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Challenges and perspectives of pharmaceutical services in the context of Brazilian foreign policy: an approach in light of the decolonization of health in the global south in the post-pandemic period

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Abstract *The National Pharmaceutical Services Policy (PNAF) was the first public policy created through social oversight. The consolidation of the National Health Council as a democratic, pluralistic, and activist space, especially in the approval of the PNAF, coincides with a strategic moment in Brazilian foreign policy and health diplomacy, focused on reconfiguring global geopolitics, especially in North-South relations. This article analyzes how Brazilian foreign policy has been coordinated with the defense of Health on the international stage over the past 20 years, especially in negotiations that affect access to safe, effective, high-quality, and affordable medicines. This qualitative, descriptive study is grounded in Brazilian Foreign Policy (BFP), innovation, and intellectual property rights. It concludes that the decolonization of Health in the Global South, especially in the post-pandemic backdrop, requires a renewed commitment to equity, social justice, and the human right to health. Brazil, with its experience in Public Health policies and local medicine production, can spearhead this transformation.*
Key words *Access to Medicines, Patents, Global Health*

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Introduction

The National Pharmaceutical Services Policy (PNAF) was enacted in 2004 by the National Health Council (CNS) through Resolution No. 338 of May 6, 2004. It was built upon discussions and proposals from the First National Conference on Medicines and Pharmaceutical Services. It is the first public policy instituted through social control, via the aforementioned council, reinforcing the importance of spaces for the collective construction of guidelines for Brazilian Public Health policies, as it allows for the contribution of civil society in a space historically limited to academics and managers[1].

The consolidation of the National Health Council as a democratic, plural, productive, and activist space, especially in the context of the approval of the PNAF, coincides with a specific moment in Brazilian foreign policy and health diplomacy in our country, in the sense of altering the geography of power on a global scale[2].

This article aims to clarify, in this context, how Brazilian foreign policy has been associated with the defense of Health in the international arena over the last 20 years, specifically in international negotiations that impact access to safe, effective, quality, and affordable medicines, especially in developing and less developed countries, and in the relationship between Public Health, innovation, and intellectual property.

Therefore, we will seek to verify how Brazil has been acting in the international arena, in order to emphasize that intellectual property is not a topic exclusively associated with commerce, but also with Public Health and human rights, thus safeguarding the PNAF's principles, especially regarding research, development and production of medicines and supplies, as well as their selection, programming, acquisition, distribution, dispensing, quality assurance of products and services, monitoring and evaluation of their use, in order to achieve concrete results and improve the quality of life of the population[3-5].

This is, therefore, a constant interdependence: domestic policies influence how a country positions itself abroad, while international conditions and dynamics can impact a country's decisions and internal stability[6].

This article presents a novel approach by exploring the interfaces between the National Pharmaceutical Services Policy and Brazilian foreign policy, highlighting debates on access to medicines in multilateral forums addressing Public Health, Innovation, and Intellectual Property. The analysis incorporates contemporary and contrasting perspectives from the governments of Jair Bolsonaro (2019-2022) and Luís Inácio Lula da Silva in his third term (2023-2026), offering an original contribution to studies on global health governance, health diplomacy, and national strategies for access to health technologies.

Methodological foundations and research design

This descriptive, qualitative study is based on a theoretical framework related to Brazilian foreign policy, innovation, and intellectual property rights. Methodological procedures included a literature review and analysis of primary and secondary data, particularly regarding the texts of international agreements, information, data, and reports extracted from Brazilian government agencies.

The theoretical framework refers to the set of concepts, theories, and approaches that guide the construction of knowledge in scientific research, serving as a basis for the analysis and interpretation of data. It is fundamental to ensuring coherence and depth in the study, especially in complex areas such as the analysis of Brazilian foreign policy, where multiple dimensions – political, economic, and social – intertwine. Through the theoretical framework, the researcher delimits the focus of the investigation and connects their work to the pre-existing academic debate, enabling a critical understanding of the processes under study. According to Cervo[7], theoretical rigor is essential to articulate empirical elements with the structural and institutional dimensions of foreign policy, conferring greater validity and relevance to the research.

The primary sources used in this research were extracted from official websites of governmental bodies and multilateral institutions, ensuring the reliability and timeliness of the information analyzed. Among these sources, the websites of the Brazilian Ministry of Health and the Ministry of Foreign Affairs stand out, as well as those of international organizations such as the World Health Organization (WHO), the World Trade Organization (WTO), and the World Intellectual Property Organization (WIPO), as shown in the Chart 1.

The following databases were used to search for articles that complement this work: Virtual Health Library (BVS), CAPES Journals, Luiz Vi-

Chart 1. International and national documents analyzed in the study.

Nº	Document	Complete title
1	WTO TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), World Trade Organization (WTO), 1994.
2	Doha Declaration on Public Health and the TRIPS Agreement	Declaration on the TRIPS Agreement and Public Health, adopted at the Fourth WTO Ministerial Conference, Doha, Qatar, November 14, 2001.
3	WHO Resolution WHA61.21	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, World Health Assembly Resolution WHA61.21, adopted in 2008.
4	WIPO Development Agenda	WIPO Development Agenda, adopted by the General Assembly of the World Intellectual Property Organization (WIPO), 2007.
5	Proposal IP/C/W/669 (Waiver TRIPS COVID-19)	Waiver from specific provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19, document IP/C/W/669, submitted to the WTO TRIPS Council on October 2, 2020.
6	Speech by Minister Nísia Trindade (2023)	Speech by the Minister of Health, Nísia Trindade Lima, at the 76th World Health Assembly, May 2023, Ministry of Health, Brazil.
7	Rio de Janeiro Declaration (2024)	Rio de Janeiro Declaration on Pandemic Preparedness, presented at the 2024 Global Pandemic Preparedness Summit, held by the Ministry of Health, Oswaldo Cruz Foundation (Fiocruz), and the Coalition for Epidemic Preparedness Innovations (CEPI), on June 25, 2024.

Source: Author.

ana Filho Academic Library, PubMed, and Google Scholar. These databases were selected due to their relevance and scope within the context of Brazilian foreign policy, health diplomacy, and access to medicines.

The search strategy was developed to retrieve current and relevant data on Brazilian foreign policy, health diplomacy, and pharmaceutical services, and identify articles pertinent to the research topic. The descriptors used were "Brazilian foreign policy", "National Pharmaceutical Services Policy", "Medicines", and "TRIPS agreement".

The horizontalized Brazilian foreign policy and the debates surrounding pharmaceutical services after the advent of the TRIPS Agreement

Considering that foreign policy is a public policy, it can be seen that its formulation and implementation are part of the dynamics of government choices, which, in turn, result from alliances, exchanges, disputes, adjustments, and combinations between representatives of diverse interests at the international level. A theoretical basis that advanced this diagnosis was that of Helen Milner[8], who suggests that decision-making processes, structured as polyarchies, form a continuum – from the national to the international, and vice versa.

In this context, we observe that Brazilian Foreign Policy (BFP) is the set of guidelines and actions adopted by Brazil in its international relations to promote its interests in the global landscape. It is configured in the analysis and study of how the Brazilian State conducts its relations with others, projecting itself into the international environment and starting from the formulation, implementation, and evaluation of externalities within its borders until its inclusion in international society[9,10].

Contemporary BFP spans from 1989 to date (2025) and is marked by new institutional and practical designs for the Brazilian foreign policy. Domestically, the political landscape is characterized by the transition from military rule to democracy, while the economic aspect saw the exhaustion of the nationalist development model. Furthermore, we see challenges in rebuilding its international image after the Bolsonaro administration (2019-2022). That administration departed from Brazilian diplomatic traditions, such as multilateralism and a focus on South-South cooperation, in favor of ideological alliances and polarizing stances[11].

In the specific context of pharmaceutical services and the BFP, the establishment of the World Trade Organization (WTO), through the Marrakesh Agreement and its annexes, such as the aforementioned TRIPS agreement of 1994, modified the global landscape of patents and ac-

cess to medicines. For the first time in history, all countries wishing to belong to this organization were obliged to level the protection of intellectual property rights to a common minimum standard, guaranteed by the TRIPS Agreement[12].

Today, it is the most representative set of guidelines on intellectual property. Internationalizing minimum intellectual property protection levels, including pharmaceutical products, impacts access to medicines worldwide, especially in countries of the Global South, considering all those countries with an interconnected history of colonialism, neocolonialism, and a social and economic structure with significant inequalities in consumption patterns, life expectancy, and access to resources[13].

This situation emerged because, until the advent of TRIPS, Brazil, as well as a range of developing and less developed countries, denied patentability to pharmaceutical products, in order to distance themselves from the cycle of economic and technological dependence on international laboratories, so that the production of medicines in these countries could freely use the state of the art protected in industrialized countries, which would represent lower production costs that would enable greater access to available medicines[13].

For Brazil, the situation was even more peculiar. The TRIPS agreement provided extended deadlines for developing and least developed countries to implement the treaty. This deadline was four more years for developing countries, and an additional five years for technological sectors that were not protected before the agreement came into effect, such as pharmaceuticals. Brazil chose not to take advantage of this extension, unlike other developing countries such as India, as if changes of this magnitude did not require complex adaptations. Furthermore, Brazilian legislation failed to adopt some of the flexibilities permitted by the agreement and, in some aspects, exceeded what was required by the aforementioned international treaty, incorporating into national legislation provisions known in legal scholarship as TRIPS-Plus[14].

This Brazilian government's stance was aligned with the tenets of the BFP of the Cardoso government (1995-2002), which was programmatically committed to dismantling the developmentalist state, moving towards a liberalizing perspective integrated with the interests of international capital and trade. It thus followed guidelines already observed during the Collor (1990-1992) and Itamar Franco (1992-1994) governments[2].

During the first two terms of Luiz Inácio Lula da Silva (2003-2010), Brazilian foreign policy gained prominence for its emphasis on international solidarity and the pursuit of greater autonomy on the global stage. This strategy aimed not only at expanding trade but also at exchanging knowledge and experiences among nations of the Global South, seeking alternatives to the traditional model imposed by developed countries[14].

One of the central themes in Lula's foreign policy was access to medicines, especially in the context of the fight against the HIV/AIDS epidemic and other diseases. Brazil adopted a firm stance in favor of the production of generic medicines, challenging the patents established by large pharmaceutical companies[14].

Brazil has sought to establish partnerships with African and Latin American countries, offering expertise in Public Health and sharing its successful experiences in medicine policies. This collaboration has reinforced the Brazilian icon of a regional and global leader, committed to reducing inequalities and promoting social well-being in the most vulnerable countries[15].

Furthermore, by addressing issues such as the reform of the World Trade Organization (WTO) and the defense of an equitable distribution of resources, Lula consolidated a vision that true international cooperation must be based on equity and solidarity, aspects that shaped his diplomatic approach in the early years of his government[15].

Of particular note during this period are the Brazilian government's initiatives to create a development agenda with the World Intellectual Property Organization (WIPO) in 2004. In addition, notable are the discussions within the WTO Dispute Settlement Panel in 2008, and Brazil's opposition to the seizure of generic medicines in transit, and the violations of the flexibilities foreseen in the TRIPS agreement, in the episode involving the seizure of a 570 kg shipment of the raw material Losartan Potassium, used in the production of high blood pressure medicines, which was detained for 36 days in the Port of Rotterdam, Netherlands, under the allegation of being counterfeit[14].

We can also mention initiatives such as the installation of ARV and other medicines factory in Mozambique, called the Mozambican Medicines Society (SMM), in partnership with the Oswaldo Cruz Foundation (Fiocruz), inaugurated in 2012, and made possible from the commitment assumed in November 2003 by Brazil through the Brazil-Mozambique Proto-

col of Intentions on Scientific and Technological Cooperation in Health[16], and the leading role of Brazilian diplomacy in the approval of Resolution WHA61.21 in 2008, together with the World Health Organization, related to the Global Strategy and Plan of Action on Public Health, Intellectual Property and Innovation (GSPOA)[17]. Brazilian initiatives were crucial in ensuring the inclusion of intellectual property issues on the WHO agenda and in guaranteeing the dissemination of the flexibilities of the TRIPS agreement and other international agreements that promote Public Health and access to medicines[15].

Dilma Rousseff's administration (2011-2015) continued the initiatives of the previous government, maintaining participation in multilateral meetings and groupings with specific objectives, but abandoning the entrepreneurial and active approach to foreign policy promoted by Lula and his Foreign Minister, Celso Amorim. The emphasis on the figure of the President was reduced, revealing a prioritization of domestic policy over foreign policy. The number of trips and countries visited by Dilma was significantly lower, as was the number of posts abroad and positions at Itamaraty. With a more technical and pragmatic approach, Dilma brought with her a social and educational background, as well as experiences, ambitions, and worldviews that differed considerably from those of her predecessor[18].

In turn, the Michel Temer (2016-2018) government's foreign policy was impacted by its lack of legitimacy among some of the Brazilian population, by successive new events that fueled the political crisis, by its nature as a transitional government, and by the economic recession. The beginning of a Brazilian geopolitical setback for South-South cooperation is evident, and at regional levels. This situation can be observed since the end of the PT governments and the start of the Temer administration, and a weakened Southern Common Market (Mercosur) was the primary example[19].

In 2017, for example, Brazil formally requested accession to the OECD. It is well known that this organization, made up of the world's wealthiest countries, has a very different view from that of developing countries regarding the protection of intellectual property, including in the pharmaceutical field. While the former have historically advocated for access to affordable medicines and the use of the flexibilities provided for in the TRIPS agreement, the latter have a vision much more related to enforcement policies and other legal tools aimed at guaranteeing the protection of intellectual property rights, which can often culminate in the preservation of undue monopolies.

The Health policy suffered several attacks during Michel Temer's government, justified by the supposed need to cut spending in the Unified Health System (SUS). One example of these attacks was the proposal for popular and accessible health plans, which became one of the pillars of his administration. Furthermore, the spending freeze imposed by Constitutional Amendment No. 95/2016 resulted in an estimated loss of BRL 654 billion in funds for the SUS. Another relevant measure was Ordinance No. 3,588/2017, which brought changes to mental health policy, compromising achievements obtained with the psychiatric reform, among other actions[20,21].

Bolsonaro's administration (2019-2022) broke with the idea of structuring South-South cooperation in Health, with an automatic alignment with US Trumpism. The foreign policy of that period was marked by an automatic alignment with the interests of the United States, reflecting a stance that prioritizes diplomacy aligned with economic pragmatism at the expense of national sovereignty. This rapprochement with Washington not only subserved Brazilian interests in several geopolitical issues but also compromised Brazilian autonomy in international forums[22].

Furthermore, this pro-American orientation directly affected essential issues such as Public Health. The sabotage and denialism in the fight against COVID-19 were reflected in the large number of deaths, in both absolute and proportional terms, making it one of the countries with the highest number of fatalities. The abandonment of progressive agendas regarding access to medicines, especially in forums such as the World Health Organization (WHO) and the World Trade Organization (WTO), is a clear example of this regression. The Bolsonaro government not only distanced itself from discussions about patent flexibility and the promotion of generic medicines but also opted for rhetoric that prioritized trade agreements over protecting the population's health rights. This situation compromised access to essential treatments for millions of Brazilians and made the country more vulnerable to pressure from large pharmaceutical companies[23].

A clear example of this subservient foreign policy occurred in 2020 at the WTO's TRIPS Council meeting, when countries discussed a

proposal (IP/C/W/669) entitled "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19", submitted by India and South Africa.

In short, the initiative sought to provide temporary exemptions from certain TRIPS obligations for all WTO members, facilitating the removal of barriers to access to health products, including vaccines, and the scaling up of research and local production. Brazil was the only BRICS country to openly oppose the proposal, aligning itself directly with the US during the Trump era. The Brazilian position began to change in early 2021, after India announced it would begin sending vaccines to its neighbors and key partner countries. Brazil received two million doses a few days after the government abstained from voting against the Indo-South African proposal at the WTO. Biden's support for the proposal seems to have left Brazil with no choice but to follow the US and the other four BRICS countries[24,25].

The return of Luís Inácio Lula da Silva to the Presidency for the 2023-2026 term represents an attempt to revive a "proud and active" foreign policy, especially in Global Health and Health Diplomacy, as can be seen from the speech of the Minister of Health, Nísia Trindade, at the 76th World Health Assembly, held in May 2023:

I also want to say that Brazil is back, which means the resumption of our agenda in defense of Health equity, the culture of peace and multilateralism, fundamental in this time. [...] We have to decentralize the production of medicines, vaccines, and strategic supplies to guarantee equitable access throughout the world. We must work to reduce inequalities, including the inequality of access to the benefits of scientific and technological knowledge. Inequality is bad for Health[26].

Thus, there is a renewed decentralization of Brazilian foreign policy, especially in the Health sector, which is a fundamental strategy for expanding international cooperation and strengthening the Brazilian stance in global forums. In recent years, the country has sought to diversify its partnerships, transcending traditional relations with powerful nations and engaging in initiatives involving developing countries. This approach allows Brazil not only to share experiences and knowledge but also to promote the defense of fairer and more equitable health systems[6,27].

The success of such initiatives aligns with the idea of decolonizing health in the Global South, which emerges as a vital concept, especially in the post-pandemic context, where structural inequalities in Health have become even more evident, as will be seen below.

Decolonizing Health in the Global South in a Post-Pandemic Context: Brazil's Role

The COVID-19 pandemic has exacerbated existing disparities, highlighting the need for a reassessment of global health policies and the urgency of ensuring equitable access to medicines and health technologies.

To effectively promote pharmaceutical services, that is, access to medicines and health technologies for all people, it is fundamental to recognize such products, including vaccines, as global public goods. It is crucial to reshape the Research and Development (R&D) and Intellectual Property (IP) ecosystem, ensuring greater technical, financial, and political autonomy, as well as greater authority and transparency for the WHO. In this context, several forms of knowledge and innovation must pursue equity and universality as central objectives[28].

The decolonization of Health involves a critique of the traditional Health model imposed by developed nations, which often marginalizes the local realities and needs of the Global South. According to Deisy Ventura *et al.*[29], the movement for the decolonization of Global Health must go far beyond criticizing the international dynamics in Research and Education, or appealing to limited initiatives to promote diversity. It should point to the need for structural reforms to combat health inequalities, which have been marginalized in recent decades by the dominant neoliberal dogmas[29].

Recent studies confirm that the introduction of patents after the implementation of the TRIPS agreement, and TRIPS-Plus devices related to pharmaceutical products, such as those adopted by Brazil, in the case of pipeline patents, and the minimum period of patent monopoly after granting of the patent letter, whose unconstitutionality was declared by the Supreme Federal Court in 2021[30], are associated with an increase in medicine prices, losses in consumer welfare and increased costs for consumers, and for national governments, of pharmaceutical products[31].

The end of the aforementioned patent extension, with the extinction of the sole paragraph of Article 40 of the Intellectual Property Law (Law No. 9,279/1996), resulted in a significant reduction in the term of validity of pharmaceutical patents in Brazil. The 2022 decision of the

Superior Court of Justice (STJ) regarding the validity of mailbox patents, influenced by the judgment of ADI No. 5,529/DF, also reduced the legal uncertainty in matters of intellectual property. In this context, the Brazilian government should explore possibilities related to local production, including the implementation of productive development partnerships (PDPs), as with the medicine adalimumab, whose technology transfer progressed after the decisions of the STF and STJ. Other strategic medicines may be the subject of PDPs and generic production with the end of the undue extension of the patent monopoly. Furthermore, the importance of implementing the flexibilities foreseen in the TRIPS agreement is reinforced, such as the reinstatement of prior approval by the National Health Surveillance Agency (Anvisa)[32].

Brazil, therefore, can be a significant example of how the decolonization of Health can be promoted through the local production of medicines and health technologies. In the context of COVID-19, initiatives such as the production of vaccines in partnership with international laboratories and the transfer of technology to the national industry have shown the importance of strengthening local capacity. These efforts not only meet immediate Health needs but also foster research and innovation, which are fundamental for developing technologies appropriate to the reality of the Global South[33].

The Global Pandemic Preparedness Summit 2024, organized by the Ministry of Health, FIOCRUZ, and the Coalition for Promoting Innovations in Epidemic Preparedness (CEPI), deserves special mention. It advocated for overcoming obstacles and disparities between the Global North and South in access to, research into, and development of vaccines, medicines, and health supplies. The Rio de Janeiro Declaration, issued at the end of the meeting, clearly asserted the need to establish health sovereignty in the Global South[34].

Furthermore, in order to overcome technological dependence and expand access to medicines in Brazil, given the enormous challenge of maintaining the sustainability of the SUS, the State must seek a balance between public and private interests in the Health sector and the articulation between existing legal instruments, under the direction of a national strategy that prioritizes comprehensive and equitable access and the alignment between its Health, Industrial, Science, Technology and Innovation (ST&I) and Intellectual Property policies[35].

Of particular note in this context is the recent publication of Ordinance GM/MS N°4.472/2024, which updates the legal framework for the Productive Development Partnership (PDP) program, providing greater transparency and legal certainty to the agreements signed, which seek to internalize strategic technologies within the SUS, including the manufacture of Active Pharmaceutical Ingredients (APIs) and Critical Technological Components (CTCs) in national territory[36]. We should also mention the recent launch of the Production and Technological Development Program for Neglected Populations and Diseases (PPDN). Finally, we underscore the approval of Law No. 14,977 of September 18, 2024, which amends Law No. 8,080 of September 19, 1990 (Organic Health Law)[37], to provide for the production of active ingredients intended for the treatment of socially determined diseases by public pharmaceutical laboratories.

The COVID-19 pandemic was not and will not be the last Public Health Emergency of International Concern. By highlighting the right of access to vaccines and pharmaceutical products as an essential component of human rights, the health diplomacy promoted by the Brazilian government, in a revival of its historical traditions, must emphasize that the current technological gap endured by countries of the Global South refers to a kind of neocolonialism. The decolonization of human rights related to access to essential medicines and pharmaceutical products is a path that developing nations must follow[38].

Final considerations

In the post-pandemic context, Brazil has a crucial role to play in advocating for increased access to medicines and health technologies in international forums. Furthermore, promoting policies that encourage research and development of technologies adapted to local conditions is fundamental to ensuring that health rights are effectively respected.

Despite the progress, Brazil faces significant challenges in the decolonization of healthcare. The growing influence of private interests in the health sector, SUS underfunding, and the difficulties in ensuring the equitable distribution of medicines represent obstacles that must be overcome.

However, opportunities are also countless. Strengthening research and development networks in the Global South, collaboration between countries, and the exchange of knowledge are promising avenues to ensure that lessons learned during the pandemic are transformed into concrete actions that benefit populations.

The decolonization of Health in the Global South, especially in the post-pandemic context, requires a renewed commitment to equity, social justice, and the human right to health. With its rich experience in Public Health policies and local medicine production, Brazil stands in a privileged position to spearhead this transformation. By promoting health autonomy and ensuring equitable access to health technologies, the country can not only improve the health conditions of its population but also contribute to building a fairer and sustainable Global Health system. This mission is not only a national responsibility but an opportunity to redefine the role of the Global South in the international health arena.

Data availability statement

The data sources adopted in the research are indicated in the article's body.

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