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Between law and management: paths to sustainable access to medicines in Brazil

Entre o Direito e a Gestão: Caminhos para a Sustentabilidade do Acesso a Medicamentos no Brasil

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ABSTRACT

Access to medicines is a sensitive dimension of the right to health in Brazil and a structural challenge for the Unified Health System (SUS). Despite a comprehensive regulatory framework, supply failures, regional inequalities, and budgetary pressures threaten the system's sustainability, supporting the hypothesis that the progress achieved depends on strengthening inter-federative governance and digital health. This article aims to critically analyze the current scenario of access to medicines in Brazil and to discuss paths for its improvement. Methodologically, it is a theoretical essay grounded in a narrative review of the scientific literature and normative acts on pharmaceutical policies, equity, and judicialization. The analysis indicates that addressing gaps in technology incorporation requires converting the guidelines of STF Theme 1234 into a catalyst for inter-institutional dialogue and for the technical strengthening of the Technical Support Centers of the Judiciary (NatJus). Furthermore, although dispensations under the Popular Pharmacy Program, now free of charge, are centrally authorized by the Ministry of Health, they remain poorly integrated into the local pharmaceutical management and care routines of the SUS, a gap that becomes more evident in light of the ongoing national transition to the e-SUS Pharmaceutical Assistance system (e-SUS AF) and its progressive integration with the National Health Data Network (RNDS). It is concluded that Brazil has made substantial progress in the institutionalization of Pharmaceutical Assistance, but the effective achievement of comprehensiveness and equity requires overcoming the fragmentation of management through the convergence of legal rationality, digital transformation, and continuous equity monitoring.

Keywords: Pharmaceutical services; Unified health system; Health's judicialization; Digital health; Access to essential medicines and health technologies.

RESUMO

O acesso a medicamentos é uma dimensão sensível do direito à saúde no Brasil e um desafio estrutural para o Sistema Único de Saúde (SUS). Apesar de um amplo arcabouço normativo, falhas de abastecimento, desigualdades regionais e pressões orçamentárias ameaçam a sustentabilidade do sistema, sustentando a hipótese de que os avanços alcançados dependem do fortalecimento da governança interfederativa e da saúde digital. Este artigo tem como objetivo analisar criticamente o cenário atual do acesso a medicamentos no Brasil e discutir caminhos para sua qualificação. Metodologicamente, trata-se de um ensaio teórico fundamentado em revisão narrativa da literatura científica e de atos normativos sobre políticas farmacêuticas, equidade e judicialização. A análise indica que o enfrentamento das lacunas de incorporação tecnológica exige converter as diretrizes do Tema 1234 do STF em catalisador de diálogo interinstitucional e de fortalecimento técnico dos Núcleos de Apoio Técnico do Poder Judiciário (NatJus). Ademais, embora as dispensações do Programa Farmácia Popular, hoje gratuitas, sejam autorizadas centralmente pelo Ministério da Saúde, elas permanecem pouco integradas à gestão farmacêutica local e

às rotinas de cuidado do SUS, lacuna que se torna mais evidente diante da transição nacional em curso para o sistema e-SUS Assistência Farmacêutica (e-SUS AF) e de sua integração progressiva à Rede Nacional de Dados em Saúde (RNDS). Conclui-se que o Brasil avançou expressivamente na institucionalização da Assistência Farmacêutica, mas a efetivação da integralidade e da equidade exige superar a fragmentação da gestão por meio da convergência entre racionalidade jurídica, transformação digital e monitoramento contínuo da equidade.

Palavras-chave: Assistência farmacêutica; Sistema único de saúde; Judicialização da saúde; Saúde digital; Acesso a medicamentos essenciais e tecnologias em saúde.

INTRODUCTION

The 1988 Federal Constitution enshrined health as a right of all and a duty of the State, the foundation upon which the Unified Health System (SUS) and its principles of universality, comprehensiveness, and equity were built, later regulated by Law No. 8,080/1990 (Brasil, 1988; Brasil, 1990). Within this framework, access to medicines occupies a central position, as it articulates clinical, economic, legal, and social dimensions of health care. Without the timely and adequate availability of medicines, the comprehensiveness of care becomes an incomplete promise, and the population's trust in the public system is weakened.

Over the past three decades, Brazil has built a comprehensive pharmaceutical policy framework, with the National Medicines Policy of 1998 (Brasil, 1998), the National Pharmaceutical Assistance Policy of 2004 (Brasil, 2004), the creation of the National Commission for the Incorporation of Technologies in the SUS (Conitec) in 2011 through Law No. 12,401/2011 (Brasil, 2011), and the expansion of programs such as the Popular Pharmacy Program of Brazil, created in the same year as the National Pharmaceutical Assistance Policy (Yamauti et al., 2015). In parallel, public funding for pharmaceutical assistance and the acquisition of medicines grew significantly throughout the 2000s, following the expansion of national policies and programs for access to medicines (Moraes et al., 2022; Vieira; Zucchi, 2013).

However, this regulatory framework has not fully translated into equitable and timely access. Population-based studies show that a significant portion of the population still cannot obtain all prescribed medicines from the SUS, with this difficulty disproportionately affecting lower-income and less-educated groups, the North and Northeast regions, and the rural population (Boing et al., 2022). Added to this is the significant growth in the judicialization of health, a phenomenon that, while legitimate from the perspective of individual rights, strains collective equity and the budgetary sustainability of the system (Chieffi; Barata, 2009).

Given this scenario, access to medicines in Brazil has advanced significantly in recent decades, but its future sustainability will depend on the capacity of the SUS to strengthen the governance of Pharmaceutical Assistance, reduce territorial inequalities, improve technology incorporation, and integrate evidence-based decision-making mechanisms. It is therefore necessary not only to diagnose the current state of Brazilian pharmaceutical policy, but also to discuss the institutional conditions for its future sustainability. Accordingly, this article aims to critically analyze the current scenario of access to medicines in Brazil and to discuss paths for its improvement, examining how territorial inequalities, Health Technology Assessment, judicialization, complementary access strategies, and digital transformation interact with inter-federative governance and the sustainability of Pharmaceutical

Assistance. To this end, the text is organized into five discussion axes: the diagnosis of access inequalities; the role of Health Technology Assessment and Clinical Protocols and Therapeutic Guidelines; the judicialization of health; complementary access strategies, with emphasis on the Popular Pharmacy Program; and governance as a structural condition for consolidating access, concluding with a prospective agenda of priorities for the coming years.

METHODS

This is a theoretical essay grounded in a narrative review of the national and international scientific literature and of normative acts on access to medicines, pharmaceutical policy, the judicialization of health, Health Technology Assessment, and complementary access strategies. The review was guided by the following question: which institutional conditions shape the sustainability and equity of access to medicines in the SUS, and how do territorial inequalities, Health Technology Assessment, judicialization, complementary access strategies, and digital transformation interact with inter-federative governance? Accordingly, the search strategy described below does not aim at the exhaustiveness of a systematic review, and the corpus analyzed should be read as an interpretive, rather than comprehensive, sample of the available literature and normative production.

Searches were conducted between January and June 2026 in PubMed, Scopus, SciELO, and LILACS, using controlled descriptors and free-text terms in Portuguese and English. The general search structure, adapted to the syntax of each database, combined terms related to the object of study ("access to medicines" OR "acesso a medicamentos" OR "pharmaceutical assistance" OR "assistência farmacêutica" OR "pharmaceutical policy" OR "política farmacêutica") AND the Brazilian context ("Brazil" OR "Brasil" OR "SUS") AND the terms of each analytical axis: (1) "inequalities" OR "equity" OR "desigualdades"; (2) "health technology assessment" OR "avaliação de tecnologias em saúde" OR "Conitec"; (3) "judicialization of health" OR "judicialização da saúde"; (4) "Popular Pharmacy" OR "Farmácia Popular"; and (5) "pharmaceutical governance" OR "governança" OR "information systems" OR "sistemas de informação". Studies were eligible if they were published from 2016 onwards, written in Portuguese, Spanish, or English, and directly related to at least one of the five axes; studies published before 2016 were retained only when they were seminal or provided a historical baseline for the topic (for example, pioneering studies on judicialization and on the creation of the Popular Pharmacy Program). Eligible document types were empirical studies of national or regional scope conducted in Brazil and literature reviews; conference abstracts, editorials, and studies unrelated to the Brazilian pharmaceutical policy context were excluded. Titles and abstracts were screened by the author against these criteria, the full texts of potentially eligible studies were read, and, within each axis, studies were retained when they provided empirical evidence or conceptual contributions directly used in the argument. Normative and jurisprudential documents (Federal Constitution, laws, Ministry of Health ordinances, STF rulings, and Conitec reports) were identified through direct consultation of the official portals of the Presidency of the Republic, the Ministry of Health, the STF, and Conitec, given that this material is not systematically indexed in bibliographic databases; they were selected when they defined or modified the institutional framework of each axis. Reports from international organizations (World Health Organization and Organisation for Economic Co-operation and Development) were included by purposive selection, as a comparative and conceptual reference, and not as a result of the database searches. The final corpus cited comprises 20 scientific articles, ten normative, jurisprudential, and official government documents, and four reports

from international organizations. Throughout the Results and Discussion, statements directly supported by the reviewed literature are distinguished from the author's interpretations and from prospective recommendations, signaled respectively by expressions such as "previous studies have shown" or "the literature indicates"; "taken together, these findings suggest" or "in our interpretation"; and "from a policy perspective, we propose".

RESULTS AND DISCUSSION

The literature and normative documents reviewed indicate that the consolidation of access to medicines in Brazil is going through a critical transition period, in which logistical bottlenecks and budgetary pressures call for coordinated responses based on inter-federative governance and digital health. The analysis was organized into five structural axes that connect the organizational reality of the public system with its legal and healthcare implications. Box 1, at the end of this section, summarizes the main challenges, current situation, consequences, and prospective paths identified in each axis.

The Paradox of Decentralization and Territorial Inequalities in the SUS

Before turning to the evidence on inequalities, it is useful to make explicit the main channels through which medicines currently reach patients in Brazil: pharmaceutical services provided directly by the SUS through municipal and state pharmacy networks, organized into the Basic, Strategic, and Specialized Components of Pharmaceutical Assistance; the Popular Pharmacy Program, which dispenses medicines free of charge through accredited private pharmacies; direct out-of-pocket purchase in the private market; and, increasingly, judicial demands for medicines not otherwise available through these channels. These channels are not mutually exclusive, and their relative importance for a given patient depends heavily on income, place of residence, and disease profile, which are precisely the sources of stratification discussed below.

Previous studies have shown, based on data from the 2013 and 2019 National Health Surveys, that although most of the Brazilian population eventually obtains the medicines they need through different sources, complete access to prescribed treatments exclusively through the SUS remains relatively low, and the proportion of people who obtain all medicines is higher among higher-income strata, even when considering only access through the public system (Boing et al., 2022). This finding is consistent with earlier studies that had already pointed to significant regional inequalities, with worse relative performance in the North and Northeast regions, and with research focused on specific populations, such as women with chronic diseases, in which access also proved to be socially stratified (Katrein et al., 2015).

In our interpretation, these patterns point to a structural paradox: the SUS is simultaneously the main mechanism for reducing health inequalities and a system whose own operation reproduces, on a smaller scale, the country's socioeconomic inequalities. The literature indicates that the most cited explanatory factors are recurring availability failures in primary health care units, the fragmentation of logistical management among federative entities, and the insufficient integration of health information systems, factors that compromise the predictability of supply and, consequently, the continuity of treatment (Mendes et al., 2014). Previous studies have also shown that access to high-cost medicines, linked to the Specialized Component of Pharmaceutical Assistance, presents organizational inequalities between states, related to management capacity, available healthcare structure, and the supply of specialized services, and that the development of municipal pharmaceutical management is associated with social and technical factors, such as the structure of services and the insertion of Pharmaceutical Assistance in municipal

health management (Rover et al., 2021; Mendes et al., 2024). Municipalities with fewer pharmacists, weaker storage infrastructure, or less developed information systems therefore tend to face greater difficulty in programming, purchasing, and distributing medicines, which directly affects the availability experienced by residents of these territories. From a policy perspective, we propose monitoring instruments that go beyond purely logistical indicators and incorporate measures of territorial and social equity.

Taken together, the evidence reviewed suggests that inequalities in access stem less from the absence of national policies than from differences in institutional capacity among federative entities: although national policies establish a common institutional framework, their implementation depends on heterogeneous state and municipal capacities (Rover et al., 2021; Mendes et al., 2024). The current challenge for Pharmaceutical Assistance is therefore predominantly organizational and managerial, and inter-federative governance becomes central to understanding why normative advances do not translate uniformly into equitable access. It becomes a barrier when responsibilities for financing, purchasing, and dispensing are shared without coordination mechanisms that compensate for these differences in capacity. In short, the proposed explanatory chain runs from socioeconomic inequality to uneven institutional capacity, from there to uneven service provision and management, and only then to differentiated possibilities of accessing medicines across territories and population groups.

Health Technology Assessment and Clinical Protocols: Evidence-Based Decision Making

The literature describes the creation of Conitec in 2011 as a milestone in the institutionalization of Health Technology Assessment (HTA) in Brazil, establishing a formal administrative process for the incorporation, exclusion, or alteration of technologies in the SUS, based on evidence of efficacy, safety, and cost-effectiveness (Vidal; Capucho; Floriano, 2021). The consolidation of the Brazilian Health Technology Assessment Network (REBRATS) expanded the country's technical capacity to support incorporation decisions, while Clinical Protocols and Therapeutic Guidelines became central instruments for standardizing clinical practice and ensuring the rational use of incorporated medicines.

However, significant challenges persist. A recent analysis of Conitec reports published between 2023 and 2025 showed that a significant portion of non-incorporations stems from the high estimated budgetary impact, and not exclusively from insufficient scientific evidence, highlighting the ongoing tension between therapeutic innovation and the financial sustainability of the system (Alves, 2026). This scenario is aggravated by the accelerated growth of advanced therapies and high-cost biological drugs, which put pressure on the public budget and increase competition for scarce resources among different health priorities, a phenomenon also observed in other universal public health systems, where budgetary sustainability has become a structuring axis of technology incorporation policies (OECD, 2021).

The literature indicates that the expansion of social participation in technology incorporation processes, as well as the strengthening of the articulation between Conitec and the Judiciary, is a necessary path to improve the quality of incorporation decisions and reduce the gap between technical recommendations and judicial demands (Souza et al., 2024). In our interpretation, more transparent, timely, and dialogical incorporation decisions tend to strengthen the legitimacy of the decision-making process and reduce, even if partially, judicial pressure on the system.

Taken together, these findings suggest that the technical maturity of Brazilian HTA already allows for technically qualified decisions, but that the political legitimacy of these decisions is still fragile, insofar as budgetary criteria are not always communicated

transparently to society and the Judiciary. The challenge, therefore, ceases to be exclusively methodological and becomes also communicational and institutional: qualifying HTA in Brazil means both improving methodologies and making the relationship between scientific evidence and allocative decision-making more transparent and dialogical, in line with international recommendations on the use of health intervention and technology assessment in support of universal health coverage (World Health Organization, 2014).

The Judicialization of Health: Between Individual Rights and Collective Equity

The judicialization of access to medicines has become a structural phenomenon within the SUS over the last two decades. Pioneering studies in the first decade of the 2000s identified a pattern of legal demands marked by requests for medicines not included in official lists, frequently prescribed by physicians in the private sector and filed by a public with greater access to information and legal assistance, characteristics that call into question the principle of equity (Chieffi; Barata, 2009; Borges; Ugá, 2010).

More recent research, however, shows a more heterogeneous picture. An analysis of lawsuits in Rio Grande do Norte identified a predominance of female plaintiffs, residing in the interior of the state and supported, in more than half of the cases, by public legal assistance, which suggests a broadening of the socioeconomic profile of litigants compared to earlier studies, without, however, eliminating the individualized and fragmented nature of judicial decisions (Oliveira et al., 2021). In the same study, only two of the ten most frequently litigated medicines were included in the National List of Essential Medicines (RENAME) at the time of the analysis. This result is compatible with the hypothesis that part of litigation reflects gaps in incorporation and in the updating of clinical protocols, and not only unequal access to legal and healthcare resources among litigants; however, a single state-level study does not allow generalization to the national profile of judicialization, and absence from RENAME does not by itself demonstrate an incorporation gap. Previous studies on the decision-making process in drug litigation had already indicated the need for technical qualification of individual decisions as a way to reduce allocative distortions (Figueiredo; Osorio-De-Castro; Pepe, 2013).

In this context of seeking legal and administrative rationalization, the judgment of Theme 1234 by the Federal Supreme Court (STF) stands out. Ruling on Extraordinary Appeal No. 1,366,243/SC, the STF established that lawsuits concerning medicines registered with the Brazilian Health Regulatory Agency (ANVISA) but not incorporated into the SUS, including oncology medicines, fall under the jurisdiction of the Federal Courts, with the Union as defendant, when the annual cost of the specific treatment, calculated according to the Government Maximum Sale Price (PMVG) published by the Drug Market Regulation Chamber (CMED), is equal to or greater than 210 minimum wages; in these cases, the costs are borne entirely by the Union. Below this threshold, lawsuits remain under the jurisdiction of the State Courts, and the Union reimburses the other federative entities, through fund-to-fund transfers, for 65% of the expenses arising from rulings in cases valued between 7 and 210 minimum wages; for oncology medicines, reimbursement is 80%, a percentage maintained for lawsuits filed after June 10, 2024 until it is changed by agreement in the Tripartite Intermanagerial Commission (CIT) endorsed by the STF. The thesis also requires, under penalty of nullity of the judicial decision, that judges analyze the administrative act of non-incorporation, restricting judicial review to the legality and regularity of Conitec's decision-making process, without substituting the administrative technical merit, and places on the plaintiff the burden of demonstrating, based on high-level scientific

evidence, the safety and efficacy of the medicine and the absence of an incorporated therapeutic substitute in the SUS (Brasil, 2024). From a public management perspective, in our interpretation, Theme 1234 should not be understood merely as a procedural rule for the distribution of competences, but also as a reflection of the inadequacies of Pharmaceutical Assistance policy: by tying federal responsibility to a financial threshold, the decision may be read as a signal that the problem of non-incorporation of high-cost technologies transcends the local sphere and demands coordinated solutions at the national level (Floriano et al., 2023).

From a policy perspective, we propose closer institutional ties between the Judiciary, SUS managers, and Conitec, with the consolidation of the Technical Support Centers of the Judiciary (NatJus) to provide magistrates with evidence-based technical support, aligning judicial decisions with federal regulatory parameters, a strategy also identified in a synthesis of evidence on responses to the judicialization of health in Brazil (Floriano et al., 2023).

Taken together, the evidence on judicialization and the recent jurisprudential arrangements suggest a possible shift in interpretation, which should nonetheless be read cautiously given the limited empirical base. Rather than being explained predominantly by unequal access to legal resources among more privileged litigants, a hypothesis that prevailed in studies from the 2000s, some recent evidence is compatible with the view that gaps in technology incorporation and in the updating of clinical protocols are an important, though not exclusive, driver of judicialization. It should be noted that a medicine's absence from RENAME does not by itself demonstrate an incorporation gap, since non-incorporation may also result from insufficient evidence, a negative HTA recommendation, an unfavorable cost-effectiveness ratio, or off-label indications. In our interpretation, this repositions part of judicialization not as a pathology to be combated exclusively through legal means, but also as a potential diagnostic signal of the shortcomings of pharmaceutical policy, which reinforces the importance of the articulation between HTA, the Judiciary, and inter-federative governance.

Complementary Access Strategies: the Popular Pharmacy Program

Created in 2004, the Popular Pharmacy Program of Brazil was initially implemented through the Own Network (Rede Própria), composed of public and philanthropic pharmacy units. In 2006, the program was expanded through the "Aqui Tem Farmácia Popular" modality, based on agreements with private pharmacies and drugstores, under which, over time, a list of medicines dispensed free of charge and a list under a co-payment regime coexisted (Yamauti et al., 2015).

The Own Network was discontinued in 2017, and the program came to operate exclusively through accredited private pharmacies (Alencar et al., 2018). The co-payment modality, which characterized an important phase of the program's trajectory, was extinguished by Ordinance GM/MS No. 6,613 of February 13, 2025, which established free provision for the entire list of medicines and health products of the program (Brasil, 2025). The current configuration therefore combines public financing with free dispensing through accredited private pharmacies, and the program's operational rules were recently updated (Brasil, 2026b). Previous studies have shown that, historically, the program significantly expanded access to treatments for chronic non-communicable diseases, such as hypertension and diabetes, reducing geographical barriers and out-of-pocket health expenditures (Inocencio; De Vivo, 2011), although a recent scoping review also identified inequalities in access related to the regional distribution of the accredited network (Martins et al., 2024). Under the former co-payment model, studies of the program's contractual incentives identified structural risks, such as mismatches between market prices and federal

reimbursement values that could create indirect access barriers (Silva; Balbinotto Neto, 2022). With universal free provision, the policy challenge has shifted: rather than financial co-participation by users, the main contemporary issues concern the equitable geographical coverage of the accredited network, supply continuity, the adequacy of the reference values paid to private pharmacies, and regulatory oversight of the accredited network.

Political analyses of the program's trajectory warned that the replacement of a directly public network by provision mediated exclusively by private pharmacies could represent a conceptual shift from access to medicines as a right toward a logic of market-mediated access, with potential negative impacts on the comprehensiveness of Pharmaceutical Assistance (Alencar et al., 2018). These analyses predate the extinction of co-payment. In our interpretation, free provision removed the direct financial barrier for users, but the program's dependence on the geographical distribution of the private network and on the attractiveness of reimbursement values for pharmacies keeps part of that concern relevant. A second issue concerns information integration. Each dispensation under the program is authorized electronically and in real time by the Ministry of Health, based on the identification of the user and the prescription, which provides the federal level with detailed transactional data for payment, monitoring, and auditing purposes (Brasil, 2026b); these records are also made available to users through the Meu SUS Digital application (Brasil, 2026c). However, the literature and normative documents reviewed do not describe the routine use of these records by the SUS pharmacy network, whose stock and dispensing management relies on separate systems, nor their systematic incorporation into primary care clinical workflows. At the same time, the SUS is undergoing an ongoing, still-incomplete transition from the Hórus System to the e-SUS Pharmaceutical Assistance system (e-SUS AF), a platform designed to integrate stock and dispensing management with the National Health Data Network (RNDS) and e-SUS Primary Care, several of whose integration components remain under implementation or pilot testing (Brasil, 2026a). Taken together, these findings suggest an information gap between the two main public channels of access to medicines: dispensations obtained through the program are recorded centrally but are not integrated into local pharmaceutical management and care routines, which hinders longitudinal pharmacotherapeutic follow-up, the identification of therapeutic duplication across channels, and the local planning of public purchases. From a policy perspective, we propose that integrating program dispensations into local pharmaceutical management and clinical care routines, through the RNDS and e-SUS AF, be treated as a priority of the digital transformation agenda. This debate is especially relevant in light of population aging and the growing burden of chronic diseases, which make the sustainability and predictability of complementary access strategies increasingly necessary, in line with international analyses of the long-term challenges of pharmaceutical spending (OECD, 2018).

Taken together, these findings suggest that the program's success in expanding access to medicines for chronic diseases coexists with an unresolved tension: depending on its future institutional trajectory, the program could either consolidate itself as a public access policy, complementary to and informationally integrated with the SUS, or remain a parallel channel whose logics of inclusion and exclusion are shaped by the distribution and incentives of the private network. In our interpretation, this ambiguity makes the twenty years of the "Aqui Tem Farmácia Popular" modality, completed in 2026, an opportune milestone for an in-depth evaluation of the program's institutional design.

Inter-federative Governance as a Cross-Cutting Theme for Achieving Effective Access

The challenges discussed in the previous sections converge on a common point: the fragility of inter-federative governance in Pharmaceutical Assistance. Decentralization, an organizational principle of the SUS enshrined in Law No. 8,080/1990 (Brasil, 1990), requires permanent coordination mechanisms between the Union, states, and municipalities; previous studies have shown that, in their absence, inequalities in management capacity translate into inequalities in access to medicines (Rover et al., 2021; Mendes et al., 2024). From a policy perspective, we propose strengthening the Tripartite and Bipartite Intermanagerial Commissions (CIT and CIB), coupled with inter-federative pacts that consider the different management capacities of federative entities, in order to reduce asymmetries and ensure that access does not depend on the administrative structure of municipalities or states in isolation.

The consolidation of this governance also requires the improvement of management tools. In our interpretation, digital transformation and the integration of information systems represent concrete opportunities to enhance access monitoring, identify logistical bottlenecks in real time, and support more timely and evidence-based decisions. Interoperability between logistical, clinical, and litigation data would expand the system's capacity to monitor the effectiveness of available treatments, identify medication-related problems, and strengthen clinical pharmaceutical services, promoting rational use and improving the quality of pharmacotherapeutic care. These advances depend on sustained investments in technological infrastructure and professional training, in line with international recommendations for equitable access to essential medicines (World Health Organization, 2004). Furthermore, integrating clinical and logistical data creates the conditions for moving toward the production of value in health, understood here as care organized around outcomes that matter to patients relative to the resources invested, rather than around the volume of services delivered or medicines dispensed.

From a policy perspective, we propose that the same logic of integration, coordination, and transparency guide the improvement of HTA. Strengthening the role of Conitec, through faster, more predictable, and transparent processes, with clear communication of the technical and budgetary criteria underpinning its recommendations, tends to confer greater legitimacy on incorporation decisions. At the same time, closer institutional ties between Conitec and the Judiciary, with the consolidation of NatJus as permanent instances of technical advice, can help reduce the gap between scientific evidence, administrative decisions, and judicial demands, allowing judicialization to be read as one of the indicators of the gaps that still exist in the system.

Thus, in our interpretation, inter-federative governance emerges not as just another component of Pharmaceutical Assistance, but as the transversal axis capable of articulating the normative, technical, technological, and care-related advances built up over the last decades. The effective realization of access to medicines within the SUS will depend, to a large extent, on the capacity to integrate these elements into a coordinated strategy guided by equity, transparency, and the use of evidence. From this perspective, inter-federative governance is a structuring condition for transforming institutional advances into effective and sustainable access to medicines for the entire population, understood not only as a matter of fiscal sustainability, but as a condition for realizing the right to health.

Box 1 – Main challenges, current situation, consequences, and prospective paths for sustainable access to medicines in Brazil, based on the literature and normative framework reviewed (1988–2026)

Challenge	Current situation	Consequence	Future path
Inequalities in access	Unequal access across regions and income levels, even through the SUS.	Reproduction of social inequalities by the public system itself.	Territorial monitoring and improvement of decentralized management
Health Technology Assessment	Technically qualified process, but budgetary criteria are not always communicated transparently.	The gap between technical decisions and the social/judicial perception of legitimacy.	Greater transparency, social participation, and dialogue with the Judiciary.
Rationalizing the Judicialization of Health	STF Theme 1234 assigned to the Federal Courts, with costs borne by the Union, lawsuits concerning medicines registered with ANVISA but not incorporated into the SUS whose annual treatment cost is equal to or greater than 210 minimum wages (PMVG/CMED); below this threshold, the State Courts retain jurisdiction, with partial reimbursement by the Union; judicial review of Conitec's administrative act is mandatory.	Greater federal financial responsibility for high-cost non-incorporated medicines and judicial decisions increasingly tied to the review of HTA decisions.	Strengthening inter-institutional dialogue and consolidating NatJus to provide magistrates with information based on scientific evidence and HTA criteria.
Information Integration of the Popular Pharmacy Program	Free dispensing through accredited private pharmacies since 2025 (Ordinance GM/MS No. 6,613/2025), with real-time electronic authorization by the Ministry of Health and records available to users in Meu SUS Digital, but not integrated into local pharmaceutical management and care routines.	Information gap between access channels, hindering longitudinal pharmacotherapeutic follow-up, the identification of therapeutic duplication, and local procurement planning.	Integration of program dispensations into local pharmaceutical management and clinical care routines (RNDS, e-SUS AF); periodic evaluation of the geographical coverage of the accredited network and of reference values paid to pharmacies.
Governance	Decentralization without sufficient inter-federative coordination	Heterogeneity of management capacity among federative entities	Strengthening the Intermanagerial Commissions (CIT and CIB) and information systems
Modernization of AF Information Systems	Ongoing, still-incomplete transition from the Hórus System to the e-SUS Pharmaceutical Assistance platform (e-SUS AF), with integration components under implementation or pilot testing (Ordinance GM/MS No. 11,585/2026).	Operational challenges during the transition across municipalities, with the prospect of reducing the historical fragmentation of stock and dispensing data.	Completion of e-SUS AF implementation and its integration with the RNDS and e-SUS Primary Care, enabling epidemiological monitoring and continuous evaluation of equity in access to treatments.

Study limitations

This study has limitations that should be considered when interpreting its findings. As a theoretical essay grounded in a narrative review, it was not designed for a systematic or exhaustive mapping of literature. The search was restricted to four databases and three languages, screening was performed by a single reviewer, and normative documents were identified through purposive consultation of official portals; relevant grey literature and very recent normative acts may therefore not have been captured. The selection of studies and normative documents involved an interpretive synthesis structured around five analytical axes, which may introduce selection bias. Furthermore, the empirical evidence mobilized across the axes varies in geographical scope, methodological design, and temporal coverage, which limits the possibility of establishing causal relationships or generalizing specific findings to the entire Brazilian population. These limitations reinforce the interpretive, rather than causal, nature of the present analysis.

CONCLUSION

This analysis indicates that access to medicines in Brazil has expanded substantially in institutional terms, but its effective realization remains unevenly distributed across territories and social groups. Over the past three decades, Brazil has built a comprehensive regulatory framework for pharmaceutical policy, with substantial progress in institutionalizing access to medicines through the SUS, Conitec, and the Popular Pharmacy Program. However, significant regional and socioeconomic inequalities persist, along with recurrent availability failures, a growing tension between technology incorporation and budgetary sustainability, and a pattern of judicialization that, while legitimate, may signal gaps in public policy. The main contribution of this essay to the debate on management and the right to health in the SUS is to show that three dimensions frequently analyzed separately, namely the sustainability of medicines policies, the management capacity of the system, and the guarantee of access as a right, are interdependent: fiscal sustainability without management capacity tends to reproduce territorial inequalities, and the recognition of access as a right without coordinated governance tends to be channeled through individual litigation. Thus, we return to the central thesis of this article: the progress already achieved does not, in itself, guarantee its future sustainability, which will depend on the capacity of the SUS to strengthen the governance of Pharmaceutical Assistance, reduce territorial inequalities, improve technology incorporation, and integrate evidence-based decision-making mechanisms.

From a policy perspective, we propose overcoming the predominantly logistical logic that still guides much of the management of Pharmaceutical Assistance, moving towards a model guided by clinical governance, care integration, and the production of value in health, as discussed in Section 3.5. In the legal dimension, this implies converting the guidelines of STF Theme 1234 into a catalyst for permanent inter-institutional dialogue, strengthening the technical opinions of NatJus, and aligning judicial decisions with federative sustainability. On the technological level, it requires completing the implementation of e-SUS AF and its integration with the RNDS and integrating Popular Pharmacy Program dispensations into local pharmaceutical management and care routines. In our view, the convergence between legal rationality, digital transformation, and the strengthening of inter-federative coordination is central to designing complementary access strategies that are equitable and less exposed to the incentives of the private market.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

DECLARATION ON THE USE OF ARTIFICIAL INTELLIGENCE

The author declares that he used Claude (Anthropic) exclusively for language revision and verification of references, during the manuscript revision stage. After using the tool, all content was reviewed, verified, and validated by the author.

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