objective of GECIS was to articulate the institutions of the different government areas in implementing the PNCTIS. It was also in charge of promoting the creation and implementation of the Brazilian regulatory framework that would provide a basis for developing and strengthening the CIS (Fonseca, Shadlen, and Bastos 2019).

Some legislation approved during this period was relevant to financing innovation in general and pharmaceutical areas. For instance, the Innovation Law (no. 10,973/2004) promoted partnerships between the academia and the manufacturing sector and authorised the granting of non-refundable resources for companies; the Tax Incentive Law (no. 11,196/2005) established the granting of tax incentives to companies that carry out research and development (R&D); and the Biodiversity Law (no. 13,123/2015) deals with access to and use of biodiversity and associated traditional knowledge, expanding legal certainty for R&D and production of new phytotherapeutics.

In 2013, the Brazilian Company for Research and Industrial Innovation (EMBRAPII) was created as a social organisation by the Federal Public Power (Provisional Measure no. 541/2011). It inaugurated a new R&D financing model to foster innovation in the Brazilian industry in cooperation with research institutions that already collaborate in research with companies. The financing scheme is divided between the three actors involved: EMBRAPII covers one-third of the project's value, the research institution provides the physical and human resources, and the company finances the other third (EMBRAPII 2022).

During this period, three financing instruments were quite significant, especially for building the productive capacities of national pharmaceutical companies. First, the Brazilian Innovation Agency (Finep) launched the *Subvenção Econômica* Programme, which consists of non-refundable resources for companies in five editions between 2006 and 2010, favouring areas such as pharmaceuticals and medicines, biotechnology, biodiversity and health. The second instrument is the *Inova Saúde* implemented by Finep, which was in operation from 2013 to 2017 to offer refundable and non-refundable resources for projects aimed at reducing the Brazilian dependence on international technology in human health. Finally, within the scope of the Brazilian Development Bank (BNDES), three phases of the Support Programme for the Development of the Industrial Health Complex (also called Profarma) (2004, 2007, and 2013) offered loans with subsidies for production, innovation, biotechnology, export, and

restructuring. As a result, Finep and BNDES financed 298 projects/operations of 142 pharmaceutical companies[vii], totalling USD 1.6 billion (BRL 8.3 billion) between 2004 and 2018 (Paranhos, Perin, et al. 2021).

The third instrument is the Productive Development Partnerships (PDPs) implemented in 2008 by the MoH to use public procurement to purchase strategic products that were locally produced using technology transfer between public-private partnerships for medicines and other products (medical-hospital equipment and diagnostic kits). Although not formally aligned with the financing instruments described above, Paranhos et al. (2021) identified that 11 pharmaceutical companies, among the 142 financed by Finep and BNDES, also participated in PDPs. Moreover, these 11 companies have 128 (91%) approved PDPs, most of which are national companies (87%), reinforcing the instrument's relevance in strengthening the industry and local productive capacity (Paranhos, Perin, et al. 2021).

The third cycle occurred after Dilma's impeachment in 2016, with the governments of by Michel Temer and Jair Bolsonaro, initiating a phase of institutional instability and new directions of industrial development stimuli (horizontal and implicit policies). This cycle was marked by the absence of explicit and vertical industrial policies, disruption of policy instruments for the pharmaceutical industry and the CIS, and disarticulation of the coordination instances in the MoH. On the STI side, the National Science, Technology and Innovation Strategy was maintained (2016-2022) but suffered a substantial reduction in the available resources for research grants and innovation funds (MCTIC 2016).

Following the implementation of STI policies for the health area, in 2017, the National Policy for Technological Innovation in Health was created, which established the objectives of promoting innovation activities in public administration and companies, including encouraging the formation of partnerships between them (Brasil 2017). Notably, in 2019, the GECIS was extinguished, thus leading to the disruption of the coordination body of the MoH concerning the production and innovation policies of the CIS and to the disarticulation of the actors.

In terms of regulation, the approval of the new Science, Technology and Innovation Framework (Law no. 13,243/2016) stands out, which modified existing laws intending to reduce the legal uncertainty of creating environments for innovation and the reduction of bureaucracy in scientific activities.

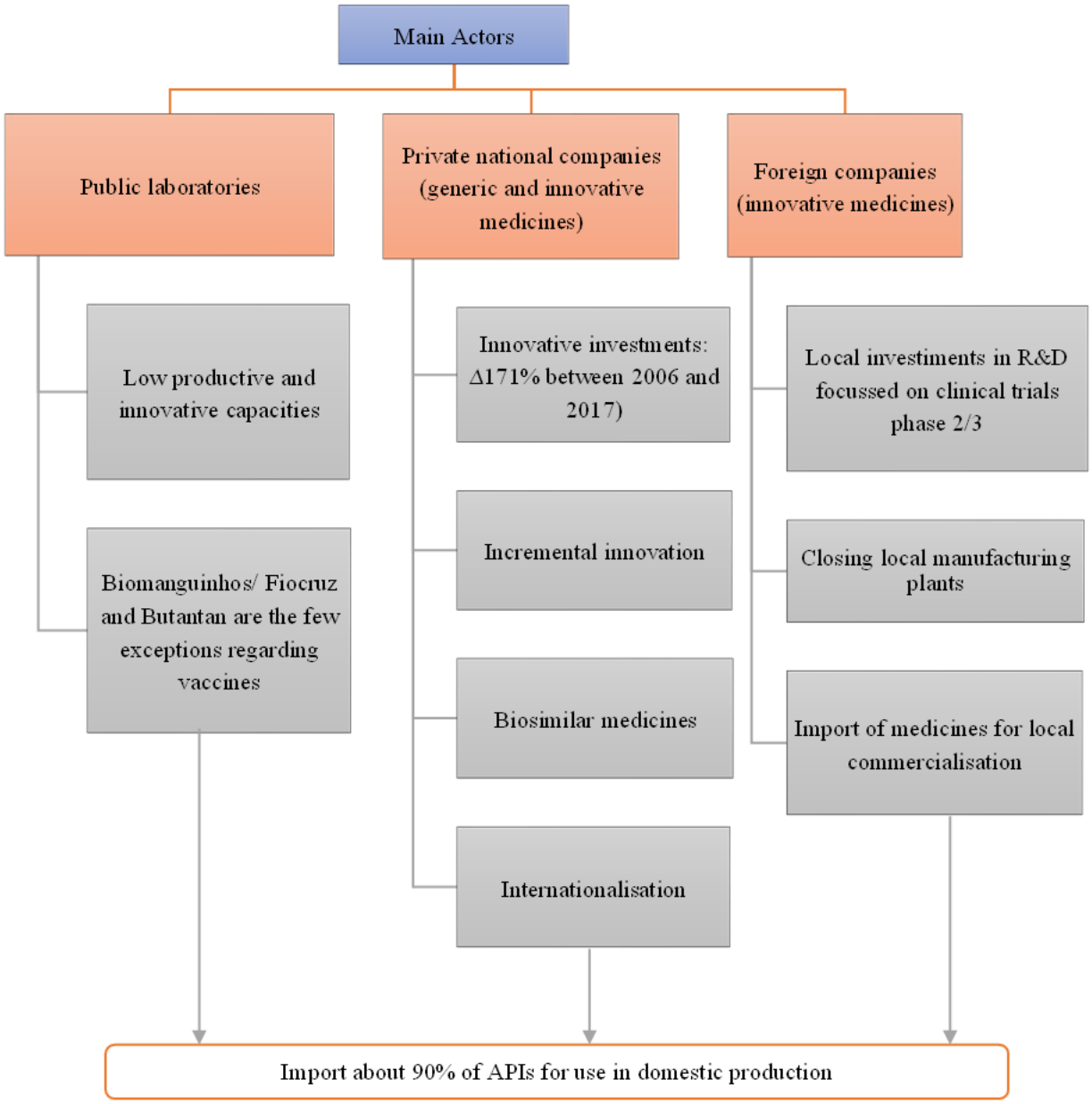
Regarding Finep resources, there was no implementation or continuity of instruments specific to the sector, in addition to a substantial contingency of resources and a strong institutional crisis (Negri and Koeller 2020; Servo et al. 2021; Tuffani 2019). As of 2016, the BNDES underwent changes and restructuring, leading to the extinction of Profarma; some resources were available to the sector but not linked to specific programmes. According to Junqueira (2020), BNDES and Finep resources for the pharmaceutical industry were reduced by 63% between 2018 and 2019. Moreover, a phase of critical legal uncertainty began regarding PDPs with purchases of bidding products in technology transfer and contract suspension. When the COVID-19 pandemic broke out, BNDES and Finep launched emergency programmes to provide financial assistance to firms offering refundable resources to address the most pressing problems (Paranhos and Perin 2021).

Production and technological capacity: companies and public laboratories

This section presents a mapping of the Brazilian pharmaceutical industry characteristics concerning its industrial organisation and its productive and technological capacities. The analysis focuses on the three main groups of actors – public and private national companies and

foreign companies – to describe the productive and technological capacities present of the country for APIs, medicines, and vaccines. Figure 1 summarises the characteristics of the main actors in the Brazilian pharmaceutical sector.

Figure 1: Main actors of the Brazilian pharmaceutical sector



Source: Own elaboration.

In 2017, five of the top ten companies in retail and public sector revenues were national. National pharmaceutical companies' production and technological capacity increased thanks to changes in the sector's institutional framework and their positive response to new strategies. Examples are the internationalisation[viii] movement of national companies, exporting generics and similar medicines to Latin American countries (Perin and Paranhos 2023), strengthening

their innovation strategies in the last two decades (Paranhos, Mercadante, and Hasenclever 2020). However, the improvement in production capacity occurred in the manufacture of final goods from the importation of pharmochemicals and intermediate inputs. Consequently, the companies' efforts have not been enough to reverse their dependence on foreign technologies and APIs for local production and export, especially for large companies. Currently, local pharmaceutical firms import about 90% of APIs used in domestic production (Mitidieri et al. 2015). The expressive technological backwardness of Brazilian firms, when compared with foreign companies, has been intensified by the change in the pharmaceutical technological trajectory from the chemical to the biological route (Malerba and Orsenigo 2015).

The advances in the institutional framework, mostly in the second cycle, contribute to enhancing pharmaceutical companies' production capacity. For example, the Generics Law provided national companies with a new activity segment, and the creation of ANVISA established the norms for the pharmaceutical production unit to be designed and operated according to good manufacturing practice (GMP) standards. In addition, the BNDES and Finep funding and the PDPs programme supported productive and innovative investments. By creating capacities to adapt to the new regulatory and legal requirements, national companies experienced business growth, which allowed them to strengthen themselves in the market and expand the generic segment (Caliari and Ruiz 2014).

Remarkably, the large national pharmaceutical companies stand out for their extensive production capacity in generics and similar drugs, with recent efforts (since 2012) to produce biosimilars and carry out innovative activities. The net sales revenue of large national pharmaceutical companies (more than 500 employees), in 2017, was equivalent to 82% of the net sales revenue of large foreign pharmaceutical companies (it was only 43% in 2008) (IBGE 2020b). Large national companies invest twice as much in innovative activities, three times more in internal R&D activities, and two and a half times more in external R&D activities than large foreign pharmaceutical companies in Brazil. They also expanded internal infrastructure and personnel engaged in R&D, of which 81% were researchers, and increased investments in internal R&D activities by 171%, from 2006 to 2017. Nevertheless, it does not mean national companies are more innovative than foreign ones. The data show important progress concerning the capacities to innovate, as they are continually expanding investments in activities focused on technological accumulation, as Bell and Pavitt (1993) pointed out.

As mentioned above, the trend of foreign companies is to concentrate their technological efforts within their headquarters, transferring to Brazil only the innovations already launched in their countries (Carlsson 2006). Therefore, they present a decrease in investments in several innovative activities over the years in Brazil but still have a more significant number of new drugs introduced in the market.

Moreover, since trade liberalisation, foreign companies import most APIs from their headquarters or international suppliers and have been drastically reducing their production activities in Brazil. Consequently, there has been a sharp increase in imports of final products and announcements about the closure of plants in Brazil, such as the cases of Eli Lilly, Roche, and Takeda between 2018 and 2020 (Paranhos, Menezes, et al. 2021). Consequently, they have low production and technological capacities being developed in Brazil and focus on imports and commercialisation activities. Nonetheless, they are important actors in the country with a strong voice pressuring for their interests, especially related to market exclusivities, intellectual property rights, drug registration, and clinical trials (Paumgartten 2016; Junqueira and Chaves 2020).

In addition to the private national and foreign companies, there are 18 public laboratories linked to the MoH, health departments in local governments, the Armed Forces, or universities. Public laboratories produce medicines, serums, and vaccines to meet the demands of the SUS (Gomes, Chaves, and Ninomya 2008; MS 2019). The public laboratories supply 30% (as an estimative) of the Brazilian pharmaceutical market (Hasenclever, Fialho, et al. 2010). Such laboratories were created to provide pharmaceutical assistance and fill the gaps in the national production of vaccines and medicines, due to the lack of interest of large pharmaceutical companies in certain therapeutic classes, such as neglected diseases that mainly affect developing countries (malaria, schistosomiasis, c*hagas*, etc.) and vaccines.

Public laboratories generally have weaker productive and technological capacities in medicines, as they are focused on mature products, including vaccines, and demonstrate great difficulties meeting regulatory requirements. Due to an unstable and reduced budget, they have a low investment in infrastructure, personnel training, and R&D activities. Nevertheless, they have been the main vaccine producers in Brazil, mostly because of private national companies' lack of interest in vaccines and foreign companies' preference to transfer the technologies for local production instead of producing them locally. In these laboratories, however, the production of biomedicines, vaccines and serums is more prominent than the production of products with more complex technology (e.g., monoclonal antibodies) (Torres and Hasenclever 2016; Hasenclever et al. 2018).

Since 2008, public laboratories have increased their investments in biopharmaceuticals due to their new role in expanding the local production of high-cost medicines through PDPs to reduce national technological dependence (Hasenclever et al. 2018). The Oswaldo Cruz Foundation (Fiocruz) and the Butantan Institute are the first and fourth public laboratories with partnerships signed between 2009 and 2017 (Pimentel 2018). Not coincidentally, both have been key actors in the production of vaccines for the National Immunisation Plan and, in 2021, in the local production of COVID-19 vaccines (Paranhos and Perin 2021). It is important to highlight that the COVID-19 pandemic was essential for these laboratories to update their production and research capacity via new voluntary licenses. Despite this leadership in the production of new-generation vaccines, both laboratories are exceptions in the group of public production, which are important for meeting primary health needs, but still hold a marginal share of the Brazilian pharmaceutical market.

In summary, this section briefly overviews Brazil's capacity for medicines, APIs, and vaccine production. The pharmaceutical sector is characterised by a non-verticalised industry, focused on the production of off-patent drugs – generics and similar – in certified factories, large participation in the domestic market by national companies and growing investments in Latin America. This scenario is also marked by the absence of links to the national production chain, generating strong external productive and technological dependence. The Brazilian pharmaceutical industry has proven to be moving slowly and gradually towards consolidating its industrial base with the support of public policies (Tigre, Nascimento, and Costa 2016). However, the cessation of incentives and the COVID-19 pandemic highlighted the sector's weaknesses and the importance of having greater independence in national production – particularly of medicines, APIs, and vaccines – and the need to prioritise the productive densification and innovation in these industries.

Conclusion: Lessons Learned and Future Directions

From the 1990s to 2020, many changes took place in the institutional framework of the pharmaceutical industry in Brazil. Given the different characteristics of the actors in this

industry, each of them was affected and responded differently with their business strategies. The growth of national companies greatly benefited from creating the generics market, and they advanced with strategies to invest in R&D and internationalise. Foreign companies took their production and investments in R&D abroad, increasing their supply to the Brazilian pharmaceutical market mainly via imports. Public laboratories lost participation in the production of drugs and did not follow the expansion of national private companies. In addition, investments in modernisation and R&D were not enough, but they increased their vaccine skills and expertise. In 2020, it was clear that the pharmaceutical industry had changed entirely, with a significant gain for national private companies in the Brazilian market and increased competition between them and foreign companies. Moreover, two public laboratories were essential for the local production of COVID-19 vaccines.

The three cycles of policies showed very different results. The trade liberalisation, the implementation of the intellectual property law and the new regulations in the first cycle created enormous barriers to developing Brazil's pharmaceutical and pharmochemical industry. It was only with the resumption of industrial and STI policies in the early 2000s and with the articulation, to a certain extent, of regulatory measures that important advances were made possible in these industries. On the one hand, national companies that could adapt to the new requirements became stronger in the Brazilian and Latin American markets. However, on the other hand, many companies could not keep up with the new conditions and ended production.

The main reason for the success of the second cycle of policies can be attributed to the combination of industrial and health policies obtained with the coordination of GECIS, which articulated health needs (demand) with the expansion of production (supply). The main lessons learned were the importance of explicit production and innovation policies, the use of non-refundable resources instruments for riskier innovations and long-term supply-side financing, and public procurement instruments to stimulate local production on the demand side.

On the opposite direction, the third cycle is marked by the dissolution of explicit industrial and innovation policies, the end of the articulation mechanism of industrial and health policies and the scarcity of funding sources, as well as uncertainty about the continuity of PDPs. The results of this period could not yet be evaluated, but the facts indicate that they will be worse than those of the previous cycle. Some public and private emergency measures aimed at transferring technology and releasing emergency resources for researching were implemented due to the emergence of the COVID-19 pandemic, accelerating the availability of vaccines in the local territory[ix].

The most important lesson for public policy is to show that the actors involved in vaccine R&D and manufacturing and the regulatory agencies act most effectively when a health emergency arises, such as COVID-19. Furthermore, it shows that establishing strategic priorities or policies oriented by missions and long-term planning is the greatest guarantee of success for production and innovation in a technology-intensive sector that has significant social impact. Moreover, the Brazilian experience in the last 20 years and the COVID-19 pandemic raised five lessons: (i) international harmonisation of regulation is relevant for industrial development, but it must consider local specificities and be complemented by industry and STI policies to promote a positive response by the local industry, (ii) the articulation of different instruments and mechanisms is fundamental for the success of the policies implementation, (iii) the pharmaceutical industry demands resources compatible with the risk degree of its innovations and the long-term maturation of its investments, (iv) public procurements are very relevant instruments of demand to increase security for investments on local production and innovation; and (v) the pharmochemical industry does not automatically follow the pharmaceutical industry

development, it requires specific instruments and policies. Nonetheless, Brazil still has a long path toward the development of its pharmaceutical industry, the reduction of external dependency, and the sustainability of the SUS.

Those results are essentially lessons for Brazil. In order to give it a broader analysis and reflet whether they can also be relevant to Latin American countries, we should highlight some Brazilian specificities: (i) large internal market in terms of both population and per capita income; (ii) a public healthcare system complemented by a private healthcare sector; (iii) research institutes with strong international reputations (e.g., the University of São Paulo, Fiocruz and Butantan Institute, the last ones mostly regarding neglected diseases and vaccines), but a tenuous link to the manufacturing sector (a characteristic also present in other countries in the region, as shown in Dutrénit and Arza (2010)); (iv) significant domestic manufacturing capacity that already exports to most Latin American countries (CEPAL 2021).

Therefore, one can say that the experience of the pharmaceutical sector development in Brazil cannot be used as a "model" for Latin American countries as it is a market with a scale and institutional characteristics very different from others. Additionally, when selecting which sectors to promote, and which instruments and policies to adopt, most of them are likely to face a much smaller range of opportunities than Brazil. In fact, most Latin American countries have smaller domestic markets, smaller and less dynamic healthcare sectors, weaker research communities, lower manufacturing capacity and, face stiff competition from Brazilian companies in their local markets. Nonetheless, Latin American countries can learn from the Brazilian experience about the importance of following some relevant lessons to obtain positive results in the implementation of industrial and STI policies. Among them: to coordinate industrial and health policies; to strengthen health regulation; to foster the institutional framework of the pharmaceutical innovation system; and, finally, to use adequate financial instruments for funding innovation in the pharmaceutical sector, in which innovation is the main form of competition and the time to innovate is longer than any other sector.

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[i] Currency exchange BRL/USD = 5.04 (02 July 21).

[ii] API is any substance or combination of substances used in a finished pharmaceutical product with the intention of providing pharmacological activity or otherwise having a direct effect on healing.

[iii] On May 12, 2021, the Federal Supreme Court (STF) ruled for the unconstitutionality of the sole paragraph of article 40 of the Law 9.279/1996 (Direct Action of Unconstitutionality 5529).

[iv] Currently recognised as the main health regulatory institution in Latin America and respected worldwide. Since 2016, Anvisa has become a regular member of the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH), world's leading forum for the harmonisation of technical requirements composed of regulatory authorities and the pharmaceutical industry.

[v] Bioavailability refers to the extent of an administered drug reaches its intended biological destination. Bioequivalence is a term used to assess the pharmaceutical equivalence between products presented in the same pharmaceutical form, containing identical qualitative and quantitative composition of active principles, and that have comparable bioavailability.

[vi] For information about price regulation in Brazil before 2003, see Miranda, Paranhos, Hasenclever (2021).

[vii] Non-reimbursable funds were offered by FINEP through public calls. Reimbursable resources and loans were offered by FINEP and BNDES based on risk analysis. In this sense the chances of nepotism, political interference and corruption are very low due to the selection criteria and the obligation for companies to present projects to obtain both types of financing.

[viii] Internationalisation is the process by which the company conducts some operation of its value chain outside its domestic market, such as sales, distribution networks, R&D centres or manufacturing.

[ix] In 2023, Luiz Inácio Lula da Silva new government took office and there are new perspectives to resume the articulation of the production and innovation policies with the health policies to reduce Brazil's dependence on pharmaceutical production. The Executive Group of the Economic-Industrial Health Complex (GECEIS) was recreated in April 2023, but no other policies or concrete actions were taken so far.