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PUBLIC PHARMACEUTICAL PRODUCTION AND HEALTH SOVEREIGNTY IN BRAZIL

A Case Study of Lafepe



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CONTENTS

01 INTRODUCTION	4
02 INSTITUTIONAL CHARACTERIZACION	6
03 Lafepe and the Productive Development Partnerships (PDP) Program	18
04 FINAL CONSIDERATIONS	33
05 REFERENCES.....	35



01

INTRODUCTION

The existence of Official Pharmaceutical Laboratories (Laboratórios Farmacêuticos Oficiais – LFOs), institutions responsible for producing medicines primarily intended to meet public health program demands, constitutes one of the defining features of the Brazilian pharmaceutical industry (OLIVEIRA, 2007). Public production of medicines and other health technologies became effectively linked to the Brazilian Unified Health System (Sistema Único de Saúde – SUS) following the 1988 Federal Constitution and, more prominently, through Law No. 8,080 of 1990.

Article 196 of the 1988 Constitution establishes the conception of health as “a right of all and a duty of the State,” complemented by the guidelines governing public health actions and services and by the foundational principles of the SUS set forth in Articles 198 to 200. The latter provision explicitly connects the production of health technologies to the activities to be carried out within the SUS framework, assigning the system responsibility for “controlling and inspecting procedures, products, and substances of interest to health, as well as participating in the production of medicines, equipment, immunobiological products, blood derivatives, and other inputs,” among other duties (BRASIL, 1988; CHAVES; HASENCLEVER; OLIVEIRA, 2016).



Law No. 8,080/1990, in turn, includes within the scope of SUS activities “the formulation of policies regarding medicines, equipment, immunobiological products, and other health-related inputs, as well as participation in their production” (Article 6, VI). Article 19-W further provides for the production of active pharmaceutical ingredients intended for the treatment of socially determined diseases (BRASIL, 1990). It is precisely this emphasis on addressing the needs of Brazil’s public health system that distinguishes LFOs from private pharmaceutical laboratories (MACHADO, 2021).

The Pharmaceutical Laboratory of the State of Pernambuco Governor Miguel Arraes (Laboratório Farmacêutico do Estado de Pernambuco Governador Miguel Arraes – Lafepe) ranks among the three largest public pharmaceutical laboratories in Brazil, alongside Farmanguinhos/Oswaldo Cruz Foundation and Butantan Institute. Lafepe is the only laboratory in Brazil, and one of the few worldwide, to manufacture benznidazole, a medication used in the treatment of Chagas disease. In addition, it is one of the principal suppliers of antiretroviral drugs (ARVs) provided through the SUS for the treatment of HIV/AIDS¹, as well as sodium hypochlorite 2.5% for cholera control and the antipsychotic medications clozapine, quetiapine, and olanzapine (BRASIL, n.d.; G1, 2025; LAFEPE, n.d.).

Despite its relevance to the Brazilian public health system, specific studies addressing Lafepe, its institutional characteristics, production profile, and challenges as a public pharmaceutical manufacturer remain scarce. References to the laboratory are found primarily in the literature dedicated to Productive Development Partnerships (Parcerias para o Desenvolvimento Produtivo – PDPs²). Notably, in 2017, the Pernambuco-based laboratory became the first institution in Brazil to complete all stages of a PDP since the program’s creation. Nevertheless, existing studies on such partnerships merely include those developed at Lafepe and do not focus exclusively on the institution itself. In light of this gap, the present case study treats Lafepe as its primary object of analysis, compiling the broadest possible range of information to address the identified deficiency in the literature.

1 VERDECIA, Mark *et al.* COVID-19 vaccine platforms: Delivering on a promise? **Hum Vaccin Immunother**, v. 17, n. 9, May 2021. Retrieved from: https://www.tandfonline.com/doi/10.1080/21645515.2021.1911204?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed.

2 According to Ministry of Health Ordinance No. 4,472/2024, Productive Development Partnerships (Parcerias para o Desenvolvimento Produtivo – PDPs) are defined as “partnerships involving cooperation through agreements between public institution(s) and/or Science, Technology and Innovation Institution(s) (STIs) and private entity(ies) for technology development, transfer, and absorption, as well as the strengthening of the country’s productive and technological capacities, with the aim of enabling the local production of strategic technologies and products to meet the demands of the SUS” (BRASIL, 2024).

02

INSTITUTIONAL CHARACTERIZATION

The Pharmaceutical Laboratory of the State of Pernambuco Governor Miguel Arraes (Laboratório Farmacêutico do Estado de Pernambuco Governador Miguel Arraes – Lafepe) was founded on May 27, 1965, and authorized by State Decree No. 1,180 of January 4, 1966, to manufacture high-quality medicines at low cost. According to the Laboratory's Articles of Incorporation:

Article 4 – The Company's corporate purpose comprises the manufacture, commercialization, representation, importation, exportation, and distribution of chemical and pharmaceutical products, dietary supplements, veterinary products and related goods, blood-derived products, eyeglass frames and lenses, cosmetics and perfumes, personal hygiene products, hospital, industrial, and household cleaning products, household sanitizing agents, and medical, surgical, hospital, and dental supplies. The Company may also identify and develop partnerships aimed at receiving and assimilating technology transfers within its field of operation, as well as conduct technical and scientific research intended to support the continuous development of its industrial activities (LAFEPE, 2025).

Law No. 8,080/1990, in turn, includes within the scope of SUS activities “the formulation of policies regarding medicines, equipment, immunobiological products, and other health-related inputs, as well as participation in their production” (Article 6, VI). Article 19-W further provides for the production of active pharmaceutical ingredients intended for the treatment of socially determined diseases (BRASIL, 1990). It is precisely this emphasis on addressing the needs of Brazil's public health system that distinguishes LFOs from private pharmaceutical laboratories (MACHADO, 2021).

During the same period, the Brazilian Health Regulatory Agency (Anvisa) was established, Law No. 9,787/1999 (the Generic Medicines Law) was enacted, and the Parliamentary Commission of Inquiry on Medicines was conducted, ultimately recommending the modernization of Lafepe. These developments, combined with the fact that medicines constitute a politically significant public good, led privatization to be perceived as a “disastrous” option, prompting the state government to abandon the proposal (OLIVEIRA, 2007).

Table 1. Key Characteristics of Lafepe

Laboratory Name	Pharmaceutical Laboratory of the State of Pernambuco Governor Miguel Arraes S/A (Lafepe)
Year of Establishment	Founded in 1965, with legislative authorization granted by State Decree No. 1,180 of January 4, 1966
Financial Autonomy	Northeast Region / Pernambuco
Financial Autonomy	Yes
Sources of Funding	Own-source revenues ³
Legal Status	Mixed-Capital Company
Link to Public Administration	Pernambuco State Department of Health
Is the laboratory served by a central legal body of the federal or state public administration?	No
Do the laboratory's bylaws or founding regulations permit commercial relationships involving the supply of products or services to private institutions (e.g., hospitals or private pharmaceutical companies)?	Yes
What are the critical operational areas?	Quality assurance, production, and quality control
Main critical issues and causes of delays	Delays in procurement processes for acquiring inputs and occasional disruptions involving production equipment
Does the laboratory have any product prequalified by an international organization?	No
Is there an intention to obtain product prequalification for sales to organizations such as PAHO/WHO, UNFPA, or UNICEF?	Yes
Are there initiatives or plans to export products to meet the needs of other countries or international organizations?	Yes. Lafepe recently sought accreditation with PAHO in order to participate in an international procurement process for the supply of benznidazole.

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Source: Adapted from Machado (2021), based on data from ALFOB/CFF (2019).

Lafepe occupies a prominent position in the history of public pharmaceutical production in Brazil, particularly in the manufacture of products intended for the treatment of Neglected Tropical Diseases (NTDs), a group of illnesses that primarily affect impoverished populations and attract limited interest from the private sector for research and development (R&D) activities (TROUILLER et al., 2002; MSF, 2021). The laboratory is the only producer in Brazil, and one of the few worldwide, to manufacture benznidazole, a medication used in the treatment of patients with Chagas disease. The pediatric formulation of benznidazole was developed and registered in 2012 through a partnership with the Drugs for Neglected Diseases initiative (DNDi) (CHAVES et al., 2018). Furthermore, Lafepe was a pioneer in the production of antiretroviral drugs (ARVs) used in the treatment of HIV infection (LAFEPE, n.d.).

The institution was the first in Brazil to implement the “**Popular Pharmacy**” concept, as early as the 1990s.⁴ In 2004, this model was expanded nationwide through a federal government initiative known as the **Brazilian Popular Pharmacy Program (Programa Farmácia Popular do Brasil – PFPB)** (LAFEPE, 2020)⁵. Currently, Lafepe operates a network of 12⁶ pharmacies distributed across different regions of the state of Pernambuco. These pharmacies sell medicines and eyeglasses manufactured by the laboratory, in addition to generic and branded generic medicines procured from selected suppliers (LAFEPE, 2024).

Law No. 14,511/2011 established the **Boa Visão Program** and assigned Lafepe the responsibility of providing affordable eyeglasses to the population. Implemented in partnership with the State Departments of Health and Education, the program seeks to identify and address visual impairments among students, teachers, and staff within the public state school system by offering ophthalmological consultations and, when necessary, corrective eyeglasses. The initiative aims to reduce school dropout and grade repetition rates associated with untreated vision problems. In 2023, approximately 4,650 pairs of eyeglasses were produced and supplied to the Boa Visão Program (LAFEPE, 2024).

³ No additional information regarding funding sources was identified in the sources consulted. However, according to the information provided by Lafepe (Annex A), the institution also receives public funding.

⁴ EMA – European Medicines Agency. **EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU**. EMA, News, 06 Jan. 2021. Retrieved from: <https://www.ema.europa.eu/en/news/>

⁵ For further information on the Brazilian Popular Pharmacy Program (Programa Farmácia Popular do Brasil – PFPB), see: <https://www.gov.br/saude/pt-br/composicao/sectics/farmacia-popular>.

⁶ Based on information available in institutional documents, it was found that the number of pharmacies operated by Lafepe throughout the State of Pernambuco declined from 27 units in 2020 to 15 in 2022 and 12 in 2023. No justification for the closure of these facilities was identified in the documents reviewed (LAFEPE, 2020; 2021; 2022; 2023; 2024).

Lafepe’s institutional objectives underscore its strategic role in strengthening health policies in Brazil. The first objective, which highlights the institution as a stabilizing and supportive actor in the supply of medicines and healthcare inputs, is directly related to maintaining the regular provision of products to the public healthcare network and ensuring the continuity of health services. The second objective, focused on technological advancement and product quality improvement, reflects the institution’s commitment to innovation and compliance with regulatory standards in order to provide the population with safe and effective medicines. Finally, the third objective, concerning the qualification of human resources, demonstrates the institution’s recognition of workforce development as a fundamental component of its productive activities and long-term sustainability (LAFEPE, 2025)

Figure 1. Lafepe’s Institutional Objectives

		
To act as a stabilizing and supportive institution in the provision of medicines and other pharmaceutical inputs to municipal, state, and federal public healthcare systems, in accordance with the general policy guidelines established by the Pernambuco State Department of Health.	To promote the technological advancement and quality improvement of its manufactured products, in compliance with policies established by the State and Federal Governments, and in alignment with the pharmaceutical policy of Brazil’s Unified Health System (SUS).	To foster the technical development and professional training of the workforce involved in its operations.

Employment at Lafepe is obtained through competitive public examinations, and labor contracts are governed by the Consolidation of Labor Laws (Consolidação das Leis do Trabalho – CLT). According to data from the eSocial system⁷ as of June 30, 2025, Lafepe employed 396 active workers. The workforce composition by sex and race/ethnicity was as follows: 56% were women (28% non-Black and 28% Black), while 44% were men (23% non-Black and 21% Black) (eSocial, 2025).

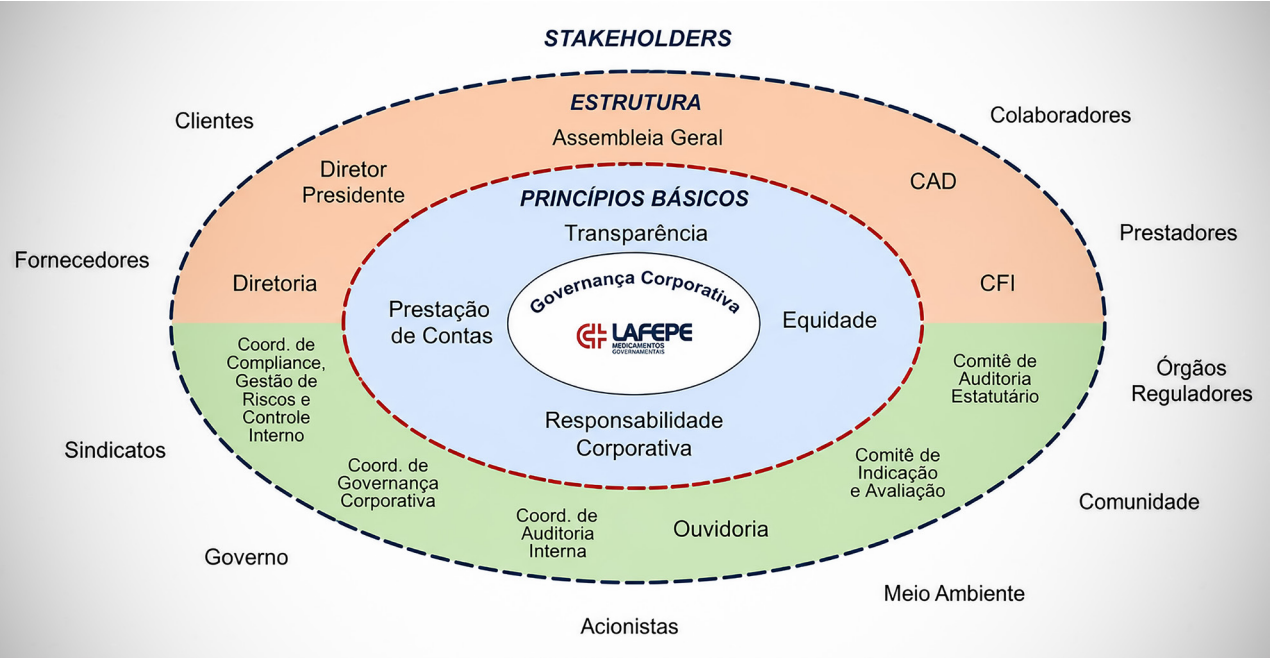
Lafepe’s corporate governance structure complies with all current legislative requirements. Since 2021, following the establishment of the Statutory Audit Committee, the institution has incorporated all oversight and control bodies required under Law No. 13,303/2016.

⁷ Digital Bookkeeping System for Fiscal, Social Security, and Labor Obligations (eSocial).

These compliance efforts earned Lafepe certification from the State Comptroller General’s Office (Secretaria da Controladoria Geral do Estado – SCGE), as well as the highest possible scores on Pernambuco’s State-Owned Enterprise Compliance Indicator (Indicador de Adequação das Estatais – IAE) and Corporate Governance Assessment Indicator (IAS), reflecting adherence to best practices in corporate governance (LAFEPE, 2024).

Lafepe’s statutory bodies include the General Assembly, the Board of Directors, the Fiscal Council, the Nomination and Evaluation Committee, the Statutory Audit Committee, and the Executive Board. The institution is also supported by governance-related units, namely the Internal Audit Coordination Office (COAUD), the Compliance, Risk Management, and Internal Control Coordination Office (COCGC), and the Corporate Governance Coordination Office (COGOV) (LAFEPE, 2024).

Figure 2. Context and Structure of Lafepe’s Corporate Governance System



Fonte: Lafepe (2024).

Portuguese	English
Stakeholders	Stakeholders
Clientes	Customers
Colaboradores	Employees
Prestadores	Service Providers
Órgãos Reguladores	Regulatory Bodies
Comunidade	Regulatory Bodies

Portuguese	English
Meio Ambiente	Regulatory Bodies
Acionistas	Shareholders
Governo	Government
Sindicatos	Trade Unions
Fornecedores	Suppliers
Estrutura	Structure
Assembleia Geral	General Shareholders' Meeting
Diretor Presidente	Chief Executive Officer (CEO)
Diretoria	Executive Board
CAD	Board of Directors
CFI	Fiscal Council
Comitê de Auditoria Estatutário	Statutory Audit Committee
Comitê de Indicação e Avaliação	Nomination and Evaluation Committee
Ouvidoria	Ombuds Office
Coord. de Auditoria Interna	Internal Audit Office
Coord. de Governança Corporativa	Corporate Governance Office
Coord. de Compliance, Gestão de Riscos e Controle Interno	Compliance, Risk Management and Internal Controls Office
Princípios Básicos	Core Principles
Transparência	Transparency
Equidade	Fairness
Prestação de Contas	Accountability
Responsabilidade Corporativa	Corporate Responsibility
Governança Corporativa	Corporate Governance

Lafepe currently holds 10 products with active registration status at the Brazilian Health Regulatory Agency (Anvisa). Among these, the oldest registration corresponds to the fixed-dose combination of zidovudine and lamivudine, granted on April 29, 1998. The most recent registration is for darunavir, approved on November 18, 2024. With regard to regulatory classification, seven registrations correspond to generic medicines, two to new medicines, and only one to a similar medicine⁸. These registrations are distributed across five distinct therapeutic classes: antiretrovirals (3), antivirals (3), antiparasitics (1), neuroleptics (1), and antipsychotics (2).

Table 2. Lafepe Products with Active Registration Status at Anvisa

Product Name	Registration Date	Regulatory Category	Therapeutic Class
darunavir	18 Nov 2024	Generic	Antiretroviral
LAFEPE - zidovudina + lamivudine	29 Apr 1998	Similar Medicine	Antiviral Agents (viral replication inhibitors)
LAFEPE benznidazole	20 Nov 2006	New Drug	Antiparasitic
clozapine	30 Aug 2010	Generic	Neurolépticos
Tenofovir Disoproxil Fumarate	24 Aug 2011	Generic	Antiretroviral
Dolutegravir Sodium	19 Jul 2021	Generic	Antiretroviral
ritonavir	05 Sep 2016	Generic	Antiviral Agents (viral replication inhibitors)
Lafepe Tenofovir Disoproxil Fumarate + Lamivudine	15 May 2023	New Drug	Antiviral Combinations for the Treatment of HIV Infection
olanzapine	05 Mar 2012	Generic	Antipsychotics
Quetiapine Hemifumarate	03 Nov 2010	Generic	Antipsychotics

Source: Prepared by the author based on data obtained from Anvisa.

⁸ According to Anvisa (2021), “a similar medicine contains the same active ingredient(s), in the same strength and pharmaceutical form, is administered by the same route, and has the same dosage regimen and therapeutic indication as the reference medicine, and is identified by a brand name or trade name.”

According to Lafepe’s response to the inquiries submitted under the Access to Information Law (Annex A), the institution currently manufactures six pharmaceutical products. Annual production reaches approximately 325 million tablets. The quantities produced and the dates on which production commenced are presented in the table below

Table 3. Medicines Currently Produced by Lafepe.

Product Name	Annual Quantity (Tablets)	Year Production Began	Therapeutic Class
Benznidazole	1 million	2010	Antiretroviral
Clozapine	50 million	2016	Antiviral Agents (viral replication inhibitors)
Darunavir	19 million	2024	Antiparasitic
Tenofovir Disoproxil Fumarate + Lamivudine	80 million	2021	Neurolépticos
Quetiapine Hemifumarate	130 million	2017	Antiretroviral
Olanzapine	45 million	2017	Antiretroviral

Source: Prepared by the author based on information provided by Lafepe (Annex A).

Official Pharmaceutical Laboratories (LFOs) may adopt different legal forms, including entities within the direct public administration, public or private foundations, mixed-capital companies, among others (ALFOB, 2023). In the case of Lafepe, it is a mixed-capital company⁹ linked to the Pernambuco State Department of Health, with administrative and financial autonomy (LAFEPE, n.d.). According to Santos (2010), this legal structure provides the institution with greater flexibility regarding its procurement model.

According to information provided by the laboratory (Annex A), the institution does not receive donations from private entities, and its resources are derived from its own revenues and public funding. However, although this institutional arrangement is consistent with its public mission, it makes the laboratory particularly vulnerable to budgetary fluctuations and shifts in public policy priorities, especially in periods of fiscal constraint.

⁹ The legal framework to which an Official Pharmaceutical Laboratory (LFO) is subject has significant implications for the process of technology incorporation, as it determines the procurement and contracting procedures applicable to the institution (ALFOB/CFF, 2019, p. 16). The Institute of Drug Technology (Farmanguinhos/Fiocruz), for example, is a technical-scientific unit of the Oswaldo Cruz Foundation (Fiocruz), a public institution established and maintained by the Federal Government and linked to the Ministry of Health. Mixed-capital companies—such as Lafepe—and public enterprises are subject, pursuant to Article 173, §1, II of the 1988 Federal Constitution, to the legal regime applicable to private companies, including with regard to civil, commercial, labor, and tax rights and obligations. Increased autonomy and operational flexibility are among the factors highlighted in the literature as justifications for revising the legal status of official pharmaceutical laboratories (BASTOS, 2006; MACHADO, 2021).

With respect to Lafepe's financial position, an analysis of its liquidity indicators suggests that the laboratory "(...)" is in a very sound financial position with respect to meeting its obligations" (LAFEPE, 2025, p. 30). The following table summarizes the institution's net profit and the distribution of its gross revenues over the last five years.

Table 1. Distribution of Lafepe's Gross Revenue and Net Income (2019–2023) (Millions)

Segment	31 December 2019	31 December 2020	31 December 2021	31 December 2022	31 December 2023
Medicines ¹⁰	R\$ 312,6	R\$ 227,7	R\$ 325,7	R\$ 711,3	R\$ 384,6
Sodium Hypochlorite	R\$ 32,1	R\$ 33,2	R\$ 43,4	R\$ 36,6	R\$ 39,7
Optical Products	R\$ 1,4	R\$ 0,8	R\$ 0,8	R\$ 1,2	R\$ 1,0
Other ¹¹	R\$ 0,0 ¹²	R\$ 3,6	R\$ 0,0 ¹³	R\$ 0,0 ¹⁴	R\$ 0,3
Total Gross Revenue	R\$ 346,1	R\$ 265,3	R\$ 370,0	R\$ 749,1	R\$ 425,5
Net Profit	R\$ 64,9	R\$ 30,2	R\$ 40,9	R\$ 40,9	R\$ 15,6

Source: Prepared by the author based on Lafepe (2020; 2021; 2022; 2023; 2024).

¹⁰ Includes revenues from generic and similar medicines.

¹¹ The "Other" segment comprises revenues from scrap sales, freight charges on sales, and related sources. In 2020, the largest share of the "Other" segment was attributable to sales of Antiseptic Hand Gel (Alcohol-Based Hand Sanitizer), which was introduced by Lafepe during that year.

¹² R\$ 14,589.83.

¹³ R\$ 6,238.50.

¹⁴ R\$ 8,054.27.

Despite the institution's positive economic performance, Lafepe's management itself recognizes its high dependence on government procurement as a major challenge. As stated in an institutional document:

It should be noted that LAFEPE's main challenge is its direct dependence on revenue derived from federal government resources, through the Ministry of Health, which account for more than 99% of the laboratory's sales revenue. Consequently, whenever federal funding for the purchase of medicines is reduced, for any reason, the Laboratory's revenues will decline during the fiscal year. This situation makes the company vulnerable to fluctuations in federal government procurement (LAFEPE, 2024, p. 14).

Although this dependence reflects Lafepe's strategic role as a supplier to the Unified Health System (SUS), it also reveals a significant institutional vulnerability: the absence of stable federal funding mechanisms. In contexts of budgetary constraints, contractual delays, or changes in pharmaceutical procurement policies, the laboratory's financial sustainability may be adversely affected, compromising its planning capacity, investment in innovation, and maintenance of productive capabilities. This dynamic imposes constraints on the adoption of long-term investment strategies, particularly in technologically complex areas such as research, development, and innovation (R&D&I). Under such conditions, Lafepe's operations tend to assume a predominantly reactive character, driven by the government's immediate demand rather than by a more forward-looking approach focused on innovation.

With regard to research, development, and innovation (R&D&I) activities, dependence on public funding is not a challenge unique to Lafepe; rather, it forms part of a broader context concerning public investments in science and technology (S&T) in Brazil. According to a study conducted by De Negri (2021, p. 10), federal investment in S&T declined by "(...) approximately 37% between 2013 and 2020, reaching in 2020 a level lower than that observed in 2009." Innovation rates also fell from 36.0% to 33.6% between 2015 and 2017, compared with the 2012–2014 period. These trends highlight the difficulties involved in consolidating scientific and technological capabilities in strategic sectors such as health, particularly affecting public institutions whose research activities depend predominantly on government funding.

Beginning in 2023, the federal government announced a series of measures aimed at rebuilding the Health Economic-Industrial Complex (Complexo Econômico Industrial da Saúde – CEIS), including the resumption of health policies and renewed investments in productive capacity and innovation. In 2024, approximately BRL 259 million was allocated to Lafepe by the Ministry of Health through the Program for the Expansion and Modernization of the CEIS Infrastructure (PDCEIS). These resources are intended to support the restructuring and modernization of the laboratory's manufacturing facilities (BRASIL, 2025), constituting a relevant intervention in response to the technological gap that characterizes Brazil's pharmaceutical sector (TICOM, 2019).

As stated by Lafepe itself (Annex A), research, development, and innovation (R&D&I) activities within the institution have taken different forms over time, shaped by prevailing public policies and the organization's stage of institutional development. Until 2023, the laboratory did not have a formal technological innovation policy, nor did it maintain a dedicated structure responsible for managing innovation projects. Consequently, any resources allocated to R&D&I activities were linked to the contracts and implementation plans of the Productive Development Partnerships (PDPs), which constituted the principal institutional arrangement adopted by Lafepe between 2015 and 2023. This circumstance makes it difficult to determine precisely the amounts invested in such activities.

This scenario changed in 2024 with the publication of Lafepe's Technological Innovation Policy (Ordinance No. 224/2024) and the establishment of an Innovation Projects Unit within the Research and Development Coordination Office. According to the institution, innovation investments have since been undertaken systematically, "with defined governance, formal partnerships, external resource mobilization, and institutional co-financing (...)" (Annex A). This institutional history suggests that, although Lafepe has engaged in innovative activities throughout its trajectory, the absence of a formal innovation policy prior to 2023 contributed to these initiatives remaining organizationally fragmented and dependent on specific contractual arrangements, such as the PDPs.

The formalization of the Technological Innovation Policy and the creation of a dedicated project management structure represent significant institutional advances for Lafepe. However, given the recent nature of these developments, their consolidation as a central pillar of the organization's strategy will depend on the institution's ability to transform isolated projects into continuous learning processes and into the sustainable strengthening of its productive and technological capabilities.

agencies, while maintaining a focus on strategic areas for the Unified Health System (SUS). According to Lafepe, the agreements established to date include the following:

(...) (i) the development of a fixed-dose combination ("2-in-1") medicine for leprosy (clofazimine and dapsone), in partnership with the Federal University of Pernambuco (UFPE), with a total investment of BRL 4,000,000 financed by the Brazilian Funding Authority for Studies and Projects (FINEP) and co-financed by Lafepe; (ii) the development of cannabis-based products for medicinal use, with a total investment of BRL 10,000,000, also supported by FINEP funding and institutional co-financing; and (iii) two projects under the Local Development and Innovation Program (Programa de Desenvolvimento e Inovação Local – PDIL), carried out in partnership with UFPE, aimed at developing innovative pediatric formulations based on clofazimine and dapsone for the treatment of leprosy, in accordance with the Clinical Protocol and Therapeutic Guidelines (Protocolo Clínico e Diretrizes Terapêuticas – PCDT) for Leprosy, with funding provided by the Ministry of Health (Annex A).

These initiatives demonstrate the continuity and deepening of Lafepe's institutional efforts to address neglected diseases, including through the development of new pharmaceutical products, thereby positioning the laboratory as a key actor in policies aimed at controlling and eliminating these conditions. It is important to note that, following a period of increasing investment in research and development (R&D) related to neglected diseases between 2007 and 2018, funding for the maintenance of existing projects and the creation of new incentives for this field declined significantly (BARBEITAS et al., 2023). Furthermore, only from 2015 onward were Neglected Tropical Diseases (NTDs) effectively incorporated into the global health policy agenda through the adoption of the Sustainable Development Goals (SDGs) by the 193 member states of the United Nations (UN): "(...) it was only from 2015 that NTDs were effectively recognized within the global health policy agenda through the adoption of the Sustainable Development Goals (SDGs) by the 193 member states of the United Nations (UN)" (BRASIL, 2024, pp. 9–10).

In this context, Lafepe's work plays a strategic role and remains aligned with the more recent agenda of strengthening the State's productive and technological autonomy, insofar as it fills gaps left by the private sector and contributes to the realization of the right to health for socially vulnerable population groups. This role directly gives effect to the constitutional mandate to protect health, since "(...) the technological independence and production capacity of Official Pharmaceutical Laboratories (LFOs) constitute central elements in guaranteeing the fundamental right to health in Brazil" (FERES; SILVA, 2022, p. 334).

03

LAFEPE AND THE PRODUCTIVE DEVELOPMENT PARTNERSHIPS (PDP) PROGRAM

Productive Development Partnerships (PDPs) are based on the centralized procurement of products considered strategic by the Ministry of Health, with the objective of promoting production autonomy among Official Pharmaceutical Laboratories (LFOs) through technology transfer processes (GADELHA; TEMPORÃO, 2018). Through the State's purchasing power, strategic arrangements are established between public and private institutions, whether domestic or international, whereby the private partner transfers technology to the public institution. In return, the private partner is granted exclusivity in supplying the product to the public sector for the duration of the technology transfer process (BRASIL, 2024).

These partnerships constitute one of the mechanisms employed to reduce technological vulnerability, balance public and private interests, and expand the population's access to medicines and other health technologies. The agreements illustrate how the State can direct production toward meeting previously identified strategic needs within the broader framework of strengthening the Health Economic-Industrial Complex (Complexo Econômico-Industrial da Saúde – CEIS) (GADELHA, 2012), whose systemic approach seeks to reduce both social and technological vulnerabilities in healthcare (FERNANDES; GADELHA; MALDONADO, 2023).

According to information provided by the Department of the Health Economic-Industrial Complex and Innovation for the Unified Health System of the Ministry of Health (Departamento do Complexo Econômico-Industrial da Saúde e de Inovação para o SUS – DECEIIS/MS, 2025), summarized in Table 4, LAFEPE has had 16 PDP proposals approved, of which 12 remain active and four have already been terminated.

Table 4. Lafepe's Productive Development Partnerships (PDPs)

Product	Technological Platform	National Private Partner	International Private Partner	API Supplier (Private Entity)	PDP Status	Phase
Clozapine	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	IV
Darunavir	Synthetic		Janssen-Cilag Farmacêutica Ltda.	Nortec Química S/A	Active	III
Dolutegravir	Synthetic	Blanver Farmoquímica e Farmacêutica S.A		CYG Biotech Química & Farmacêutica Ltda	Active	III
Dolutegravir	Synthetic	Blanver Farmoquímica e Farmacêutica S.A		Nortec Química S/A	Active	III
Fingolimod	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Nortec Química S/A	Active	II
Olanzapine	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	IV
Oseltamivir	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Globe Química S/A	Active	II
Quetiapine	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	IV

Product	Technological Platform	National Private Partner	International Private Partner	API Supplier (Private Entity)	PDP Status	Phase
Raltegravir	Synthetic		MSD	Nortec Química S/A	Discontinued (2015)	No Development Phase
Ritonavir (Soft Capsule)	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda			Discontinued (2015)	No Development Phase
Heat-Stable Ritonavir	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	IV
Tenofovir	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	IV
Tenofovir + Lamivudine (2-in-1)	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Cristália Produtos Químicos Farmacêuticos Ltda	Active	III
Tenofovir + Lamivudine (2-in-1)	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda		Globe Química S/A	Active	III
Tenofovir + Lamivudine + Efavirenz (3-in-1)	Synthetic	Cristália Produtos Químicos Farmacêuticos Ltda			Discontinued (2017)	No Development Phase
Botulinum Toxin	Biotechnological	Cristália Produtos Químicos Farmacêuticos Ltda			Discontinued (2015)	No Development Phase

Source: Prepared by the author based on data from DECEIS/MS (2025).

Nearly all products covered by PDPs at Lafepe—15 out of a total of 16—are synthetic medicines. Botulinum toxin is the only biotechnology-based product among them. The predominance of synthetic products reflects the broader landscape of PDP projects in Brazil when analyzed by technological platform. Of the 153 partnerships established to date, 88 involve synthetic medicines, 39 biotechnological products, 18 medical devices, 5 vaccines, and 3 blood-derived products (DECEIS/MS, 2025). Furthermore, considering the general characteristics of the Brazilian pharmaceutical industry, there has historically been a gap in the production of highly complex innovative medicines, particularly biological products (PARANHOS et al., 2019; PERIN, 2019), which also contributes to this pattern.

Lafepe’s principal domestic private-sector partner is Cristália Produtos Químicos Farmacêuticos Ltda., with a total of 12 partnerships. Cristália is also the laboratory’s main supplier of active pharmaceutical ingredients (APIs), performing this role in six partnerships. Among international private-sector partners, only Janssen-Cilag Farmacêutica Ltda. and MSD have agreements with Lafepe, corresponding to the PDPs involving the active pharmaceutical ingredients darunavir and raltegravir, respectively.

Of the 12 active PDPs, two are currently in Phase II (PDP project stage), five are in Phase III (implementation stage), and another five are in Phase IV (verification of technology internalization). Similar to the PDP established for the production of clozapine (25 mg and 100 mg), the partnerships involving quetiapine (100 mg and 200 mg), olanzapine (5 mg and 10 mg), ritonavir (100 mg), and tenofovir plus lamivudine (300 mg + 300 mg)—all currently in Phase IV—have successfully completed the internalization of their manufacturing stages (LAFEPE, 2024).

Table 2. Quantities Procured and Total Value of Products under Lafepe’s Productive Development Partnerships (PDPs)

Product	Dosage Form / Strength	Quantity Procured	Total Value
Clozapine	Tablet (100 mg)	102.041.068	R\$ 156.990.238,88
	Tablet (25 mg)	3.850.560	R\$ 1.375.009,48
Darunavir	Film-coated tablet (800 mg)	32.824.680	R\$ 328.365.033,00
Dolutegravir	Film-coated tablet (50 mg)	79.500.000	R\$ 325.950.000,00
Olanzapine	Tablet (10 mg)	127.863.264	R\$ 581.627.326,02
	Tablet (5 mg)	89.858.220	R\$ 240.863.978,55

Quetiapine	Tablet (100 mg)	90.771.598	R\$ 181.974.205,40
	Tablet (200 mg)	88.917.216	R\$ 376.438.324,58
	Tablet (25 mg)	69.435.672	R\$ 49.288.379,42
Heat-Stable Ritonavir	Film-coated tablet (100 mg)	388.613.520	R\$ 387.839.499,30
Tenofovir	Tablet (300 mg)	84.150.000	R\$ 316.011.390,00
Tenofovir + Lamivudine (2-in-1)	Film-coated tablet (300 mg + 300 mg)	403.257.870	R\$ 913.498.415,40
Botulinum Toxin	100 UI	36.276	R\$ 14.954.781,00
Total		1.561.119.944	R\$ 3.875.176.581,03

Source: Prepared by the author based on data from DECEIS/MS (2025).

The procurement of nine medicines in different formulations amounted to more than BRL 3.8 billion between January 2011 and April 2025. In terms of both quantity procured and total expenditure, the largest acquisition involved the fixed-dose combination of tenofovir and lamivudine (“2-in-1”), an antiretroviral medicine indicated for the treatment of HIV infection¹⁵. More than 400 million units of this combination were purchased by the Ministry of Health at a total cost of approximately BRL 913 million.

According to information provided by the Ministry of Health and reproduced in Table 4, the PDP for dolutegravir (50 mg) remains active. However, the procurement of part of the product’s stock was prevented by patent barriers and alleged anti-competitive practices involving ViiV Healthcare Company and the Japanese company¹⁶ Shionogi & Co., Ltd. (FONSECA et al., 2023).

According to Lopes et al. (2025):

¹⁵ Since the 1990s, Brazil has made a variety of medicines available through the public health system for the treatment of HIV/AIDS. Law No. 9,313/1996 (the Sarney Law), which guarantees universal and free access to antiretroviral medicines, marked a significant milestone in this period. Concurrently, the country initiated local production of antiretroviral drugs through reverse-engineering processes (ZUCOLOTO et al., 2024).

¹⁶ Joint venture established in 2009 by GlaxoSmithKline (GSK) and Pfizer.

DTG is the subject of at least 18 patent applications filed in Brazil, one of which (PI0610030-9) has been granted and constitutes a barrier to the entry of generic manufacturers into the Brazilian market until April 2026. In 2018, the National Institute of Industrial Property (INPI) issued its first technical opinion regarding patent application PI0610030-9. After considering technical submissions provided by Anvisa, the Brazilian Interdisciplinary AIDS Association (ABIA), and Blanver, the INPI recommended that the patent not be granted. In 2019, following the applicant's challenge to the 2018 opinion and the submission of revised claims, a second technical opinion recommending non-granting was issued. This period coincided with Ministry of Health purchases of DTG from GSK at the lowest prices recorded in Brazil, possibly reflecting the likelihood of patent rejection and the establishment of the PDPs. However, in August 2020, the INPI granted patent application PI0610030-9.

According to information provided by Lafepe regarding the dolutegravir PDP, the private partner conducted an assessment of the patent landscape and "(...) assumed full legal and financial responsibility for disputes concerning the validity of the existing patent." In addition, the Office of the Attorney General of the State of Pernambuco issued a favorable opinion regarding the feasibility of the partnership. According to the institution, "the technology transfer process under the PDP was maintained between Lafepe and the private partner, with only the supply of the product to the Ministry of Health being interrupted as a result of a judicial decision" (Annex A).

The dolutegravir PDP illustrates one of the structural constraints affecting the implementation of partnerships within the Brazilian pharmaceutical sector, namely uncertainty regarding patent protection. In this case, a particularly significant aggravating factor was the inconsistency of decisions issued by the National Institute of Industrial Property (INPI), which altered its position on the validity of the patent even after endorsing multiple technical opinions recommending that the patent not be granted. Although the laboratory acted in accordance with the prevailing institutional and legal frameworks, the case highlights the exposure of Official Pharmaceutical Laboratories (LFOs) to systemic risks that extend beyond their managerial capacity, particularly when industrial policy is not aligned with intellectual property policy.

Ministerial Ordinance GM/MS No. 4,472/2024, the new regulatory framework governing PDPs, introduced important changes concerning intellectual property. Among these, it requires either the absence of patent restrictions or the expiration of the relevant patent within 36 months of proposal submission as a condition for project eligibility (Art. 4, II). This provision aims to direct partnerships toward technologies that are either in the public domain, approaching patent expiration, or otherwise free from significant legal barriers to technology transfer and production. Furthermore, the regulation establishes that project proposals must explicitly address intellectual property issues related to the technology involved, including the existence of exclusivity agreements, commercial arrangements, and any restrictions on product licensing, as provided for in Art. 8, Section V.

Over time, and as PDPs have progressed through their different phases, studies have demonstrated reductions in medicine procurement prices—including those of antiretroviral drugs (ARVs)—as well as significant savings in public expenditure (PIMENTEL, 2018). Chaves, Hasenclever, and Oliveira (2018), for example, identified a 40% reduction in the unit sale price of tenofovir offered by its developer, Gilead, in 2010 following the rejection of the patent application by the National Institute of Industrial Property (INPI) and the announcement of the PDP for local production of the medicine. Comparing the prices observed during the implementation of the partnership (2011–2013), the authors also found an additional reduction of more than 20% relative to the 2010 price, although the product remained more expensive than generic versions available internationally.

Another study, conducted by Albareda and Torres (2021), identified not only an increase in the quantities procured but also a reduction in the purchase prices of 37 out of the 39 medicines analyzed following the establishment of the partnerships. In the case of dolutegravir (50 mg), another antiretroviral medicine used in the treatment of HIV infection, Lopes et al. (2025) found that the price reduction may have been influenced by the establishment of the PDP between Lafepe and Blanver, together with indications that the patent application would be rejected by the INPI. However, the subsequent reversal of this position and the maintenance of patent protection for dolutegravir ultimately prevented further procurement of the product through the PDP mechanism, as discussed previously.

In light of these considerations, and given the availability of data on purchases made through Lafepe's PDPs to date, this study proposes to assess the potential savings generated for the Ministry of Health through such acquisitions. For comparative purposes, the Maximum Government Selling Price (Preço Máximo de Venda ao Governo – PMVG), established by the Drug Market Regulation Chamber (Câmara de Regulação do Mercado de Medicamentos – CMED), will be used as a benchmark for both the reference medicine and its corresponding generic version. This approach makes it possible to estimate the percentage reduction achieved through PDP procurement relative to the PMVG applicable to the reference product, as well as to verify whether the PMVG of the generic medicine complies with the expected regulatory parameter, namely a maximum price equivalent to 65% of the reference medicine's price (a minimum reduction of 35%), in accordance with the pricing criteria established by CMED Resolution No. 2/2004.¹⁷

¹⁷ <https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/Regulacao/arquivos/5517json-file-1/view>

The calculations were performed for five medicines, with each pharmaceutical presentation analyzed separately, taking into account the unit price paid under the PDP (per tablet) and the PMVG excluding taxes (December 2025). The values were not adjusted for inflation. Although this estimate is simplified and relies on the PMVG as a benchmark—which does not necessarily reflect the prices effectively paid in all public procurement transactions—the calculations provide evidence of the potential percentage savings associated with acquisitions carried out through PDPs.¹⁸

Table 3. Percentage Reduction in Prices Paid through PDPs

Product	Dosage Form / Strength	Manufacturer	Tax-Exempt PMVG	PMVG per Unit	Generic PMVG (%) Lower than Reference Product	Unit Price Paid under the PDP	PDP Price (%) Lower than Generic PMVG	PDP Price (%) Lower than Reference Product PMVG
clozapina	25 MG COM CT BL AL PLAS TRANS X 30	Lafepe	31,29	1,04	≈ 41%	0,36	≈ 65%	
	100 MG COM CT BL AL PLAS TRANS X 30		111,15	3,71	≈ 48%	1,54	≈ 58%	
Leponex	100 MG COM CT BL AL PLAS PVC TRANS X 30	Viatris Farmacêutica do Brasil Ltda	212,32	7,08				≈ 78%
	25 MG COM CT BL AL PLAS PVC TRANS X 20		35,19	1,76				≈ 79%

¹⁸ The estimated savings are based on a comparison between the prices actually paid by the Ministry of Health through PDP procurement and the Maximum Government Selling Price (PMVG) established by CMED. As such, they represent potential savings relative to the applicable regulatory price ceiling and should not be interpreted as a comparison with prices that would necessarily have prevailed under alternative procurement mechanisms.

Product	Dosage Form / Strength	Manufacturer	Tax-Exempt PMVG	PMVG per Unit	Generic PMVG (%) Lower than Reference Product	Unit Price Paid under the PDP	PDP Price (%) Lower than Generic PMVG	PDP Price (%) Lower than Reference Product PMVG
	25 MG COM CT BL AL PLAS PVC/PE/PVDC TRANS X 20		35,19	1,76				≈ 79%
	100 MG COM CT BL AL PLAS PVC/PE/PVDC TRANS X 30		212,32	7,08				≈ 78%
dolutegravir sódico	50 MG COM REV CT FR PLAS PEAD OPC X 30	Lafepe	658,65	21,96	≈ 59%	4,10	≈ 81%	
	50 MG COM REV CX 50 FR PLAS PEAD OPC X 30		32.931,69	21,95	≈ 59%	4,10	≈ 81%	
Tivicay	50 MG COM REV CT FR PLAS PEAD OPC X 30 Glaxosmithkline Brasil Ltda.	Glaxosmithkline Brasil Ltda.	1.600,48	53,35				≈ 92%
hemifumarato de quetiapina	25 MG COM REV CT BL AL PLAS TRANS X 30	Lafepe	55,60	1,85	≈ 43%	0,71	≈ 62%	
	100 MG COM REV CT BL AL PLAS TRANS X 30		197,85	6,60	≈ 40%	2,00	≈ 70%	

Product	Dosage Form / Strength	Manufacturer	Tax-Exempt PMVG	PMVG per Unit	Generic PMVG (%) Lower than Reference Product	Unit Price Paid under the PDP	PDP Price (%) Lower than Generic PMVG	PDP Price (%) Lower than Reference Product PMVG
	200 MG COM REV CT BL AL PLAS TRANS X 30		352,38	11,75	≈ 40%	4,23	≈ 64%	
Seroquel	25 MG COM REV CT BL AL PLAS PVC OPC X 14	Pharlab Indústria Farmacêutica S.A.	45,93	3,28				≈ 78%
	100 MG COM REV CT BL AL PLAS PVC OPC X 28		305,57	10,91	≈ 59%	4,10	≈ 81%	≈ 82%
	200 MG COM REV CT BL AL PLAS PVC OPC X 28		549,64	19,63				≈ 78%
olanzapina	5 MG COM REV CT BL AL/AL X 30	Lafepe	262,18	8,74	≈ 38%	2,68	≈ 69%	
	10 MG COM REV CT BL AL/AL X 30		499,55	16,65	≈ 41%	4,55	≈ 72%	

Product	Dosage Form / Strength	Manufacturer	Tax-Exempt PMVG	PMVG per Unit	Generic PMVG (%) Lower than Reference Product	Unit Price Paid under the PDP	PDP Price (%) Lower than Generic PMVG	PDP Price (%) Lower than Reference Product PMVG
Zyprexa	5 MG COM REV CT BL AL AL X 30	Eli Lilly do Brasil Ltda.	423,80	14,13				≈ 81%
	10 MG COM REV CT BL AL AL X 30		847,65	28,26				≈ 84%
ritonavir	100 MG COM REV CT FR PLAS OPC X 30	Lafepe	40,53	1,35	≈ 43%	1,00	≈ 26%	
Norvir	100 MG COM REV CT FR PLAS OPC X 30	Abbvie Farmacêutica Ltda.	71,64	2,39				≈ 58%

Source: Author’s calculations.

The results presented in Table 3 make it possible to distinguish three different levels of percentage savings: (i) those resulting exclusively from CMED price regulation, expressed by the difference between the PMVG of the reference medicine and the PMVG of the corresponding generic medicine; (ii) the additional savings achieved when the price actually paid through a PDP is lower than the PMVG established for the generic medicine itself; and (iii) the total savings generated for the Ministry of Health, measured by comparing the price paid through the PDP with the PMVG of the reference medicine. A comparison between the unit prices paid through PDPs and the PMVGs of both the generic and reference medicines demonstrates that these partnerships effectively generated savings for the Ministry of Health.

First, and as expected under the pricing criteria established by CMED, the maximum prices (PMVGs) defined for the generic medicines produced by Lafepe were between 38% lower (olanzapine 5 mg) and 59% lower (dolutegravir 50 mg) than those of their respective reference medicines. All generic medicines analyzed complied with—and exceeded—the regulatory minimum discount requirement of 35%.

Comparing the actual unit price paid through the PDP with the PMVG established by CMED for the corresponding generic version, also on a per-unit basis, the smallest reduction identified was approximately 26% (ritonavir 100 mg), while the largest reached 81% (dolutegravir 50 mg). In other words, although the PMVG for the generic medicine already incorporates a discount relative to the reference product, comparison with the price paid through the PDP demonstrates that the partnership generates even greater savings. The price negotiated under the PDP was substantially lower than the maximum price permitted for the generic medicine. These findings suggest that PDPs generate additional savings that derive not from price regulation itself, but rather from the productive and institutional arrangements established through the partnership mechanism.

The final column of Table 3 presents the percentage reductions achieved by comparing the prices paid through PDPs with the PMVG of the corresponding reference medicines. In this case, the largest differences are observed, with reductions ranging from 58% (ritonavir 100 mg) to 92% (dolutegravir 50 mg). These results indicate that the prices effectively paid by the Ministry of Health through PDPs were substantially lower than the maximum prices that could have been charged for the corresponding reference medicines.

Overall, the findings suggest that Lafepe's PDPs not only complied with regulatory pricing requirements but also generated additional savings for the Ministry of Health, given that the prices paid under the partnerships were lower than the PMVGs applicable to both generic and reference medicines.

Several advantages of PDPs have already been identified in the literature, among which cost-effectiveness and the economic benefits of public procurement are particularly noteworthy (ALBAREDA; TORRES, 2021). Other frequently cited benefits include expanded access to medicines and technological learning within public laboratories (FERNANDES; GADELHA; MALDONADO, 2023). Beyond these direct economic effects, PDPs may also play a significant role in building national productive capabilities by enabling the internalization of manufacturing activities and the transfer of technology (FERNANDES; GADELHA; MALDONADO, 2023).

According to Varrichio (2017, p. 207), partnerships involving synthetic medicines and vaccines are primarily oriented toward technology absorption, with the objective of overcoming the technological lag of the domestic pharmaceutical industry, given the historically limited investment in research and development required for technology internalization. As the author further argues, PDPs therefore constitute “a policy aimed at strengthening the productive capabilities of national institutions.”

The existence of local production capacity is a fundamental condition for ensuring access to medicines within the Unified Health System (SUS), particularly in contexts of instability affecting global supply chains. The ability to respond rapidly and effectively to public health challenges, such as the COVID-19 pandemic, depends on the prior existence of productive infrastructure, accumulated knowledge, and institutional experience that can be mobilized to meet the population’s healthcare needs.

However, assessments of the effects of PDPs on the technological capabilities of public laboratories should be approached with caution, as the available evidence remains limited to a relatively small number of institutions. As noted by Vieira and Santos (2020, p. 29):

The low levels of investment in R&D and the limited importance attributed by laboratories to this area—whose principal indicator is the absence of established internal learning routines—demonstrate that their technological capabilities have remained weak and that the role of the public sector in pharmaceutical production continues to be poorly defined. Furthermore, overlaps in production across therapeutic classes persist among public laboratories.

For Lafepe, the importance of PDPs is manifested in several dimensions. According to the institution::

Internally, the impacts of these partnerships are highly significant in advancing physical infrastructure modernization and the acquisition of new equipment, incorporating state-of-the-art technologies, expanding research and development activities, and enhancing personnel training. In addition, they contribute to substantial financial results, thereby consolidating the conditions necessary for the investments required for the laboratory to continue meeting the contractual obligations associated with ongoing PDPs (LAFEPE, 2024, p. 14).

From this perspective, PDPs should not be understood as merely isolated policy instruments but rather as structural mechanisms of public policy whose effects may extend well beyond immediate economic gains. Following a period of instability, “marked by the dismantling of the PDP institutional framework, reflecting the breakdown of a long-term policy approach” (PIMENTEL; PARANHOS; CHIARINI, 2022, p. 401), recent years have witnessed the resumption and strengthening of federal policies aimed at consolidating the Health Economic-Industrial Complex (Complexo Econômico-Industrial da Saúde – CEIS). On September 26, 2023, the National Strategy for the Development of the Health Economic-Industrial Complex was launched through Decree No. 11,715/2023 (BRASIL, 2023a). The Strategy is structured around six programs¹⁹ designed to expand access to healthcare, increase domestic production of items considered strategic for the Unified Health System (SUS), and reduce Brazil’s external dependence in the health sector (BRASIL, 2023b).

Within this framework, PDPs were reinstated as a key instrument of the Strategy, guided by a reconstruction agenda aimed more explicitly at reducing the vulnerabilities of the SUS and expanding the population’s access to medicines and other health technologies. In addition to the revision of the PDP regulatory framework through Ministerial Ordinance GM/MS No. 4,472/2024 (BRASIL, 2024), new rounds of partnerships have been approved, focusing on medicines and technologies considered strategic for the SUS (SECTICS/MS, 2025).

Lafepe continues to play a significant role in this new cycle of partnerships. In 2024, shortly after the publication of the new PDP regulations, the laboratory launched a public call to select partner companies for technology transfer initiatives (LAFEPE, 2024). In addition, investments financed through both the institution’s own resources and agreements with the Ministry of Health—including funding provided under the New Growth Acceleration Program (Novo PAC)—have been announced to support the establishment of a new production facility and the modernization of existing equipment.

According to the laboratory’s management, R\$259 million will be invested in replacing the institution’s entire equipment base (G1, 2025). The objective is to double production capacity by 2026, including the manufacture of new medicines for neglected diseases such as leprosy (BELFORT, 2025; ESPECIAL PARA..., 2025).

19 The Strategy is structured around six programs: the Productive Development Partnership Program (Programa de Parceria para o Desenvolvimento Produtivo – PDP); the Local Development and Innovation Program (Programa de Desenvolvimento e Inovação Local – PDIL); the Vaccine, Serum, and Blood Products Preparedness Program (Programa para Preparação em Vacinas, Soros e Hemoderivados – PPVACSH); the Neglected Diseases and Vulnerable Populations Program (Programa para Populações e Doenças Negligenciadas – PPDN); the Healthcare Modernization and Innovation Program (Programa de Modernização e Inovação na Assistência – PMIA); and the CEIS Infrastructure Expansion and Modernization Program (Programa para Ampliação e Modernização da Infraestrutura do CEIS – PDCEIS) (Brasil, 2023b).

In this context, Lafepe benefits from the experience accumulated through previous PDPs and reaffirms its central role as a public pharmaceutical laboratory in meeting the demands of the Unified Health System (SUS), reducing external dependence, and expanding the population's access to healthcare.

04

FINAL CONSIDERATIONS

Public pharmaceutical laboratories are part of the set of institutions responsible for giving effect to the principles of Brazil's Unified Health System (SUS), as they contribute directly to the provision of medicines and strategic health inputs to the population. Their role is particularly relevant in addressing demands that are not considered priorities by the private sector, whether because of limited economic returns or the epidemiological profile of the affected populations. In this regard, strengthening these institutions as a long-term public policy priority is both essential and urgent, especially in light of the growing demand for healthcare services and the challenges associated with sustaining a universal and free public health system.

As demonstrated throughout this study, Lafepe stands out nationally not only for its strategic production, which meets part of the demand for antiretroviral medicines and treatments for neglected diseases, but also for the positive economic impacts it generates for the SUS through reduced external dependence and the use of technology transfer mechanisms. Lafepe is therefore an institution whose importance extends beyond its productive function, assuming a strategic role in strengthening the State's capacity to respond to public health needs. This justifies prioritizing public investment in the provision of resources, institutional stability, and the enhancement of its operational and technological capabilities.

Furthermore, Lafepe's location in Brazil's Northeast region contributes to the decentralization of public pharmaceutical production, which has historically been concentrated in the Southeast. This aspect has important implications both from a logistical perspective and in terms of addressing regional inequalities in access to medicines. Investments in local production tend to contribute positively to reducing geographical inequities, promoting regional development, and improving access to health technologies. In this regard, Lafepe represents a strategic hub for job creation, the promotion of research activities, and the attraction and retention of talent capable of contributing to innovation and local economic development.

A critical issue identified in this study, which extends beyond the specific context of Lafepe and affects other institutions as well, concerns the barriers imposed by intellectual property rights on products covered by PDPs.

The dolutegravir case demonstrates how patent-related uncertainties and disputes can compromise the continuity of public procurement, undermine productive sovereignty, create risks of supply shortages, and impose additional costs on the healthcare system. Moreover, the abusive exercise of monopoly power to impose higher prices on the Ministry of Health adversely affects the sustainable management of public resources. In this context, greater coordination among the institutions involved in PDPs is essential to ensure the systematic assessment of intellectual property-related risks and the legitimate and strategic use of the flexibilities provided under the TRIPS Agreement and incorporated into Brazilian legislation.

Another significant challenge concerns the need to align Lafepe's production strategies with the future demands of the SUS, taking into account changes in the epidemiological profile of the population, advances in the production of more complex technologies, and increasing pressures related to economic and environmental sustainability. In addition, the concentration of production in traditional chemically based medicines may, in the long term, limit the institution's ability to compete technologically and to generate endogenous innovation. This scenario reinforces the need for consistent technological diversification strategies, as well as sustained investments in research, development, and innovation.

Finally, strengthening Lafepe should be understood as part of a broader national strategy aimed at consolidating Official Pharmaceutical Laboratories (LFOs) and other institutions within the Health Economic-Industrial Complex (CEIS). Such a strategy requires greater predictability of government demand, stable financing mechanisms, public procurement policies aligned with innovation objectives, and recognition of health as a fundamental right that is inseparable from economic development, productive autonomy, and the country's health sovereignty.

05

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