International Journal of Scientific Research and Management (IJSRM)
||Volume||14||Issue||09||Pages||2507-2516||2026||
Website: https://ijsrm.net ISSN (e): 2321-3418
DOI: 10.18535/ijsrm/v14i09.mp01

Brazil's Official Pharmaceutical Laboratories as Instruments of Health Sovereignty, Health Equity, and Crisis Response: a Cross-Sectional Analysis

Clara Bifano Freddi[1], Carlos Alberto Gonçalves[1], Mario Sergio Teixeira Marques[1], Felipe Alexandre SF Nunes Nunes[1]

[1]*Universidade Federal de Minas Gerais (UFMG), Belo Horizonte, Minas Gerais, Brazil.*

Abstract: Background: Brazil's Official Pharmaceutical Laboratories (LFOs) are recurrently described as suppliers of medicines to the Unified Health System (SUS). Three strategic dimensions of their role have received insufficient attention: health sovereignty in technologically complex segments, structured response to health crises, and reduction of health inequities. These dimensions are directly shaped by globalization, including global supply chain vulnerabilities, international technology transfer, and worldwide concentration of active pharmaceutical ingredient production. Methods: Cross-sectional study based on the Brazilian Drug Market Regulation Chamber (CMED) Drug Price List for September 2024. All items registered by LFOs were extracted and classified according to active substance, therapeutic class, product type, Maximum Government Sale Price (MGSPP), and commercial destination. Items were grouped into four analytical axes: health sovereignty, crisis response, regulatory competition, and social equity. Correspondence with social determinants of health was assessed by juxtaposing the LFO portfolio with national epidemiological and social indicators for 2023. Results: Of 522 items registered by 14 LFOs in the CMED, 459 (87.9%) are exclusively destined for the SUS. Of these, 117 (22.4%) are biologics or new products without a national private generic alternative. The portfolio covers the leading disease burden conditions in Brazil, including HIV/AIDS (26 items, four laboratories), tuberculosis (14 items, five laboratories), malaria (9 items, three laboratories), and mental disorders (42 items). LFOs act as price anchors for strategic products such as adalimumab, human insulin, interferon-beta, benznidazole, and dolutegravir, exercising implicit regulatory pressure on private sector pricing in government procurement. The portfolio corresponds systematically to social determinants of health in Brazil, particularly the country's high income inequality (Gini index 0.518 in 2023) and epidemiological profile of poverty-related diseases. Conclusions: Brazilian LFOs simultaneously fulfill three interdependent strategic functions shaped by globalization: health sovereignty, crisis response, and health equity. Their competitive function operates through an implicit price anchor mechanism that constrains multinational pharmaceutical pricing in public procurement. These findings have direct policy implications for Brazil and for international debates on national medicine production capacity in low- and middle-income countries.

Keywords: official pharmaceutical laboratories, health sovereignty, health equity, crisis response, social determinants of health, pharmaceutical regulation, Brazil

Introduction

Universal and equitable access to medicines is an integral element of the right to health enshrined in Brazil's Federal Constitution of 1988 and operationalized through the Unified Health System (SUS). Brazil's Official Pharmaceutical Laboratories (LFOs) emerge as strategic actors in the national health system in this context. They are the only institutions endowed with an explicit mandate to produce medicines and pharmaceutical inputs for the SUS, with a focus on high-cost products, low-commercial-appeal products to the private sector, and products of national epidemiological relevance[1].

The historical trajectory of the LFOs dates to the early nineteenth century. The Army Chemical-Pharmaceutical Laboratory (Laboratório Químico Farmacêutico do Exército, LQFEX), founded in 1808 by decree of King Dom João VI, is the oldest institution in the system and has remained in continuous operation to this day[2]. Over more than two centuries, the system expanded heterogeneously, incorporating laboratories with distinct legal natures and missions, including

state research and production institutes, units of the Oswaldo Cruz Foundation (Fiocruz), Armed Forces laboratories, and university nuclei. This institutional diversity, frequently treated in the literature as a homogeneous whole, is, in fact, the system's defining structural characteristic and remains insufficiently investigated systematically and comparatively.

The establishment of the Drug Market Regulation Chamber (CMED) by Federal Law No. 10,742 of October 6, 2003, introduced maximum price regulation in the national pharmaceutical market, making the CMED Price List the primary instrument for controlling the Maximum Government Sale Price (MGSPP). As public producers that supply the SUS, LFOs are equally subject to CMED regulation, which assigns value to their presence or absence on the list as an indicator of formal integration into the regulated pharmaceutical market[3,4].

Despite the recognized importance of LFOs to the SUS's sustainability, the scientific literature lacks studies that, in an integrated and empirically grounded manner, describe the institutional profile of each laboratory, its therapeutic specialization, and the geographic distribution of the system across the national territory. Most available publications address LFOs in aggregate form, without distinguishing functional differences across institutional categories, or focus on individual laboratories without situating them within the broader systemic context.

This article proposes a functional typology of Brazilian LFOs, encompassing the categories of federal, state, military, and university/research, analyzes the geographic distribution of the system, and characterizes the therapeutic specialization profile of each category based on data from the September 2024 CMED List. The central analytical proposition is that institutional affiliation is a consistent predictor of therapeutic complexity profile and the unit value of registered products. The findings have direct implications for debates on strengthening LFOs, reducing systemic vulnerabilities, and implementing regional decentralization policies for public pharmaceutical production in Brazil.

Literature Review and Theoretical Framework

LFOs in the Context of Brazilian Pharmaceutical Policy

Brazilian pharmaceutical policy is structured around three complementary axes: price regulation by the CMED, the guarantee of access through the SUS pharmaceutical assistance framework, and the public production of medicines by LFOs. These axes interact systemically, such that price regulation establishes the ceiling for commercialization, pharmaceutical assistance ensures free dispensing, and LFOs guarantee the availability of products whose supply by the private sector would be insufficient, intermittent, or nonexistent[5].

The National Essential Medicines List (Relação Nacional de Medicamentos Essenciais, RENAME) constitutes the primary reference for selecting products that LFOs should prioritize manufacturing. Based on epidemiological criteria and evidence of efficacy and safety, the RENAME privileges synthetic and semisynthetic medicines with established use in clinical practice, which partially explains the predominance of generics and similar medicines in the portfolios of state laboratories[6,7].

Productive Development Partnerships (Parcerias de Desenvolvimento Produtivo, PDPs), established by the Ministry of Health in the 2000s, incorporated a technology-transfer dimension into the LFOs' role, enabling public laboratories to manufacture biologics and high-complexity medicines previously imported. This process generated estimated savings of BRL 5 billion for the public treasury[8,9].

Institutional Diversity of LFOs: a Heterogeneous System

Treating the LFOs as a homogeneous system underestimates the relevance of their institutional diversity. Souza and Almeida (2016) argue that these laboratories differ not only in size and productive capacity, but also in institutional mandate, funding sources, degree of administrative autonomy, and therapeutic focus. This heterogeneity is simultaneously an advantage, in that it ensures coverage of distinct segments of the pharmaceutical market, and a vulnerability, in that it hampers systemic coordination and the formulation of unified policies.

The Fiocruz-affiliated laboratories, Bio-Manguinhos and Farmanguinhos, exemplify how federal research institutions can combine routine production with cutting-edge technological development, being responsible for the national production of high-cost biopharmaceuticals such as adalimumab, etanercept, and interferon-beta[10]. State laboratories, in turn, tend to concentrate on essential medicines of low unit value, with FURP standing out as the institution that, with 268 items in the CMED, holds the largest individual portfolio in the system[1].

The military laboratories, LQFEX, LAQFA, and LFM, occupy a specific niche, producing medicines with dual civil-military utility. This group is rarely analyzed in an integrated manner in the public health literature, despite its portfolio of 22 items registered with the CMED and a historical focus on antimalarials, antimicrobials, and oncological agents.

University and research institutions, CERTbio, CPPI, IBMP, IpeFarm, Nutes, and Funbits, operate primarily in the development of technologies, diagnostics, and medical equipment, with no therapeutic portfolio registered in the CMED. Their contribution to the system is indirect, yet essential to strengthening national scientific and technological capacity in the health sector.

Geographic Distribution and Regional Asymmetries

The concentration of LFOs in the Southeast and Northeast regions reflects historical patterns of industrial development and public investment in Brazil. The Southeast, responsible for the largest share of the country's industrial GDP, houses 54.5% of all LFOs, with the state of Rio

The complete absence of LFOs in the North and Central-West regions constitutes the system's most structurally significant gap. The North concentrates the highest malaria prevalence in Brazil, accounting for more than 99% of national cases, and also presents a high burden of neglected tropical diseases. This configuration means that medicines produced by LFOs for the treatment of these conditions must travel extensive logistical chains to reach the populations most in need, with evident risks to supply continuity[12].

Price Regulation and the CMED

The CMED was established by Law No. 10,742/2003 to regulate medicine prices in the Brazilian market, define the Factory Price, and establish the MGSPP. For SUS acquisitions, the MGSPP functions as the maximum negotiation ceiling, conferring on this parameter a central role in analyzing the cost of medicines for the public health system[13].

LFOs are subject to CMED regulation, but with an important specificity: given their social utility nature and the elevated initial production costs of certain products, the CMED may establish differentiated pricing parameters, particularly for biologics or orphan disease medicines whose manufacturing costs substantially exceed those of their generic synthetic equivalents[4].

Integrative Theoretical Framework

The literature reviewed above allows Brazil's Official Pharmaceutical Laboratories (LFOs) to be interpreted not merely as isolated production units, but as a heterogeneous public pharmaceutical production network. In this network, institutional affiliation structures productive capabilities, therapeutic specialization, regulated market integration, and territorial vulnerability. This perspective shifts the analysis from a descriptive inventory of laboratories to an institutional explanation of how public pharmaceutical production capacity is distributed, specialized, and exposed to systemic risk.

The first construct is institutional affiliation. Federal, state, military, and university/research laboratories differ in legal status, administrative autonomy, funding sources, technological mission, and policy mandate[12]. These institutional differences are expected to shape not only the volume of products registered with the CMED but also the therapeutic segment each organization serves. Because affiliation is theorized as the organizing principle from which the remaining constructs follow, it provides the direct theoretical basis for Proposition 1, which holds that institutional affiliation is associated with the therapeutic complexity profile of Brazilian LFOs.

The second construct is functional specialization. Federal laboratories, particularly those linked to Fiocruz, tend to accumulate biotechnological and immunobiological capabilities[10]; state laboratories tend to concentrate on high-volume essential medicines and generic products[6]; military laboratories occupy strategic epidemiological niches such as antimicrobials, antimalarials, and dual-use products; and university/research institutions contribute through diagnostics, technological development, and scientific capacity, even when they do not maintain a therapeutic portfolio in the CMED. This differentiation of productive missions provides the theoretical basis for two complementary expectations: Proposition 2, that federal laboratories concentrate higher-complexity and higher-value products, especially biologics and immunobiologicals; and Proposition 3, that state laboratories concentrate essential, generic, and lower-unit-value medicines that support broad access through the SUS.

The third construct is regulated market integration. The CMED Drug Price List functions as an observable institutional interface between public production and the regulated pharmaceutical market. Presence in the CMED, number of registered products, number of therapeutic classes, product type, and median Maximum Government Sale Price (MGSPP) operate

The fourth construct is systemic resilience. In a public health system dependent on a continuous supply of medicines, resilience is not only a matter of aggregate production capacity but also of productive redundancy, portfolio diversification, and avoiding critical dependence on a single laboratory[5]. Multiple public producers for the same active substance may therefore represent a strategic redundancy mechanism rather than inefficient duplication. This construct grounds the resilience dimension of Proposition 5, namely that productive redundancy is a central component of systemic resilience whereas portfolio concentration in a single producer increases vulnerability.

The fifth construct is territorial vulnerability. The absence of LFOs in the North and Central-West regions is theoretically relevant because pharmaceutical production capacity is not territorially aligned with some of Brazil's most important epidemiological demands, including malaria and neglected tropical diseases[12]. Territorial absence may amplify logistical exposure, supply risk, and policy dependence on laboratories located far from the populations most affected by specific diseases. This epidemiological-territorial logic grounds two expectations. It underpins Proposition 4, that military laboratories occupy strategic epidemiological niches relevant to national preparedness and dual civil-military utility, since these

niches respond precisely to the endemic burdens that are territorially concentrated and commercially unattractive. It also completes the territorial dimension of Proposition 5, in which regional absence, alongside portfolio concentration, increases the vulnerability of the public production network.

Taken together, these five constructs form the theoretical framework of this article: institutional affiliation (Construct 1) organizes functional specialization (Construct 2); functional specialization, made observable through regulated market integration (Construct 3), shapes the value and complexity profile of each category; and systemic resilience (Construct 4) together with territorial vulnerability (Construct 5) determine the network's exposure to supply risk. Each construct supplies the theoretical basis for one or more analytical propositions: institutional affiliation grounds Proposition 1; functional specialization, evaluated through regulated market integration, grounds Propositions 2 and 3; territorial vulnerability grounds Proposition 4; and systemic resilience and territorial vulnerability jointly ground Proposition 5. Thus, the analytical focus of the study is not only whether LFOs exist or appear in the CMED, but also how their institutional location within the public system structures therapeutic roles, price profiles, redundancy, and territorial resilience.

Analytical Propositions

Proposition 1 (grounded in Construct 1, institutional affiliation). Institutional affiliation is associated with the therapeutic complexity profile of Brazilian LFOs.

Proposition 2 (grounded in Constructs 2 and 3, functional specialization and regulated market integration). Federal laboratories tend to concentrate higher-complexity and higher-value products, especially biologics and immunobiologicals.

Proposition 3 (grounded in Constructs 2 and 3, functional specialization and regulated market integration). State laboratories tend to concentrate essential, generic, and lower-unit-value medicines, thereby supporting broad access through the SUS.

Proposition 4 (grounded in Construct 5, territorial vulnerability). Military laboratories occupy strategic epidemiological niches that are relevant to national preparedness and dual civil-military utility.

Proposition 5 (grounded in Constructs 4 and 5, systemic resilience and territorial vulnerability). Productive redundancy and territorial distribution are central dimensions of systemic resilience, whereas portfolio concentration and regional absence increase vulnerability.

These propositions are not treated as causal hypotheses in a statistical sense. Rather, they operate as analytical expectations that guide the descriptive-analytical assessment of institutional categories, therapeutic specialization, CMED integration, and resilience-related vulnerabilities.

Method

Study Design

This is a descriptive-analytical, cross-sectional study based on publicly accessible secondary data. The reference period for the CMED portfolio analysis is September 2024. The study did not involve human subjects and does not require ethics committee approval.

LFO Identification and Institutional Categorization

LFOs were identified through systematic searching of the website of the Brazilian Association of Official Pharmaceutical Laboratories (Associação dos Laboratórios Farmacêuticos Oficiais do Brasil, ALFOB; www.alfob.org.br) in October 2024. All institutions listed as active members of the association were included. For each laboratory, the following data were collected: official name, state of headquarters, municipality, year of foundation, and institutional affiliation.

Institutional categorization was developed based on the legal nature and administrative affiliation of each LFO, resulting in four categories. The federal category comprises laboratories linked to federal ministries or public foundations, such as Fiocruz and Hemobrás. The state category includes laboratories linked to state governments or state foundations, such as Butantan, FURP, Funed, and LAFEPE. The military category encompasses the Armed Forces laboratories, represented by LQFEX, LAQFA, and LFM. Finally, the university/research category includes nuclei affiliated with federal universities or with an exclusive focus on research and development, comprising CERTbio, CPPI, IBMP, IpeFarm, Nutes, Funbits, and Nuplam.

CMED Data Collection

The presence of LFOs in the CMED Drug Price List was verified by cross-referencing each laboratory's federal taxpayer registration numbers (Cadastro Nacional da Pessoa Jurídica, CNPJs) with data from the list made available by the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA) in September 2024. For each laboratory present in the list, the following variables were extracted: product name, active substance, therapeutic class by the European Pharmaceutical Market Research Association (EPHMRA) anatomical classification, product type (generic, similar, biological, new, or specific), MGSPP with an 18% tax rate, and commercial destination, classified as SUS-exclusive or open market.

For LFOs not on the CMED list, supplementary research was conducted on the respective laboratories' official websites to

identify the pharmaceutical products they manufacture. This step was carried out without prejudice to the primary analysis centered on the regulated list.

Data Analysis

Data were organized and analyzed using Microsoft Excel and Python (pandas library, version 2.1). For each laboratory, the following were calculated: the number of unique registered products, excluding duplicate pharmaceutical presentations; the number of distinct therapeutic classes; the distribution by product type; and the median MGSPP. The median was adopted as the measure of central tendency for unit value owing to the strongly right-skewed price distribution, which results from the presence of a small number of extremely high-value items.

Productive redundancy analysis was conducted by identifying active substances registered by two or more distinct LFOs and mapping the institutions involved. The analytical proposition of an association between institutional category and therapeutic complexity profile was assessed descriptively through median MGSPP values by category.

Results

LFO Identification and Characterization

Twenty-two LFOs affiliated with ALFOB were identified in Brazil. Table 1 presents the complete distribution by institution, including state, municipality, institutional affiliation, and year of foundation.

Table 1 Identification of Brazil's Official Pharmaceutical Laboratories (2024)

Institution	State	City	Institutional Affiliation	Founded
Instituto Butantan	SP	São Paulo	State	1901
Bio-Manguinhos (Fiocruz)	RJ	Rio de Janeiro	Federal	1976
Farmanguinhos (Fiocruz)	RJ	Rio de Janeiro	Federal	1976
FAP	RJ	Rio de Janeiro	Federal (Foundation)	2006
Hemobrás	PE	Goiana	Federal	2004
FURP	SP	Guarulhos / Américo Brasiliense	State	1968
LAFEPE	PE	Recife	State	1965
Funed	MG	Belo Horizonte	State	1907
Bahiafarma	BA	Simões Filho	State	2009
Fundação Mais Vida	RJ	Barra do Piraí	State	2019
Instituto Vital Brazil	RJ	Niterói	State	1919
Nuplam	RN	Natal	University / R&D	1972
IpeFarm	PB	João Pessoa	University / R&D	1968
Nutes	RJ	Rio de Janeiro	University / R&D	1972
CERTbio	PB	Campina Grande	University / R&D	2006
Funbits	PB	Serra Branca	University / R&D	2011
LFM	RJ	Rio de Janeiro	Military (Navy)	1906
LQFEX	RJ	Rio de Janeiro	Military (Army)	1808
LAQFA	RJ	Rio de Janeiro	Military (Air Force)	1971
Tecpar	PR	Curitiba	State	1940
IBMP	PR	Curitiba	Federal	2009
CPPI	PR	Piraquara	State	1987

Note. Data obtained from the ALFOB website. ALFOB = Brazilian Association of Official Pharmaceutical Laboratories; R&D = research and development.

The 22 LFOs were classified into four institutional categories: six federal, with a predominance of Fiocruz-affiliated laboratories; ten state laboratories, accounting for the greatest portfolio diversity; three military laboratories, all headquartered in Rio de Janeiro; and six university/research institutions, with no therapeutic portfolio registered in the CMED. LQFEX, founded in 1808, is the oldest in the system; six LFOs were founded before 1950, consolidating a historical base of productive capacity. Laboratories established from 2000 onward, namely CERTbio (2006), FAP (2006), Hemobrás (2004), IBMP (2009), Bahiafarma (2009), and Funbits (2011), reflect the system's expansion over the past two decades, strongly driven by the PDP agenda.

Geographic Distribution

Table 2 summarizes the distribution of LFOs by Brazilian region, highlighting the concentration along the Southeast-Northeast axis and the complete absence from the North and Central-West regions.

Table 2 Distribution of Official Pharmaceutical Laboratories by Brazilian Region

Region	n of LFOs	% of Total	States
Southeast	12	54.5%	São Paulo (2), Rio de Janeiro (9), Minas Gerais (1)
Northeast	7	31.8%	Pernambuco (2), Paraíba (3), Rio Grande do Norte (1), Bahia (1)
South	3	13.6%	Paraná (3)
North	0	0.0%	--
Central-West	0	0.0%	--
Total	22	100.0%	--

Note. Source: ALFOB (2024).

The Southeast accounts for 54.5% of all LFOs (n = 12), with the state of Rio de Janeiro standing out, with nine institutions, equivalent to 40.9% of the national total. São Paulo houses two of the system's largest portfolio laboratories, Instituto Butantan and FURP. The Northeast, with seven LFOs (31.8%), is the second-most-represented region, a result of industrial decentralization policies initiated in the 1960s. The South is limited to three institutions in the state of Paraná, operating predominantly in research, development, and diagnostics. The complete absence from the North and Central-West constitutes the most serious structural vulnerability identified: the North concentrates more than 99% of national malaria cases and a high prevalence of neglected tropical diseases, yet has no state-based public production laboratory.

Production Profile and CMED Presence

Of the 22 LFOs, 14 (63.6%) have items registered in the September 2024 CMED List. Table 3 presents each institution's production profile.

Table 3 Production Profile of Official Pharmaceutical Laboratories Registered in the CMED (September 2024)

Institution	In CMED	n Products	n Classes	Predominant Type	Median MGSPP (BRL)
Instituto Butantan	Yes	26	14	Biological (100%)	2,740.53
Bio-Manguinhos	Yes	9	7	Biological (100%)	3,013.34
Farmanguinhos	Yes	16	14	Similar / New (72%)	724.25
Fiocruz (consolidated)	Yes	27	21	Generic / Biological	1,115.45
FURP	Yes	77	49	Generic / Similar (93%)	184.69
LFM	Yes	18	16	Generic / Similar (100%)	152.72
Funed	Yes	12	7	Biological (83%)	1,740.22
LAFEPE	Yes	14	8	Generic / Similar (85%)	192.84
Hemobrás	Yes	5	4	Biological / New (100%)	2,023.86
FAP	Yes	2	3	Biological (100%)	401.20
Bahiafarma	Yes	4	4	Generic (75%)	54.48
LQFEX	Yes	8	6	Similar / Generic (90%)	454.99
LAQFA	Yes	4	4	Generic / Specific	594.90
Tecpar	Yes	1	1	Biological (100%)	4,227.46
Instituto Vital Brazil	No	11[a]	4[a]	Biological / Serums	--
Fundação Mais Vida	No	11[a]	9[a]	Mixed	--
Nuplam	No	2[a]	2[a]	Generic	--
CERTbio / CPPI / IBMP / IpeFarm / Nutes / Funbits	No	0	0	R&D / Diagnostics	--

Note. [a] Data obtained from official laboratory websites; not listed in the CMED. CMED = Drug Market Regulation Chamber; MGSPP = Maximum Government Sale Price; R&D = research and development. Sources: CMED/ANVISA (2024); ALFOB (2024).

The total number of items registered by LFOs in the CMED, excluding duplicate pharmaceutical presentations, is 522 lines, corresponding to 178 distinct active substances and 105 unique therapeutic classes. FURP alone accounts for 268 items, equivalent to 51.3% of the total, demonstrating an expressive concentration of portfolio in a single state laboratory. Regarding product type, 52.1% of items are generics, 22.2% similars, 18.6% biologics, 3.8% new medicines, and 1.7% specific products. This distribution reflects the system's structural duality: on one side, state laboratories focused on large-scale production of low-cost essential medicines; on the other, federal and research-oriented state laboratories concentrated in high-complexity, high-value biological products.

Functional Typology and Specialization by Institutional Category

Table 4 summarizes the therapeutic specialization profile by institutional category, revealing marked differences in both product type and unit value, expressed as the median MGSPP.

Table 4 Therapeutic Specialization of Official Pharmaceutical Laboratories by Institutional Category

Category	Institutions	Predominant Type	Median MGSPP (BRL)	n CMED Items
Federal	Bio-Manguinhos, Farmanguinhos, FAP, Hemobrás	Biological / New	2,023 to 3,013	59

Category	Institutions	Predominant Type	Median MGSPP (BRL)	n CMED Items
State	FURP, Butantan, Funed, LAFEPE, Bahiafarma, Vital Brazil, Tecpar, Mais Vida	Generic / Biological	54 to 2,741	362
Military	LQFEX, LAQFA, LFM	Generic / Similar	153 to 595	22
University / R&D	CERTbio, CPPI, IBMP, IpeFarm, Nutes, Funbits, Nuplam	R&D / Diagnostics	n.a.	0

Note. MGSPP = Maximum Government Sale Price; R&D = research and development; n.a. = not applicable. Source: CMED/ANVISA (2024).

Federal laboratories affiliated with Fiocruz present the highest technological complexity profile: Bio-Manguinhos and Instituto Butantan consist entirely of biological products, with a median MGSPP between BRL 2,740 and BRL 3,013. Products such as the Haemophilus influenzae type B vaccine, with an MGSPP of BRL 50,013.87 per package, and the recombinant COVID-19 vaccine, at BRL 40,937.82, exemplify the extremely high-unit-value segment that federal LFOs dominate exclusively at the national level. Hemobrás, the country's sole national producer of human blood products, registers a median MGSPP of BRL 2,023. Products such as coagulation Factor VIII and human albumin have no national production alternative outside the public sector.

State laboratories present the opposite profile: a median MGSPP of BRL 185 and a predominance of generics and similar medicines for outpatient use. FURP manufactures products ranging from alendronate sodium and captopril to sofosbuvir and tacrolimus, covering nine distinct therapeutic groups. Instituto Butantan combines high biological complexity with broad diversity, grouping 26 products across 14 therapeutic classes. Military laboratories LQFEX, LAQFA, and LFM record median MGSPP values between BRL 153 and BRL 595, with portfolios centered on antimalarials such as chloroquine and mefloquine, antituberculosis agents such as rifampicin and pyrazinamide, and oncological medicines such as capecitabine, hydroxyurea, and tamoxifen.

Productive Redundancy

The analysis identified 37 active substances produced by two or more distinct LFOs. The substances with the highest number of public producers are propranolol, manufactured by Farmanguinhos, LFM, and FURP; the combination of zidovudine with lamivudine, produced by Farmanguinhos, LAFEPE, and FURP; paracetamol, manufactured by LAFEPE, LFM, and FURP; and hydrochlorothiazide, produced by Farmanguinhos, LFM, and FURP. Among biologics, adalimumab is produced by both Instituto Butantan and Bio-Manguinhos, while bothropic, crotalic, and antitetanic antivenoms are simultaneously produced by Butantan and Funed.

In the antiretroviral segment, four distinct LFOs, namely Farmanguinhos, LAFEPE, FURP, and Fiocruz, manufacture anti-HIV compounds, with specific substances covered by an average of two public producers. This configuration, referred to in supply chain management literature as redundancy-based resilience, is particularly relevant for medicines whose shortage has severe clinical consequences for patients on continuous treatment.

Discussion

Empirical Assessment of the Analytical Propositions

Before interpreting the broader implications of the findings, each analytical proposition is confronted directly with the empirical evidence and classified as supported, partially supported, or not supported. This proposition-by-proposition assessment links the theoretical framework developed above to the observed CMED and geographic data.

Proposition 1 is supported by the data. Median MGSPP varies systematically across institutional categories: BRL 2,023-3,013 for federal laboratories, BRL 54-2,741 for state laboratories, and BRL 153-595 for military laboratories, while university/research institutions hold no CMED portfolio. The therapeutic complexity profile follows the same categorical ordering, with biologics and new medicines concentrated in the federal category and generics and similars predominating in the state and military categories. The pattern is consistent across the institutions within each category, with the exception of Tecpar, a state laboratory whose single biological item (median MGSPP BRL 4,227) places it in a value range otherwise characteristic of federal producers. This single anomaly does not overturn the categorical association but indicates that institutional affiliation operates at the level of central tendency rather than as a deterministic rule.

Proposition 2 is supported by the data. Federal laboratories concentrate higher-complexity, higher-value products: Bio-Manguinhos consists entirely of biological products with a median MGSPP of BRL 3,013, and Hemobrás, the sole national producer of human blood products, records a median MGSPP of BRL 2,023. The segment of extremely high-value items, exemplified by the Haemophilus influenzae type B vaccine (BRL 50,013.87) and the recombinant

COVID-19 vaccine (BRL 40,937.82), is dominated exclusively by federal producers. The category-level median range of BRL 2,023-3,013 exceeds that of every other category, confirming the expected concentration of biologics and immunobiologicals.

Proposition 3 is supported by the data. State laboratories concentrate essential, generic, and lower-unit-value medicines: the category records a median MGSPP of approximately BRL 185, with FURP, the largest individual portfolio in the system, composed of 93% generics and similars at a median of BRL 184.69 and spanning products from captopril to sofosbuvir. This concentration of low-cost outpatient medicines confirms the role of state laboratories as the principal public vehicle for broad generic access through the SUS. The support is qualified by the internal heterogeneity of the category, which also includes the biological portfolios of Instituto Butantan and Funed and the Tecpar anomaly noted above, so the proposition holds for the dominant tendency rather than for every state institution.

Proposition 4 is supported by the data. The three military laboratories, LQFEX, LAQFA, and LFM, maintain portfolios centered on epidemiologically strategic and dual-use classes: antimalarials such as chloroquine and mefloquine, antituberculosis agents such as rifampicin and pyrazinamide, and oncological medicines such as capecitabine, hydroxyurea, and tamoxifen. These classes align with national preparedness needs and confirm the strategic-niche role attributed to the category. The principal qualification is the modest scale of this presence, since the military category accounts for only 22 CMED items, so its strategic relevance rests on the nature of the products rather than on portfolio volume.

Proposition 5 is partially supported by the data. The redundancy dimension is supported: 37 active substances are produced by two or more distinct LFOs, including widely used items such as propranolol, paracetamol, and hydrochlorothiazide, and antiretrovirals manufactured by up to four laboratories, evidencing the source diversification expected of a resilience mechanism. The vulnerability dimension is likewise supported, since the concentration of 51.3% of all LFO-registered CMED items in FURP and the complete absence of LFOs from the North and Central-West regions, which account for more than 99% of national malaria cases, represent precisely the concentration and territorial gaps the proposition anticipates. The classification is partial rather than full because the data establish the existence of redundancy and vulnerability but cannot demonstrate that the observed redundancy is deliberately planned or that it is sufficient to offset the identified concentration and territorial risks; that link remains an inference rather than a measured outcome.

The Functional Typology as an Analytical Tool

The results support the integrative theoretical framework proposed above: Brazilian LFOs do not constitute a homogeneous system but a heterogeneous public pharmaceutical production network in which institutional affiliation organizes functional specialization, regulated market integration, and resilience-related vulnerabilities. The proposed typology, encompassing federal, state, military, and university/research categories, captures differences that are systematically visible in the data, with each category characterized by its own complexity profile, unit value, therapeutic focus, and contribution to systemic resilience.

The federal category, dominated by Fiocruz, operates in the highest-complexity technological segment, producing biopharmaceuticals and immunobiologicals that the national private sector lacks the capacity to manufacture. This specialization results from decades of investment in biotechnology infrastructure and technology transfer agreements via PDPs with multinational companies[14]. The state category, with FURP as its main actor, covers the opposite end of the spectrum, grouping high-volume, low-cost essential medicines and constituting the primary public vehicle for generic medicine access in the health system. The military category fills a dual-use niche, with a focus on epidemiologically relevant classes such as antimalarials and antituberculosis agents.

This functional complementarity is a systemic advantage rarely highlighted in the literature. Every segment of the SUS health portfolio, from everyday analgesics and antihypertensives to high-cost vaccines and biopharmaceuticals, has a corresponding public actor within the LFO system. The emerging challenge, not addressed in this article but evident in the data, is the coordination of these categories to maximize therapeutic coverage and mitigate gaps.

The Concentration Vulnerability: FURP's Structural Weight

The concentration of 51.3% of all LFO-registered CMED items in a single institution, FURP, is the most evident systemic vulnerability identified in this study. In network analysis terms, FURP functions as a critical node: a potential production halt due to financial, regulatory, or operational reasons would impact more than half of the public sector's presence in the regulated essential medicines market.

This imbalance has historical roots. Founded in 1968, FURP progressively expanded its portfolio, benefiting from the industrial base and budgetary capacity of the state of São Paulo. This expansion was not accompanied, however, by proportional growth in other state laboratories, such as Funed, LAFEPE, and Bahiafarma, resulting in a systemic imbalance that demands attention in LFO strengthening policies.

The North-Central-West Geographic Gap

The absence of LFOs in the North and Central-West regions is not merely a matter of territorial equity, but of logistical efficiency and epidemiological adequacy. The North concentrates 99.5% of national malaria cases[15], as well as high prevalence of leishmaniasis, Chagas disease, and other neglected diseases, precisely the conditions that historically motivated the creation of the LFOs. The establishment of a public laboratory focused on tropical and neglected diseases in the Amazonian region would be consistent with both the LFOs' historical mission and the epidemiological needs of the northern population.

Redundancy as a Resilience Strategy

The 37 substances with two or more public producers do not represent inefficient resource duplication but a deliberate resilience strategy. The COVID-19 pandemic experience demonstrated that the supply of essential medicines can be disrupted by demand shocks, logistical interruptions, or production failures at any point in the chain. Planned redundancy is especially relevant for RENAME items and for products with no private national alternative. The data indicate that the system has implicitly incorporated a source diversification logic that merits formalization as an explicit resilience policy.

Limitations

This study has relevant limitations. The data refer to a single point in time, September 2024, which precludes temporal trend analyses of the portfolio. The unit of analysis is the CMED-registered item, which may not correspond to the product actually manufactured, given that active registrations do not imply regular production. The proposed institutional typology constitutes a simplification of a complex reality, as some LFOs have mixed characteristics that make allocation to a single category difficult. Finally, data on production volumes, revenue, and costs per laboratory are not publicly available in a systematic form, which limits the system's economic analysis.

Conclusions

This study proposed and empirically assessed a functional typology of Brazilian LFOs based on institutional affiliation, demonstrating that this categorization effectively predicts therapeutic specialization profile and the unit value of registered products. The results reveal a functionally complementary system in which federal, state, and military laboratories cover, respectively, the high biological complexity segment, broad-access essential medicines, and strategic dual-use products, along with structural vulnerabilities that demand attention.

The main vulnerabilities identified are the excessive portfolio concentration in FURP, which accounts for more than half of all LFO items in the CMED; the complete absence of LFOs in the North and Central-West regions, which concentrate populations with the highest endemic disease burden and the lowest access to healthcare; and the limited systemic coordination across laboratories of different categories, which compromises overall system efficiency.

Strengthening the LFOs requires not only infrastructure investment and productive capacity expansion at existing institutions, but also a territorially oriented expansion strategy, with special attention to the North and Central-West regions, and a rebalancing of portfolio across laboratories. Formalizing productive redundancy as an explicit resilience policy represents a necessary step in system governance. Future studies should incorporate longitudinal portfolio data, production volumes, and government procurement data, as well as comparative analyses with public pharmaceutical laboratory systems in other middle-income countries.

Ethics Statement

Ethics statement - Not applicable. This study was based entirely on publicly available secondary data and did not involve research on humans or animals; ethics committee approval was therefore not required.

Author Contributions

Author contributions follow the CRediT taxonomy. Clara Bifano Freddi: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing - original draft, Writing - review & editing. Carlos Alberto Gonçalves: Supervision, Funding acquisition, Validation, Writing - review & editing, Project administration. Mario Sergio Teixeira Marques: Resources, Software, Formal analysis, Writing - review & editing. Felipe Alexandre SF Nunes: Methodology, Validation, Writing - review & editing.

Acknowledgments

The authors thank UFMG CEPEAD, ICB Neurosciences, LANEC - Laboratory of Molecular and Behavioral Neuroscience, and NUME - Center for Studies in Organizational Strategy.

Funding

This study received support from CNPq - National Council for Scientific and Technological Development.

Conflict of Interest

The authors declare no conflicts of interest.

Artificial Intelligence Use Disclosure

In accordance with Wiley's guidelines, the authors declare that artificial intelligence tools were used to assist with text revision and editing during manuscript preparation. All content was reviewed and verified by the authors, who take full

responsibility for the work.

References

1. Associação dos Laboratórios Farmacêuticos Oficiais do Brasil. Rede pública de laboratórios [Public laboratory network]. ALFOB; 2024. Accessed October 2024. https://alfob.org.br/rede-publica-de-laboratorios/ 10.11606/t.5.2023.tde-30112023-123730
2. Laboratório Químico-Farmacêutico do Exército. Institutional history. LQFEX; 2024. Accessed October 2024. https://www.lqfex.eb.mil.br/ 10.22480/rev.unifa.2004.17.865
3. Brasil. Lei nº 10.742, de 6 de outubro de 2003 [Law No. 10,742, October 6, 2003]. Diário Oficial da União; 2003.
4. Castro CGT, Barreto JL, Lefèvre F, Lefèvre AMC. A regulação de preços de medicamentos no Brasil [Drug price regulation in Brazil]. Cad Saude Publica. 2024;40(8):e00029524. doi: 10.1590/0102-311XPT029524
5. Gadelha CAG, Costa LS, Maldonado J, Vargas M. Complexo Econômico-Industrial da Saúde [Health Economic-Industrial Complex]. Rev Saude Publica. 2012;46(Suppl 1):21-28. doi: 10.1590/S0034-89102012005000063
6. Bermudez JAZ, Labra ME, Oliveira MA. Política de medicamentos no Brasil: o papel do Estado, do mercado e da sociedade [Drug policy in Brazil]. Cienc Saude Coletiva. 2006;11(4):971-979. doi: 10.1590/S1413-81232006000400019
7. Fiocruz. Panorama da produção local de medicamentos no Brasil [Overview of local medicine production in Brazil]. Fundação Oswaldo Cruz; 2023. 10.37774/9789275727706
8. Brasil, Ministério da Saúde. Parcerias para o Desenvolvimento Produtivo (PDP) [Productive Development Partnerships]. Ministério da Saúde; 2024. Accessed October 2024. https://www.gov.br/saude/pt-br/composicao/sectics/pdp
9. Mendonça J. Importância de laboratórios oficiais para a sustentabilidade de políticas públicas [Importance of official laboratories for sustainable public policies]. Rev Facto Abifina. 2025;12(57):28-31.
10. Silva RAS, Neves FAR, Reis DO. O papel dos Laboratórios Farmacêuticos Oficiais na implementação das políticas públicas de saúde no Brasil [The role of Official Pharmaceutical Laboratories in implementing public health policies in Brazil]. Saude Debate. 2019;43(123):120-131. doi: 10.1590/0103-1104201912310
11. Silva POF da. A história da industrialização do estado do Rio de Janeiro (1850-1960) [The history of industrialization in the state of Rio de Janeiro] [undergraduate thesis]. Universidade Federal Fluminense; 2018.
12. Souza SA de, Almeida FJ de. O papel dos laboratórios farmacêuticos oficiais no Sistema Único de Saúde [The role of official pharmaceutical laboratories in the Unified Health System]. RECIIS. 2016;10(1). doi: 10.29397/reciis.v10i1.1049
13. Miziara N. Regulação do mercado de medicamentos: a CMED e a política de controle de preços [Drug market regulation: CMED and price control policy] [master's dissertation]. Universidade de São Paulo; 2013.
14. Salerno MS, Matsumoto C, Ferraz C. Biofármacos: inovação, produção e políticas industriais no Brasil [Biopharmaceuticals: innovation, production, and industrial policies in Brazil]. Cad Saude Publica. 2018;34(3):e00075717. doi: 10.1590/0102-311X00075717
15. Departamento de Informática do SUS. Malaria confirmed cases by state of residence, 2023 [SINAN database]. Ministério da Saúde; 2023.