Review

Antimicrobial Use and Resistance in Brazil: An Overview of Regulatory Measures, Consumption Patterns, and Stewardship Challenges

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Abstract

Antimicrobial resistance is one of the most important global public health challenges, particularly in low and middle-income countries where antimicrobial consumption remains high. In Brazil, several regulatory measures have been implemented over the last decade to improve control over antimicrobial use, including restrictions on over-the-counter sales and strengthened monitoring of antimicrobial dispensing. This article provides an overview of antimicrobial use, regulatory measures, and resistance-related challenges in Brazil. Evidence from epidemiological studies, antimicrobial dispensing records, national monitoring initiatives coordinated by the Brazilian Health Regulatory Agency (ANVISA), the National System for Controlled Product Management (SNGPC), and antimicrobial resistance surveillance efforts, including GLASS/BR-GLASS and national reports on healthcare-associated infections and resistance, was considered to identify trends in antimicrobial consumption, regional variation, and the influence of public health policies. Available data indicate that antibiotics such as amoxicillin, azithromycin, and cephalosporins remain among the most commonly dispensed antimicrobials in community settings. Regulatory measures have strengthened prescription requirements, improved oversight of antimicrobial dispensing, and reduced unrestricted non-prescription sales, although their broader impact on inappropriate clinical use and resistance trends remains heterogeneous across settings. Hospital settings continue to show high rates of broad-spectrum antimicrobial use, especially in intensive care units. The COVID-19 pandemic also influenced antimicrobial use patterns, particularly by increasing the consumption of macrolides despite limited evidence of bacterial coinfection. Continued efforts involving prescriber education, antimicrobial stewardship programs, microbiological diagnostics, and integrated surveillance are essential to support more rational antimicrobial use and help address antimicrobial resistance in Brazil.

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1. Introduction

Antimicrobial resistance (AMR) is one of the most important threats to global public health, compromising the effective treatment of bacterial infections and increasing morbidity, mortality, length of hospital stay, and healthcare costs [1,2]. The inappropriate use of antimicrobial agents in human medicine, agriculture, and veterinary practices has accelerated the emergence and dissemination of resistant microorganisms [2]. Recent global estimates indicate that bacterial AMR was associated with approximately 4.71 million deaths worldwide in 2021. With projections suggesting a substantial increase by 2050 if current trends continue, reinforcing the urgent need for coordinated action across clinical care, surveillance, and public health policy [3].

In low- and middle-income countries, rising antimicrobial consumption has been driven by population growth, broader access to medicines, and uneven regulatory enforcement, expanded healthcare access, and insufficient regulation of pharmaceutical markets [4]. Brazil has historically exhibited high levels of antimicrobial consumption across both hospital and community settings, as demonstrated by national surveillance and dispensing data [5,6]. The availability of antibiotics without prescription in community pharmacies for many years contributed to widespread self-medication and inappropriate antimicrobial use [7,8]. these findings highlight marked regional, sex, and age-related differences in antimicrobial use and reinforce the importance of continuous monitoring of community consumption patterns [6].

Recognizing these challenges, Brazil progressively strengthened its regulatory and surveillance framework for antimicrobial control. Resolution RDC n° 20/2011 represented an important milestone by requiring medical prescriptions for antimicrobial dispensing and reinforcing control over community pharmacy sales [9]. This framework was later consolidated and updated by RDC n° 471/2021, which established criteria for the prescription, dispensing, control, packaging, and labeling of prescription antimicrobials [10]. In parallel, the National System for Controlled Products Management (SNGPC), regulated by RDC n° 22/2014, became a central mechanism for monitoring antimicrobial dispensing in the retail sector [11].

Broader national strategies were subsequently reinforced through the National Action Plan for the Prevention and Control of Antimicrobial Resistance under the One Health approach (PAN-BR) and, more recently, through the PAN-Serviços de Saúde 2023–2027 [12,13]. Which expanded actions related to infection prevention, antimicrobial stewardship, and resistance control in healthcare services. Brazil has also strengthened antimicrobial resistance surveillance through participation in the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) and the BR-GLASS initiative [14,15].

Despite these advances, antimicrobial resistance remains a major public health concern in Brazil. Earlier Brazilian studies, including Rossi (2011) [16], were important in documenting the emergence of clinically relevant resistance patterns; however, more recent official surveillance documents provide a more appropriate basis for describing the current national scenario [14,15]. Recent Brazilian reports continue to characterize antimicrobial resistance as a major threat, particularly in healthcare-associated infections, and highlight the relevance of clinically important pathogens such as *Escherichia coli, Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa*, and the *Acinetobacter baumannii* complex. These reports also emphasize the growing importance of carbapenem resistance and carbapenemase-producing organisms in Brazil, especially in hospital settings [14,15]. The patterns of antimicrobial use vary considerably across Brazilian regions due to socioeconomic disparities, differences in healthcare infrastructure, and variations in prescribing practices, reinforcing the need to connect dispensing data, microbiological evidence, and health-service surveillance more effectively [5,6].

Pharmacoepidemiology plays a crucial role in understanding antimicrobial consumption patterns and evaluating how regulatory measures and surveillance strategies may influence antimicrobial use [17]. By analyzing dispensing data, surveillance systems, and epidemiological

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trends, it becomes possible to identify critical gaps in antimicrobial stewardship and guide public health interventions. This article provides an overview of the pharmacoepidemiological profile of antimicrobial use in Brazil, with emphasis on consumption patterns, regulatory measures, surveillance initiatives, and current public health challenges related to antimicrobial resistance in the Brazilian healthcare context.

2. Pharmacoepidemiology of Antimicrobial Use in Brazil

Antimicrobial consumption in Brazil has increased steadily over the past two decades, reflecting global trends observed in developing countries [4]. National pharmaceutical sales data indicate that antibiotics remain among the most widely consumed therapeutic classes in both community and hospital settings [5,6].

Studies analyzing data from the Brazilian National System for Controlled Products (SNGPC) reported more than 500 million antimicrobial sales or dispensing records between 2014 and 2021, with beta-lactams representing the largest proportion of dispensed agents [6]. Amoxicillin, azithromycin, cephalexin, and ciprofloxacin consistently appear among the most frequently dispensed antimicrobials in outpatient settings [6].

Table 1. Major studies evaluating antimicrobial consumption trends in Brazil.

Study	Study Period	Data Source	Key Findings
Lopes et al. (2024)	2014–2019	National pharmaceutical sales database	Antibiotic consumption increased by approximately 30% during the study period, with higher use observed in the Southeast region of Brazil.
Barbosa et al. (2025)	2014–2021	SNGPC database	More than 532 million antimicrobial sales/dispensing records were recorded; amoxicillin, azithromycin, and cephalexin were the most frequently dispensed antimicrobials.
Del Fiol et al. (2022)	2019-2021	National pharmacy dispensing records	A substantial increase in azithromycin consumption occurred during the COVID-19 pandemic.
Mattos et al. (2017)	2008–2012	Regional pharmacy sales data	Implementation of RDC No. 20/2011 significantly reduced antibiotic sales in community pharmacies.

Regional differences in antimicrobial consumption have also been documented. The Southeast and Northeast regions account for the largest proportion of antibiotic sales records reflecting higher population density and greater access to healthcare services [5,6]. However, patterns of antibiotic use vary widely across regions, influenced by socioeconomic factors, healthcare infrastructure, and access to medical care.

Age and gender differences have also been reported in antimicrobial use patterns. Women showed higher frequencies of antimicrobial dispensing records than men, particularly in the adult population, which may be associated with higher rates of urinary tract infections and healthcare utilization. Additionally, elderly patients often receive multiple antimicrobials prescriptions due to increased comorbidity burden and susceptibility to infections [6].

Hospital settings demonstrate even higher antimicrobial consumption rates, particularly in intensive care units (ICUs). Broad-spectrum antimicrobials such as carbapenems, glycopeptides, and third-generation cephalosporins are frequently used in critically ill patients, contributing to increased selection pressure for resistant pathogens [18].

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These pharmacoepidemiological patterns highlight the need for continuous monitoring of antimicrobial consumption and improved stewardship strategies to optimize antibiotic prescribing practices in Brazil.

3. Regulatory Policies and Antimicrobial Control in Brazil

Regulatory interventions have played a crucial role in controlling antimicrobial consumption in Brazil. Prior to 2010, antibiotics were widely available without prescription in community pharmacies, contributing to inappropriate self-medication and excessive antimicrobial use [7,8].

The implementation of RDC n°. 20/2011 represented a major regulatory milestone, requiring medical prescriptions for antimicrobial dispensing and mandating pharmacy record systems for monitoring antibiotic sales [9]. Studies evaluating the impact of this regulation reported a significant reduction in antibiotic sales shortly after its implementation, particularly in community pharmacies [8].

Subsequent regulatory updates further strengthened antimicrobial control policies in Brazil. In addition to RDC n° 20/2011, ANVISA consolidated the regulatory framework through RDC n° 471/2021, which established updated criteria for the prescription, dispensing, control, packaging, and labeling of prescription antimicrobials [10].

In parallel, the National System for Controlled Products Management (SNGPC), regulated by RDC n° 22/2014, became a central mechanism for monitoring antimicrobial dispensing in the retail sector and for supporting pharmacoepidemiological analyses of outpatient antimicrobial use [11]. These measures demonstrate the progressive strengthening of antimicrobial control policies in Brazil and the expansion of regulatory oversight beyond prescription requirements alone [9–11].

Table 2. Main Regulatory Policies for Antimicrobial Control in Brazil.

Regulation / Policy	Year	Responsible Institution	Main Objective
RDC n° 20	2011	ANVISA	prescription requirement and dispensing control.
RDC n° 22	2014	ANVISA	SNGPC monitoring system
National Action Plan for Antimicrobial Resistance (PAN-BR)	2018	Ministry of Health	One Health national action plan to combat antimicrobial resistance.
RDC n° 471	2021	ANVISA	updated antimicrobial prescription and dispensing framework in Brazil.
PAN-Serviços de Saúde	2023	ANVISA	Infection prevention, stewardship and resistance control in healthcare services

In addition to regulatory policies, Brazil adopted the National Action Plan for the Prevention and Control of Antimicrobial Resistance under the One Health framework (PAN-BR), which integrated strategies across human health, veterinary medicine, agriculture, and environmental sectors [12]. More recently, the PAN-Serviços de Saúde 2023–2027 expanded this agenda within healthcare services by reinforcing actions related to infection prevention and control, microbiological support, and antimicrobial stewardship in hospitals and other health facilities [13].

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Brazil has also strengthened antimicrobial resistance surveillance through participation in the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) and through the BR-GLASS initiative, which contributed to the standardization of national resistance monitoring and the generation of more recent data on clinically relevant resistant pathogens in the country [14,15].

Despite these regulatory advances, challenges remain in ensuring consistent implementation and adherence to antimicrobial control policies across the country. Differences in healthcare infrastructure, laboratory capacity, and regulatory enforcement contribute to variability in compliance among regions and healthcare institutions [13–15].

4. Impact of the COVID-19 Pandemic on Antimicrobial Consumption

The COVID-19 pandemic substantially affected antimicrobial use patterns worldwide, including in Brazil [19,21]. Although bacterial coinfection was relatively uncommon among patients with COVID-19, empirical antibiotic therapy was frequently prescribed during the early stages of the pandemic because of diagnostic uncertainty and concerns about secondary bacterial infection [19,20].

In Brazil, this period was marked by an important increase in outpatient azithromycin (macrolide) dispensing, particularly during 2020 and 2021, despite limited evidence supporting its effectiveness against viral infection [21]. This shift in consumption patterns raised concerns regarding the potential amplification of selection pressure for resistant microorganisms.

In hospital settings, broad-spectrum antimicrobials such as cephalosporins and fluoroquinolones were also widely used in patients with COVID-19, especially among critically ill individuals and those admitted to intensive care units [18,22].

Table 3. Most Frequently Dispensed Antimicrobials in Brazil.

Antibiotic	Pharmacological Class	Common outpatient use contexts	Public Health Concerns
Amoxicillin	Beta-lactam	Respiratory infections	Overuse in outpatient care
Azithromycin	Macrolide	Respiratory infections	Increased use during COVID-19
Ciprofloxacin	Fluoroquinolone	Urinary tract infections	Rising resistance among Gram-negative pathogens
Cephalexin	Cephalosporin	Skin and soft tissue infections	Community prescribing pressure

At the same time, pandemic-related pressures disrupted routine antimicrobial stewardship and surveillance activities in many healthcare institutions, reducing the capacity for antimicrobial monitoring and audit during this period [23]. Together, these findings suggest that the pandemic did not simply increase antimicrobial use, but altered prescribing and dispensing patterns in ways that may have important implications for antimicrobial resistance in Brazil [19,21,23]

5. Antimicrobial Stewardship and Public Health Strategies

Antimicrobial stewardship programs (ASPs) are among the most effective strategies for optimizing antimicrobial use and reducing antimicrobial resistance [24–26]. These programs typically involve multidisciplinary teams, including infectious disease physicians, pharmacists, microbiologists, and infection prevention professionals, and aim to improve antimicrobial selection, dosing, route of administration, and duration of therapy [24,25]. Evidence from systematic reviews indicates that stewardship interventions can reduce unnecessary antibiotic use, improve prescribing quality, and contribute to better clinical and organizational outcomes [26].

In Brazil, stewardship initiatives have expanded in recent years, but implementation remains heterogeneous across healthcare settings [13,27]. This heterogeneity is particularly relevant in a context where hospital care, intensive care, and community dispensing all contribute to antimicrobial selection pressure. Accordingly, national strategies should not be limited to hospital-based

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stewardship alone; they should also incorporate microbiological support, infection prevention and control, professional education, and actions aimed at rational antimicrobial use in outpatient and primary care settings [13,24,25].

Educational interventions targeting both healthcare professionals and the general public remain important components of this agenda, especially because regulatory measures can strengthen dispensing control but do not, by themselves, ensure appropriate clinical use [8–10,13].

6. Challenges and Future Perspectives

Despite Despite regulatory advances, important challenges continue to limit effective antimicrobial control in Brazil. A major barrier remains the uneven availability of microbiological diagnostic capacity across healthcare facilities, particularly outside large urban and tertiary referral centers [13–15]. Limited access to timely and reliable microbiological results often leads to the empirical use of broad-spectrum antibiotics and hinders the alignment of prescribing practices with local resistance profiles. In parallel, adherence to antimicrobial stewardship practices remains highly variable across institutions, reflecting disparities in infrastructure, workforce capacity, laboratory support, and institutional commitment [13,27]. These inconsistencies weaken the overall effectiveness of stewardship interventions and contribute to heterogeneous patterns of antimicrobial use across the country. Future progress in Brazil will likely depend less on the introduction of new regulatory frameworks and more on strengthening implementation, enhancing surveillance integration, and expanding service capacity [13–15]. Priority actions should include reinforcing laboratory networks, improving the quality, standardization, and interoperability of antimicrobial consumption and resistance data, and broadening stewardship support across both hospital and outpatient settings. These pragmatic strategies are likely to yield more immediate and sustainable benefits than reliance on highly speculative or resource-intensive technological solutions.

In this context, greater integration between antimicrobial dispensing data, microbiological surveillance systems, infection prevention and control programs, and national monitoring frameworks will be essential to ensure a more coordinated and effective response to antimicrobial resistance in Brazil [13–15]. Recent population-based evidence further underscores the importance of strengthening surveillance at the community level, as substantial antibiotic consumption persists outside hospital settings. This highlights the need for comprehensive and integrated approaches that address antimicrobial use across the full continuum of care, encompassing both outpatient and inpatient environments [28].

7. Conclusions

Antimicrobial use in Brazil remains a significant public health concern, with amoxicillin, azithromycin, and cephalosporins consistently ranking among the most frequently dispensed agents in community settings, despite the implementation of regulatory measures aimed at promoting rational use. Pharmacoepidemiological evidence indicates that these antimicrobials continue to dominate outpatient prescriptions, while hospital settings rely heavily on broad-spectrum agents, reinforcing selective pressure for antimicrobial resistance.

Regulatory policies in Brazil have contributed to strengthening prescription requirements and reducing non-prescription sales; however, their impact on inappropriate clinical use and resistance patterns remains uneven across regions and healthcare settings. Persistent challenges include regional disparities, inconsistent adherence to antimicrobial stewardship programs, and limited access to microbiological diagnostics, which collectively hinder effective antimicrobial management.

The COVID-19 pandemic further exacerbated these challenges by altering antimicrobial use patterns, notably increasing macrolide consumption and reinforcing empirical prescribing practices in both outpatient and hospital care. These findings underscore the vulnerability of antimicrobial stewardship efforts during public health emergencies and highlight the need for more resilient and adaptive strategies.

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Future progress will depend on the expansion and consolidation of antimicrobial stewardship programs, improved access to rapid and accurate diagnostic tools, strengthened infection prevention and control measures, and the implementation of integrated surveillance systems capable of linking antimicrobial consumption data with resistance trends. A coordinated, data-driven, and context-sensitive approach will be essential to mitigate antimicrobial resistance and ensure the sustainable use of antibiotics within the Brazilian healthcare system.

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