White Paper

FIFARMA Patient W.A.I.T. Indicator & Root Causes 2026 — Latin America

Brazil

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Overview of the study

- Improving the availability of innovative medicines in Latin America is a priority for all stakeholders in the healthcare system, especially policymakers, pharmaceutical manufacturers, and patients. Since 2004, the European pharmaceutical industry association (E.F.P.I.A.) has run the Patients W.A.I.T. (Waiting to Access Innovative Therapies) Indicator, enabling stakeholders to measure the availability rate of innovative medicines in 37 European countries. This study has been replicated to understand availability rate in ten Latin American Countries.
- The first EFPIA Patients W.A.I.T. Indicator was developed to understand the "availability" of innovative molecules, by creating a standardized method of comparing access to innovative medicines across distinct healthcare systems, and across years. FIFARMA (Federación Latinoamericana de la Industria Farmacéutica) developed indicators in a similar vein in Colombia (2016), Chile (2018) and Peru (2019), eventually leading to the first official LATAM W.A.I.T. Indicator study conducted in 2022.
- This year's FIFARMA Patient W.A.I.T. survey marks the fifth regional edition and measures the level of availability to innovation across ten Latin American countries, covering >80% of the LATAM population. These countries are Argentina (AR), Brazil (BR), Chile (CL), Colombia (CO), Costa Rica (CR), Dominican Republic (DO), Ecuador (EC), Mexico (MX), Panama (PA), and Peru (PE).
- The following pages feature analyses that benchmark the rate of availability and accessibility of innovative medicines in each of the ten LATAM countries, including analysis on regional availability, and how it has evolved over the period of investigation. This year's study includes 447 innovative molecules globally approved* from 2014-2025, which represent >80% of the globally approved NAS** in this period. These molecules span treatments across five therapeutic areas (TA): oncology, inflammation and immunology, central nervous system, cardiometabolic, and transversally, orphan drugs.
- Local pharmaceutical member associations (eight in total, see appendix for more details of the methodology and associations participating) worked in partnership with FIFARMA and IQVIA to develop the W.A.I.T Indicator study, chiefly in ensuring local market nuance is captured within parameters for the study, as well as local/regional directors of market access from manufacturer organizations who provided and validated the relevant aspects of the dataset.
- Ultimately, the goal of this reoccurring study is to create a lens into what access looks like across LATAM, with a specific eye towards understanding if, why, and in what direction the needle has moved in recent years. The learnings that are outlined are intended to serve as a catalyst for meaningful discussions across stakeholders to improve access to innovative medicines.

*'**Availability**' is used throughout to permit **standardized measurement** across 10 healthcare systems; **availability** represents the local reimbursement of a globally approved innovative medicine*

*Global approval is defined as a molecule that has regulatory approval in the United States of America by the FDA, or in Europe by the EMA
**NAS refers to New Active Substances as defined by the IQVIA Institute, see appendix for definitions and selection criteria

Additional scope and validation

- Access to innovative medicines across LATAM remains highly uneven, with notable disparities between countries and between public and private healthcare sectors. To further understand these disparities, this year's report includes a Root Causes section that adds quantitative and qualitative insight into the structural drivers of access delays and barriers. It focuses on the tension between innovation development and the healthcare systems and processes that govern access at the country level, as well as broad regional trends.
- Key areas explored include:
  - High-level disease burden, innovation, and novel medicine development trends
  - Structural features of healthcare systems that influence access
  - A deeper view into how these dynamics translate into access outcomes and the challenges faced along the route to access
  - Series of core principles to support constructive, multi-stakeholder dialogue and initial ideas to explore and build upon
- Together, the WAIT Indicator and its Root Causes section aim to support more informed, collaborative, and equitable decision-making across LATAM, ultimately contributing toward the multi-faceted effort to improve patient access to innovative medicines across the region.

The study is undertaken with private/public sector validation through multiple sources:

Added in 2026

"It's an optimistic view still, there are more challenges for real-life access than what we see here."

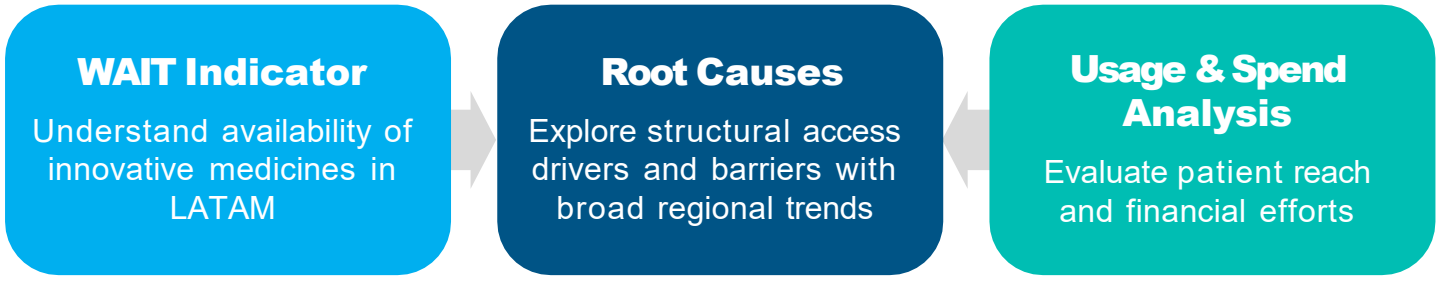
- ex-Minister of Health

Acronyms: NRC: Non-Retail Channels; AFIDRO: Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo; AMIIF: Asociación Mexicana de Industrias de Investigación Farmacéutica; MoH: Medical Officer of Health; TA: Therapeutic Area

Drug usage and spend analysis

- In addition to evaluating access, the 2026 WAIT report incorporates an analysis of drug usage (units) and spending (USD). Leveraging the FIFARMA WAIT Indicator 2025 alongside IQVIA MIDAS and country-level usage and spending datasets, this analysis quantifies not only availability but also extent of investment at a high level to reflect adoption of innovative therapies across LATAM.
- **Data sources and scope*:** Pharmaceutical spending and utilization data are derived from IQVIA MIDAS, and IQVIA country-level NRC databases, representing standardized estimates of market activity adjusted to support international comparability. Data reflects spend estimates based on list prices and projections, not net spending. It quantifies total market activity (all drugs) versus WAIT-specific activity (403 innovative drugs). The analytic period corresponds to MAT October 2025 (Moving Annual Total), a standardized measure representing cumulative sales or volume observed over the preceding twelve months, ensuring alignment with the WAIT reference window. A constant exchange rate (local currency to USD) methodology is applied for most countries; an exception is made for Argentina, where inflationary pressure and controlled exchange rates required a variable exchange rate methodology.
- **Channel segmentation*:** Usage and spending data are segmented between Retail and Non-Retail distribution channels. In many LATAM countries, Non-Retail channels are predominantly financed by government sources, while Retail channels are largely private and funded through patient out-of-pocket expenditures. This segmentation provides a useful proxy for assessing public-sector involvement and drug funding. In Brazil, only the public Non-Retail channel is considered, removing private payer (HMO) activity. Argentina and Colombia may show less direct correlation between channel and financing due to some public/private funding of Retail channels, but financing source separation is not possible in these cases. Data is also segmented into prescription and Over-the-Counter (OTC) drugs, with OTC defined as products that do not require a prescription and may be dispensed directly to consumers.
- **Normalization and context*:** Macroeconomic and demographic indicators were obtained from the WHO Global Health Expenditure Database (GHED) and the World Bank. These enable normalization of pharmaceutical spending across countries, allowing consistent evaluation of metrics such as drug spending per capita and drug spending as a share of GDP, providing essential economic framing for interpreting access and market behavior.

Full scope of the FIFARMA 2026 WAIT report

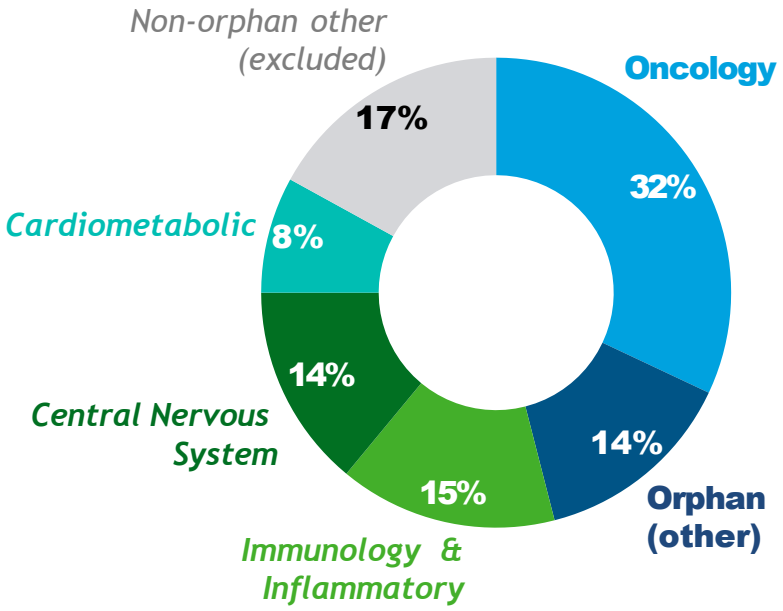


*See appendix for definitions, exchange rates, and indicators
Acronyms: NRC: Non-retail Channels; USD: US dollars; WHO: World Health Organization

Methodological considerations

A total of 447 new active substances approved between 2014-2025 by FDA/EMA across five therapeutic areas are analyzed

Molecule selection by therapeutic area 2026



The selection accounts for >80% of new active substance (NAS) in the study period (see appendix for further detail)

- A total of 447 molecules were selected based on several primary criteria:
  - New active substance
  - FDA or EMA approved between 2014-2025 (with no generics/biosimilars available in LATAM)
  - Global launch in the US, EU, UK, JP, so as to reflect molecules that are most likely to reach the global market, excluding agents that are launched predominantly for a given local market (e.g., local Chinese PDL1 inhibitors)
  - Utilization in treatment of disease (i.e., diagnostics, imaging agents, etc. are excluded)

Additional detail is outlined in the appendix

After initial filtering of NAS molecules based on primary criteria, therapeutic areas were selected in conjunction with FIFARMA to optimize the percentage of NAS included in the study, as well as the representativity and comparability of the molecules. Three main criteria were used:

- Percentage of NAS molecules
- Procurement e.g., TAs with percentages of supranational purchases like infectious disease, were excluded
- Global sales as per IQVIA MIDAS data

Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

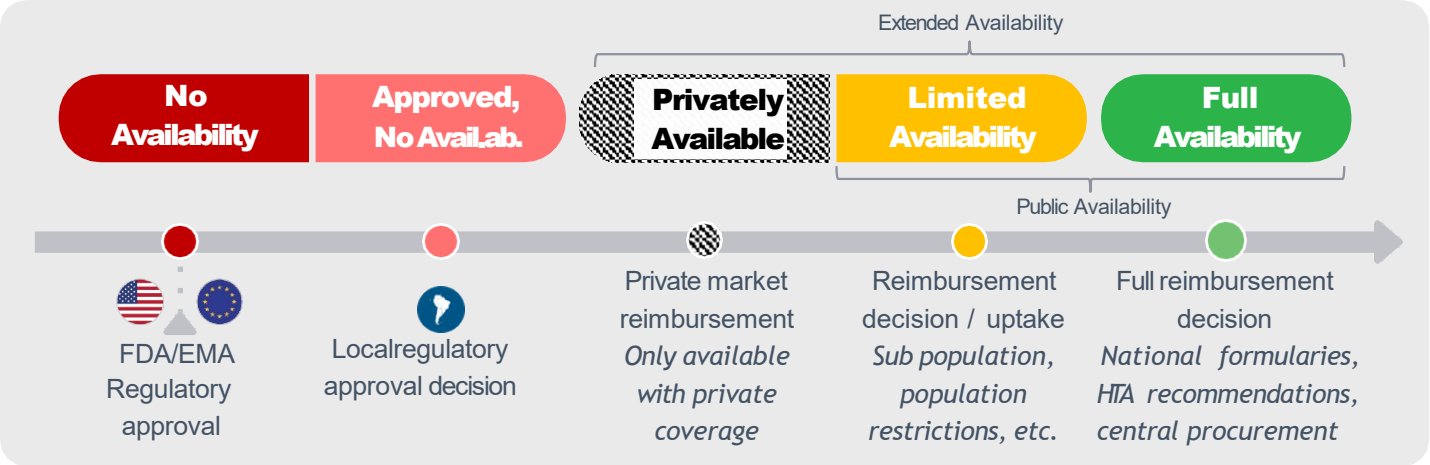
Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; NAS: New Active Substance; JP: Japan; US: United States; EU: European Union; UK: United Kingdom; PDL1: programmed death-ligand 1

Same as full report

Methodological considerations

Results from the study are shown in terms of different levels of availability and compared across countries

Availability definitions



NO AVAILABILITY

Not submitted, or in regulatory evaluation process

Marketing authorization is not granted either because it is in process of regulatory review, or not submitted for local approval

APPROVED, NOT AVAILABLE

Commercially available, but not reimbursed

Molecules that have obtained regulatory approval but are not available through either private or public healthcare; patients typically pay fully out-of-pocket, importations or compassionate use

PRIVATELY AVAILABLE

Reimbursed in the private market only

Medicines available only in the private market but not the public sector, generally limiting the overall patient population that has access

LIMITED AVAILABILITY

Reimbursement but not for a broad population, or uptake

The molecule is available to some extent in the public sector, but not to the broad population either because of discrepancies sub-nationally, or it is limited to specific patient sub-populations, limited number of treatment centers, or has significant volume of legal injunctions / administrative processes that result in a meaningful level of uptake

FULL AVAILABILITY

Broad, national reimbursement

Medicines are fully available at national level for a broad population in both the public and private sectors; full availability is frequently tied to national formulary listing, positive HTA recommendations, and/or central procurement

Extended Availability
Availability in either public or private sector; in a bottoms-up access paradigm, is indicative of the system reach and potential but not broad access

Public availability
Availability either via limited or full availability; indicative of the level of access to the broader national population, and where governments are investing

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; SoC: Standard of care; HTA: Health Technology Assessment

Methodological considerations

The detailed definitions for molecules' availability status in Brazil involved inclusion to public health formularies like the ANS ROL, as well as centralized purchasing

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1]	*Positive CONITEC recommendation with centralized purchasing or subnational guidelines (oncology), Central Purchasing or Subnational Guidelines to be validated using IQVIA sales data and Gov. Tenders*	CONITEC website & subnational guidelines	**Retail:** *Available* **Hospital / Non-Retail:** *Available*
	Limited	*Positive CONITEC recommendation, no centralized purchasing or restricted subnational guidelines* *Subnational / state level uptake considering a minimum and recurrent volume but restrict to the main treatment centers*		
	Only Private[2]	*ANVISA Approval and ANS ROL placement, no positive CONITEC decision, no centralized purchasing* *ANS DUT publishing date is the reference for all products except Oncology IV, which considers ANVISA label update date*	ANVISA Website & ANS ROL	
	Not Available	*ANVISA Approval, no ANS ROL placement, no positive CONITEC decision, no centralized purchasing* *Mostly OOP or Legal Injunctions*		

Note: Approval dates consider ANVISA, not CMED
[1]The date of first contract (central proc.) or subnational uptake considering a minimum and recurrent volume across multiple treatment centers (e.g., States Secretaries, CACONs)
[2]Oncology IV products are automatic reimbursed in the private setting; therefore marketing authorization date is considered as the reference if the reimbursed indication is the first, or the label update date found on ANVISA label change tracking for the specific indication

Note: change vs. 2024 edition to use stricter criteria on uptake/sales thresholds in private / public sectors, in absence of CONITEC decision, to approximate and adjust for use of legal injunction. For limited availability: 10% or more of its total institutional sales in the public sector, and 50% or more of the public sales in the Government Channel. For only privately available: 5% or more of its institutional private sector sales in the HMO channel. If criteria were not met, they were classified as approved, not available.

Methodological considerations

The study focuses on four key metrics that provide a panorama of availability of innovative medicines to patients in LATAM

Metric	Research Question	Content
1 Availability Status	*What is the availability of innovative medicines across LATAM?*	Breakdown of availability across the region, by country and by therapeutic area
2 Time to Availability	*How long does it take for innovative medicines to become available?*	Time from global regulatory approval to local approval, and local availability
3 Availability Over Time	*What is the maturity of innovative medicines available?*	Evolution of availability status by year of global approval
4 Improvement Index	*At what rate does availability for innovative medicines improve?*	Comparison of availability status of molecules from 2025 W.A.I.T. to 2026 W.A.I.T.

Important considerations

1. The study results reflect a snapshot of the **current availability of innovative medicines in LATAM** as of April 2026, and aims to increasingly shed light on its evolution over the years

2. The five therapeutic areas selected allow for an ample view of innovative medicines **with >80% of global, new active substance approvals (NAS)*** captured, and >80% of Latin America's population across ten countries

3. The study considers the **first locally approved indication** for analysis at the molecule level as the most consistent comparison subsequent indications are not captured due to inconsistent availability of data (public or otherwise)

4. **Comparability by countries to the extent possible** is ensured through rigorous validation across a wide group of local and regional experts, and further detail can be found in accompanying country-level reports

*NAS refers to New Active Substances as defined by the IQVIA Institute, see appendix for definitions and selection criteria

Summary of key W.A.I.T. metrics - Brazil

Time to Availability

Represents the length of time from both global and local market authorization until full, limited, or private availability is reached

- Total time to availability is on average 68 months between the countries in scope, which reflects the total of time to marketing authorization and time to reimbursement (full or limited), as of FDA/EMA approval
- The average time to local availability, post-marketing authorization, is 32 months between the countries in scope, approximately 2.7 years

  Brazil's time to approval is lower than the regional average (25 vs 36), but local time to availability is 9 months over the regional average (32 vs 41 months)

- Time to availability varies substantially in Brazil across therapeutic areas, with oncology showing the longest delays taking ~57 months to become locally available compared to ~32 months of the regional availability . Orphan and CNS become available relatively faster.

Patients on average have been waiting over 5.7 years to get access to an innovative medicine in LATAM; meanwhile they may have no means of obtaining it in their country, or face significant out of pocket costs

Availability Status

Represents the degree of availability of an innovative medicine in a given country according to regional definitions

- ~60% of molecules that are globally approved are approved in at least one of the geographies in scope in LATAM; out of these regionally approved, 80% are approved in Brazil
- 40% of molecules with regional public availability (limited or full availability) have public availability in Brazil
- 63% of molecules approved in Brazil have some level of availability; out of this extended availability, only 19% reached full availability status
- The TA with highest extended availability is oncology, with 64% of the locally approved molecules having availability

Availability Over Time

Pinpoints the degree of current availability according to global market authorization year to estimate the maturity of available molecules

- Over 50% of molecules that received global approval from 2014 to 2018 are approved in Brazil; more than half of these are also available
- For therapies approved globally after 2018, both approval and availability rates decline sharply, approval reaching 3% and availability 0% by 2025.

Improvement Index

Outlines the extent that molecules have changed availability status from year to year between reports

- 16% of the molecules in Brazil have improved their availability status over the past year, doubling the regional average of 7%
- Brazil had 22 newly approved molecules this year

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; TA: Therapeutic Area; CNS: Central Nervous System

Summary of Regional Root Causes and Opportunity

Innovation is outpacing system capacity, driving saturation and delays

The volume and complexity of globally approved medicines continue to rise, creating mounting challenges for Brazil's regulatory and healthcare systems, which have not expanded capacity at the same pace. As a result, approval timelines have lengthened, backlog pressures persist, and gaps between global innovation and local access remain evident—despite recent improvements in approval activity.

Low investment constrains institutions, fragments processes, and reduces competitiveness

Persistent underinvestment in Brazil's healthcare system—relative to OECD benchmarks—limits regulatory agility, slows coordination across stakeholders, and increases operational risk for manufacturers. These structural limitations contribute to delays in patient access, variability in decision-making, and reduced ability to consistently absorb more complex therapies into the system.

Access improves when clinical value and system readiness are mutually reinforcing

Regulatory approval alone does not ensure access in Brazil. Timely uptake requires alignment between local evidence generation, diagnostic infrastructure, delivery capabilities, and budgetary frameworks.

When these elements are in place, access becomes more predictable and scalable; when they are not, complexity translates into delays and restricted availability.

Emerging opportunities signal potential for strategic repositioning

Growing pharmaceutical investment, increased adoption of innovative therapies, and gradual system modernization present an opportunity for Brazil to strengthen its position within the global landscape.

Targeted improvements in governance, infrastructure, and cross-sector collaboration could translate into faster access, improved outcomes, and greater readiness for complex innovation.

Sustained progress requires collaboration, integration, and forward planning

Delivering sustainable access in Brazil will depend on coordinated action across regulatory authorities, payers, and providers. Priorities include improving institutional collaboration, integrating new technologies to enhance efficiency and transparency, and strengthening long-term planning to manage rising complexity and demand.

Brazil's access challenges are not due to a lack of innovation, but rather a mismatch between accelerating therapeutic complexity and the system's ability to absorb it. While progress is underway, closing this gap will require sustained investment, structural reforms, and a proactive approach to managing complexity across the healthcare ecosystem.

Acronyms: OECD: Organization for Economic Co-operation and Development

Key regional takeaways

Innovation is accelerating as disease burden evolves

A growing and complex disease burden in Brazil is driving demand for more targeted and advanced therapies, placing additional pressure on the system to adapt to higher-impact innovation

Access challenges are intensifying as innovation grows

As the volume and complexity of innovation increases, Brazil's reliance on fragmented, sequential processes is becoming less effective, contributing to delays and variability in patient access

Structural underinvestment amplifies access inefficiencies

Persistent capacity constraints and relatively low healthcare investment limit Brazil's ability to absorb innovation efficiently, leading to delays, operational misalignment, and uneven access outcomes

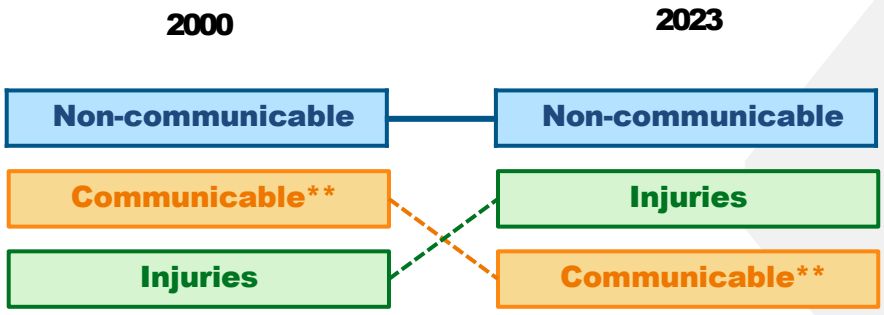
A window for transformation is emerging

Ongoing system evolution, increasing focus on innovation, and gradual investment growth create a timely opportunity to improve access pathways, and enhance readiness for more complex therapies

Non-communicable diseases drive Brazil's health burden

The epidemiological transition toward chronic conditions creates rising demand for innovative medicines and sustainable access pathways

Evolution of Disease Burden in Brazil - DALYs per 100,000



Diseases with the Highest Burden of Morbidity Classified by Level 2, 2023, excl. injuries

1	Cardiovascular disease
2	Neoplasms
3	Mental Disorders
4	Musculoskeletal disorders
5	Other non-communicable
7	Diabetes & CKD
8	Neurological disorders
9	Respiratory infections & TB
11	Digestive disorders
12	Maternal and neonatal

- Brazil's disease burden is driven by non-communicable diseases, confirming a mature epidemiological profile. Brazil has completed the epidemiological transition seen across LATAM, moving decisively away from infectious and early-life conditions toward chronic diseases.
- This shift has critical implications for healthcare systems and pharmaceutical needs. Unlike acute infectious diseases, NCDs are chronic in nature, requiring long-term management. Yet, the decline on the burden from communicable diseases, does not eliminate the dual pressure. The system must be able to support simultaneously infectious disease control while scaling capacity for chronic disease management.
- Many of the most significant advances in NCD treatments have come from innovative medicines (e.g., targeted oncology therapies, novel immunomodulators for inflammatory diseases, advanced treatments for metabolic and cardiovascular conditions) that address unmet needs and improve survival, function, and quality of life; key drivers of productivity.
- As NCD burden rises, so does the demand for access to both new and existing treatments. The therapeutic areas prioritized in this report are those most aligned with the region's disease profile
- However, the growing need for innovative therapies comes at a time when healthcare budgets face competing pressures, regulatory and systems manage increasing submission volumes, and access pathways remain fragmented. The alignment between disease burden and pharmaceutical innovation underscores the urgency of understanding where and why access gaps persist.

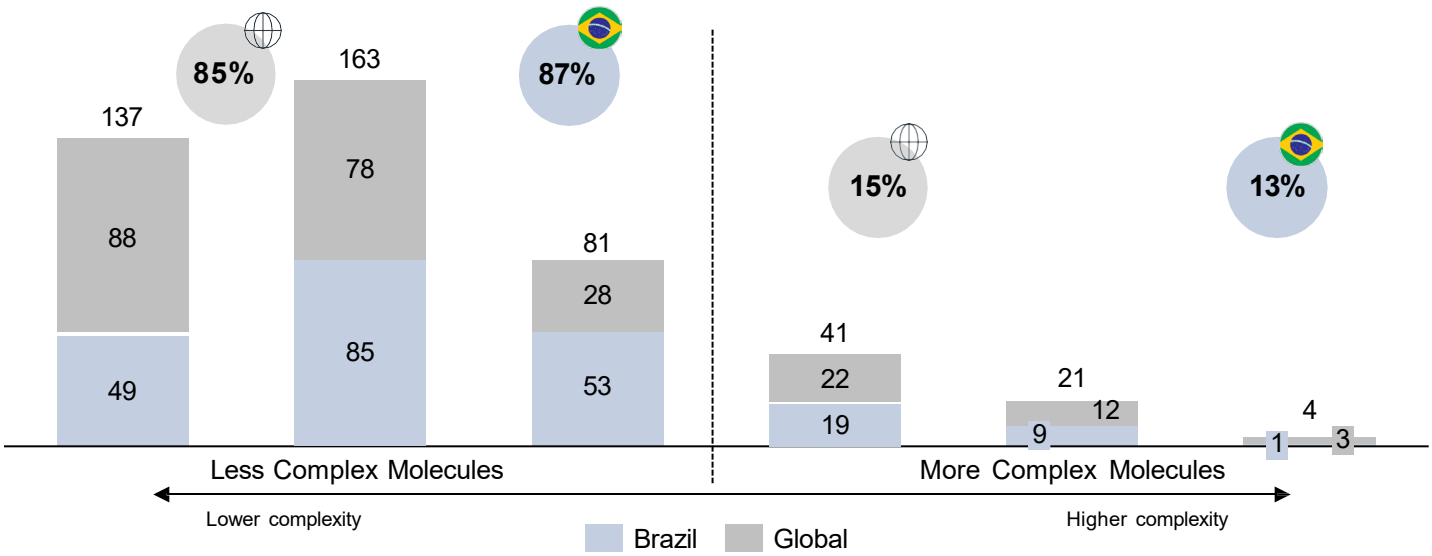
Brazil's disease profile justifies the focus on innovative medicines for NCDs, while the rising burden underscores the importance of timely access to novel therapies

Acronyms: DALYs: disability-adjusted life year; NCD: non-communicable diseases
Sources: Institute for Health Metrics and Evaluation

Complexity introduces additional considerations for systems

Brazil closely follows the LATAM complexity distribution, with ~87% of molecules approved concentrated in lower-complexity segments

Complexity of Global and Local Approved Molecules – WAIT Dataset



- The complexity levels shown reflect a set of factors that place additional strain on health systems and require capabilities or expertise beyond standard regulatory, and implementation processes
    - Biologic or next generation therapies (e.g., nucleotide, RNAi, gene, cell, tissue, immunotherapy): Require specialized manufacturing, handling, and regulatory expertise beyond small-molecule drugs
    - Innovative / first-in-class therapies: Novel mechanisms may lack precedent, requiring deeper reviews and raising uncertainty around long-term safety and real-world efficacy
    - Precision medicine (i.e., diagnostic required): Companion diagnostics require parallel validation and infrastructure deployment before therapies can be administered effectively
    - Orphan population: Often target smaller populations, making large-scale trials difficult and limiting the availability of robust comparators
    - Route of administration: Complex routes (e.g., infusion, intrathecal, one-time delivery) demand specialized infrastructure, trained staff, and coordinated care pathways
- From a system-facing perspective, complexity magnifies capacity constraints. From a technical perspective, complex molecules pose greater challenges in evidence generation and interpretation.
- Brazil's complexity index closely mirrors LATAM, with ~87% of molecules concentrated in the lower-complexity side versus ~13% in higher complexity, indicating a consistent regional distribution pattern

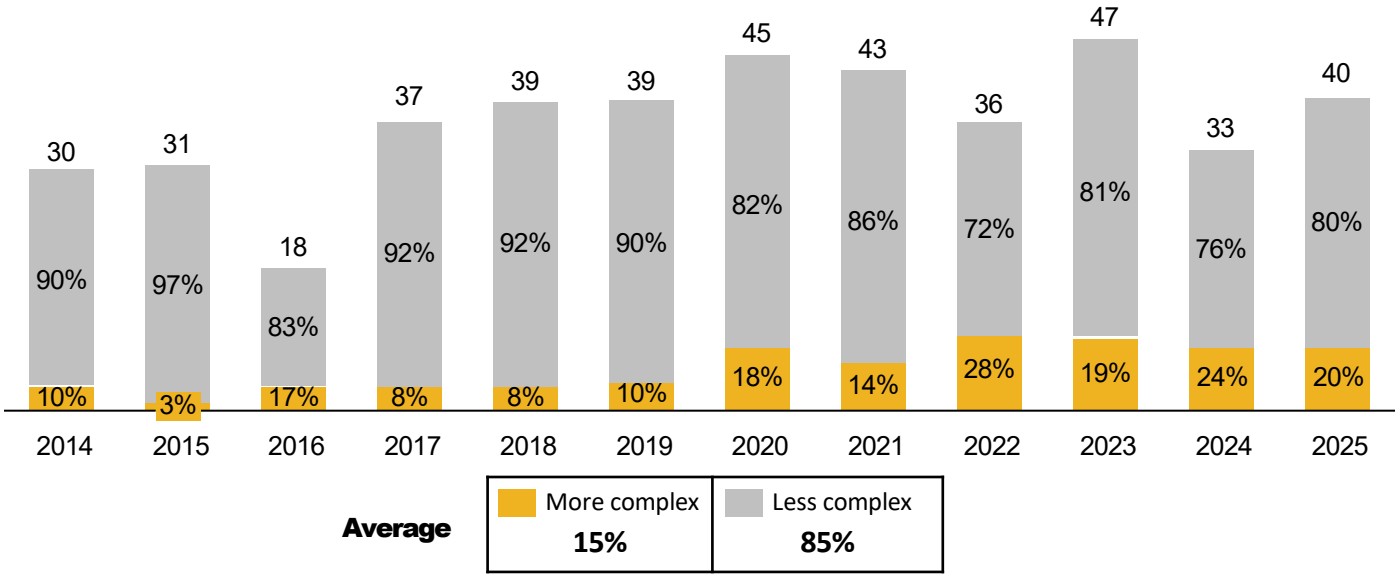
Innovation often introduces technical challenges during evaluation and creates downstream system constraints for regulators, payers, and providers in resource-limited settings

Acronyms: RNAi, RNA interference

Innovation is also becoming more complex

The share of complex therapies among global approvals has doubled since 2014, creating evidence and assessment challenges for regulatory and payer systems

Complexity of Global Approvals - WAIT Dataset



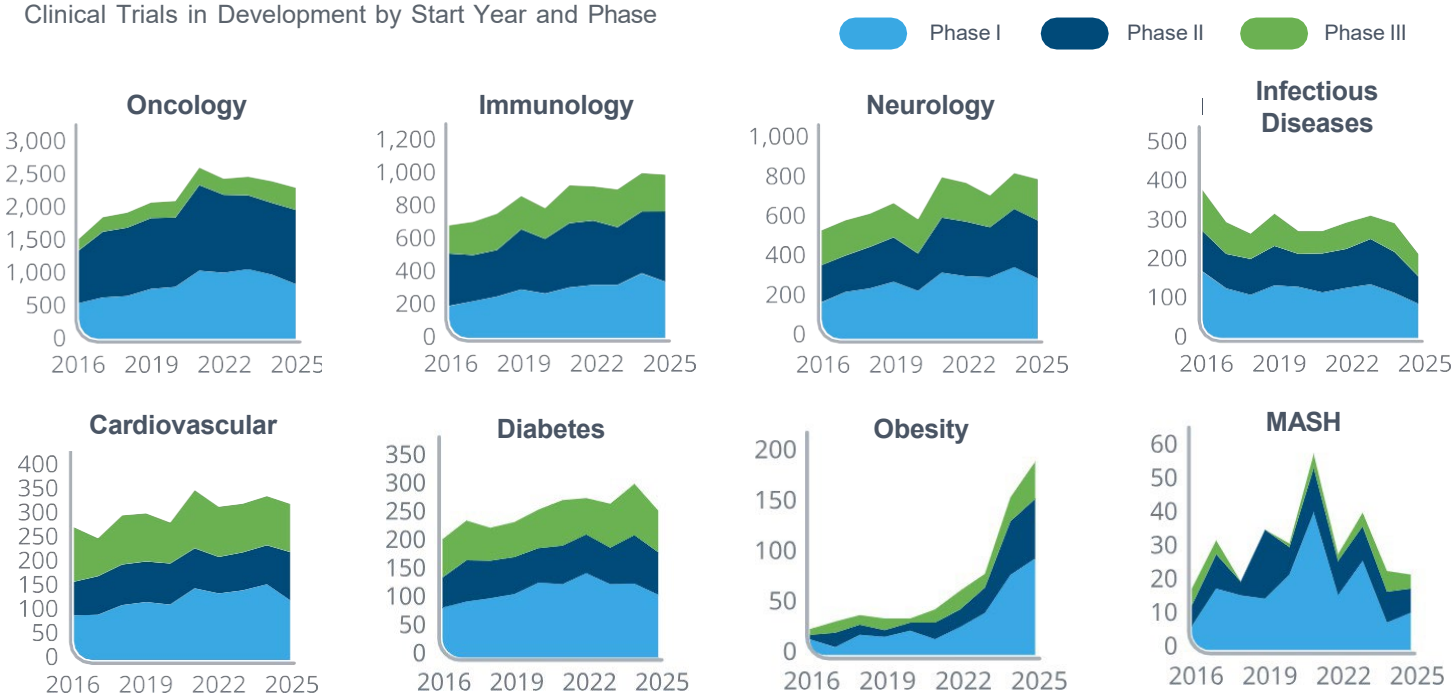
- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)
- While these innovations address persisting unmet needs and offer transformative benefits, they also introduce challenges across the access pathway
- Complex therapies often face inherent difficulties in evidence generation, related to demonstrating efficacy and safety in sufficient patients, over sufficient timeframes, and versus a relevant clinical comparator. Thus, creating additional operational and technical challenges for regulators and payers
- This can increase uncertainty around real-world efficacy, long-term safety, and budget impact, creating tension between the desire to provide early access and the need for robust evidence to inform reimbursement decisions
- For regulators and payers in LATAM, rising complexity compounds existing operational and technical challenges. Regulatory agencies may lack specialized expertise to evaluate novel modalities or interpret endpoints and accelerated approval pathways. Systems often rely on traditional frameworks, which may not adequately address uncertainty, value over time, or broader societal benefits
- As complexity increases without matching capacity-building, timelines risk lengthening, and access decisions may become more conservative or inconsistent across systems. Each additional point on the scale, to some extent, reflects an additional layer of uncertainty to contend with

Rising therapeutic complexity requires evolution of regulatory and frameworks in LATAM as well as renewed focus on technical capacity; without adaptation, complexity becomes an additional barrier

A robust global pipeline signals sustained innovation and mounting system pressure

This continued innovation creates opportunity, but only if access bottlenecks are eased

Clinical Trials in Development by Start Year and Phase



- The global pharmaceutical pipeline remains strong, with a sustained flow of new treatments expected in the short and long term. Ongoing clinical trial activity suggests that the number of innovative medicines reaching regulatory review will continue to grow rather than level off.
- Advances in biologics, precision medicine, gene-based therapies, and novel small molecules are expanding treatment options across a wide range of chronic and complex diseases
- Pipeline concentration closely aligns with LATAM's disease burden. These areas reflect global priorities in addressing cancer, cardiovascular disease, diabetes, obesity, and related metabolic conditions, many of which require long-term treatment and sustained system engagement.
- While this innovation momentum represents progress for patients, the increasing volume of molecules, often with novel mechanisms and higher uncertainty, will further strain already saturated health systems. As more therapies seek regulatory approval, pricing, reimbursement, and delivery within existing capacity constraints, access challenges are expected to intensify, particularly in systems with limited sources, fragmented pathways, and budgetary pressures.
- The continued expansion of the pipeline underscores the importance of ensuring that access frameworks evolve alongside innovation

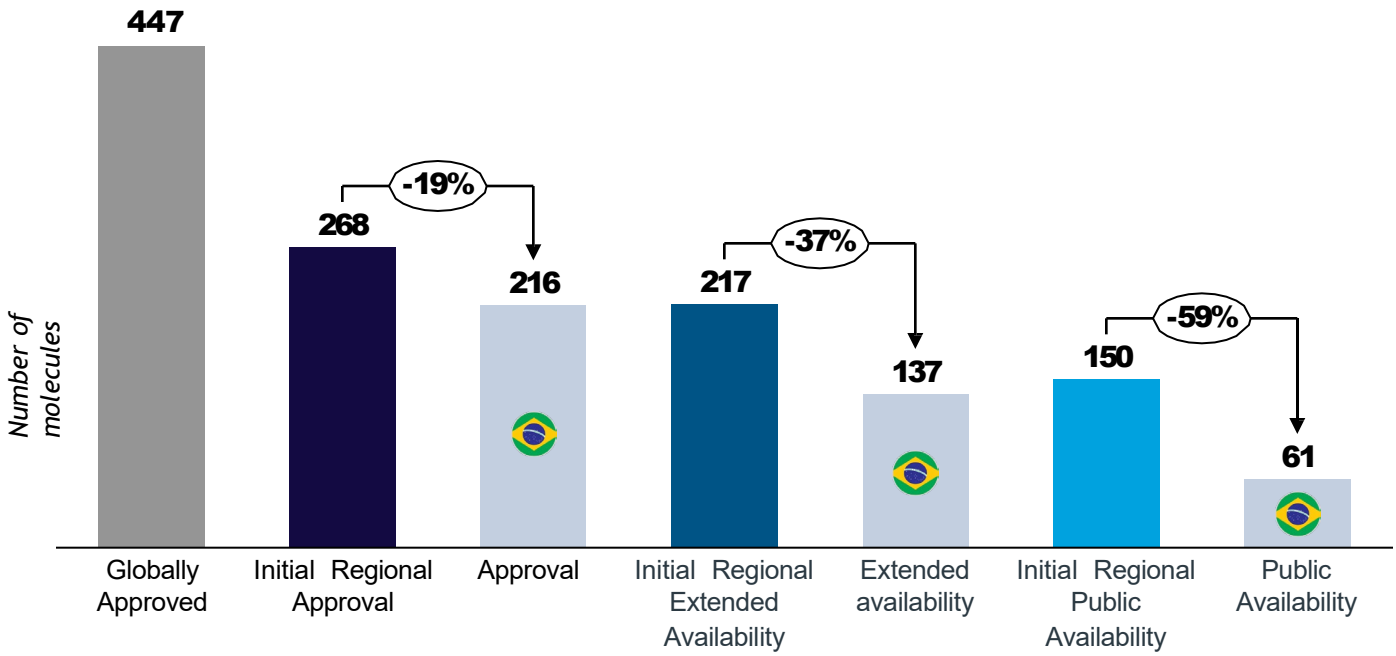
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

Acronyms: MASH: Metabolic dysfunction-associated steatohepatitis
Sources: IQVIA – Global R&D Trends 2026

Brazil's key challenge lies beyond regulatory approval

Initial approvals do not translate into access, with major losses at extended and public availability stages

Breakdown of Initial Regional and Local Availability (2014 - 2025) — Combined



- Initial regional approval and availability represents where a molecule is approved or is available in at least one country in the region, the comparative graph represents Brazil's status
- While Brazil shows strong regional approval ~80% of the regions total, this rate diminishes when considering broader availability, indicating specific constraints
- The conversion from approval to extended availability is limited, with only 137 molecules reaching broader availability, which reflects delays in the processes and systematic adoption
- The most pronounced gap is shown when considering public availability. Where only ~40% of the molecules are available compared to the regional benchmark
- Brazil in general, has a strong regulatory stage and performs well in the early stages of the process, however, it underdelivers on the public availability limiting patient access significantly
- In Brazil, drivers of lower rates of availability include reimbursement, the incorporation to the SUS, procurement and medication distribution.
- A total of 40 molecules are exclusively approved in Brazil, spanning approval statuses from approved not available through to full availability, with no approval observed in any of the other analyzed countries

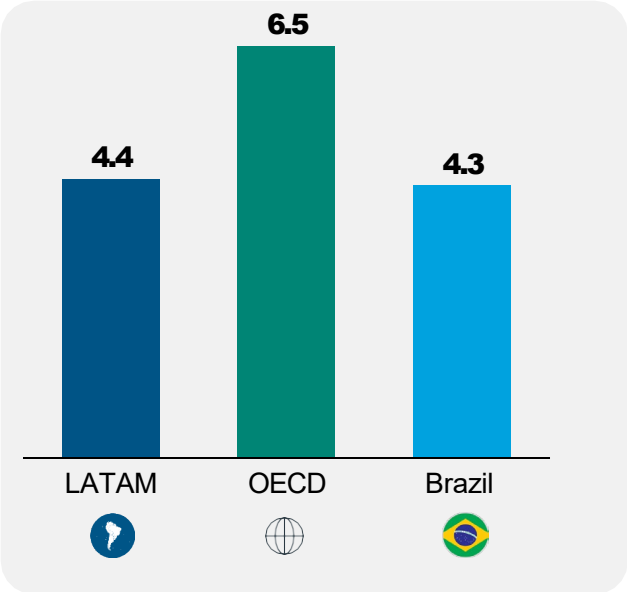
Brazil has the lowest regulatory barrier in the region driven by the ANVISA organizational maturity, as well as the opportunity in OOP and private sector access

Acronyms: SUS: Sistema Único de Saúde; ANVISA: Agência Nacional de Vigilância Sanitária; OOP: out-of-pocket

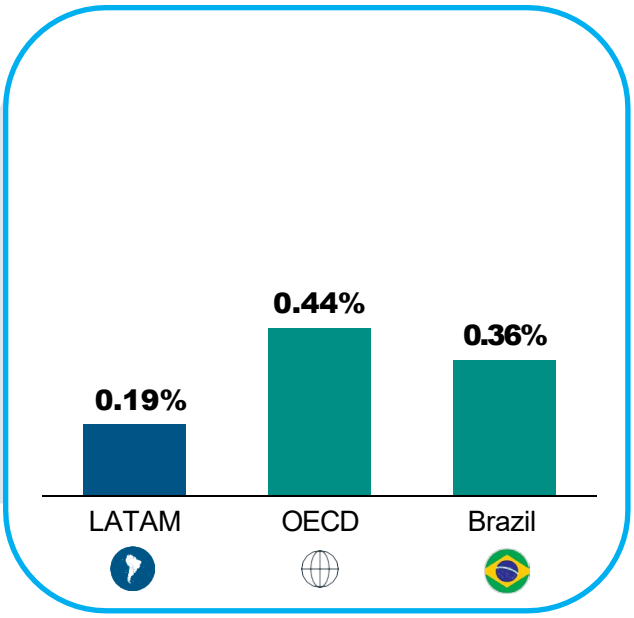
Brazil's health spending is below the OECD target

Public and innovation-specific health spending in Brazil remain below OECD benchmarks, limiting system capacity and slowing the adoption of high-value therapies

Average Public Spending on Health (% of GDP, MAT October 2023-2025)



Average Public Spending on Innovative Treatments (% of GDP, MAT October 2023-2025)



- Public spending in Brazil remains lower than the recommended 6% GDP share by WHO and the OECD average, but remains in line with its LATAM peers, indicating structural underfunding
- Brazil allocates a higher share of GDP (~0.36%) to innovative treatments compared to the regional benchmark (~0.19%); however, the country remains below the OECD benchmark, limiting the system capacity to grant access to innovation
- This two-part constraint results in strict budget allocation and selective prioritization where funding is directed toward maintaining baseline coverage rather than scaling access to new therapies
- The divergence between public and private access is reinforced by the funding limitations and public spending for healthcare and innovation, in Brazil in particular, burdening the population and private sector to a larger extent
- More broadly, budget constraints impact ability to evaluate and invest in key technologies, capacity for pullthrough on reimbursement decisions once made, and in turn the extent industry is able to invest in the sector

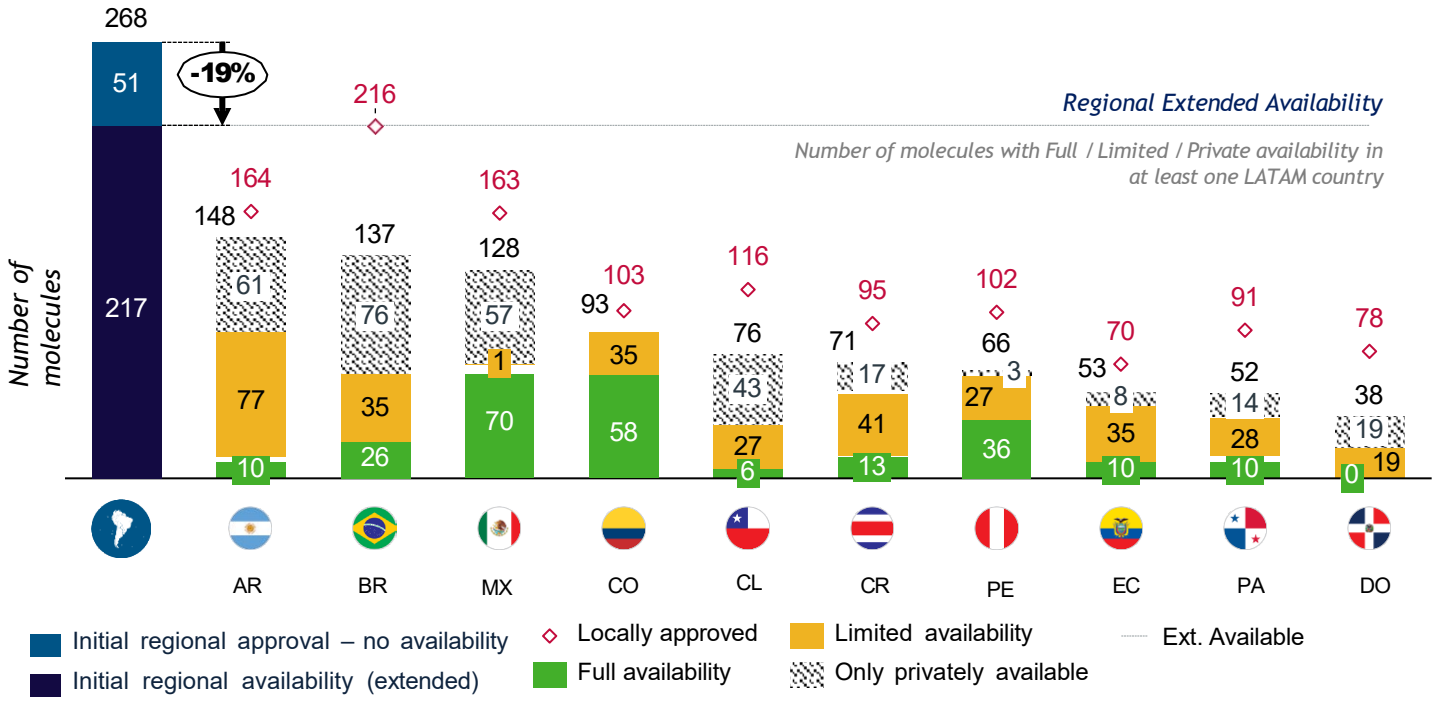
Brazil's relatively stronger investment in innovation within LATAM is insufficient to offset broader system-level funding deficits, underscoring the challenges of integrating new technologies into a system for an immense population sustainably, and the importance of scaling investment in innovation and healthcare alike

Acronyms: GDP: Gross Domestic Product; WHO: World Health Organization; OECD: Organization for Economic Co-operation Development; MAT: Moving Annual Total

Availability rates vary widely by country

Brazil drives initial regional approval, Colombiahas historically been a leader in public availability but Mexico has made strides recently that have resulted in the highest full availability rate

Breakdown of Local Availability (2014 - 2025) — Combined



- There is a gap of 19% between molecules that are approved in at least one country in LATAM, and those that are available
- The trend in approvals vs. availability is not consistent across countries; Brazil, Chile, Dominican Republic and Panama show a more pronounced gap between approvals and availability
- Argentina and Brazil have a disproportionately high contribution from the private sector vs. the public sector, helping bridge the gap between regulatory approvals and availability, but also potentially exacerbating the delay in time to public availability
- Mexico has the highest levels of full availability by a wide margin, followed by Colombia and Peru
- These patterns reflect underlying system characteristics, where high private contribution is typically associated with fragmented systems and limited public budgets, high public availability aligns with centralized structures and more mature processes, and approval–availability gaps point to regulatory capacity being outpaced by HTA and pricing delays driven by process saturation and limited transparency

Patients face different challenges by country: where private coverage is high it affords better access but for a subset of patients, whereas where there is a high rate of public coverage, typically there are fewer molecules available, heightening inequalities

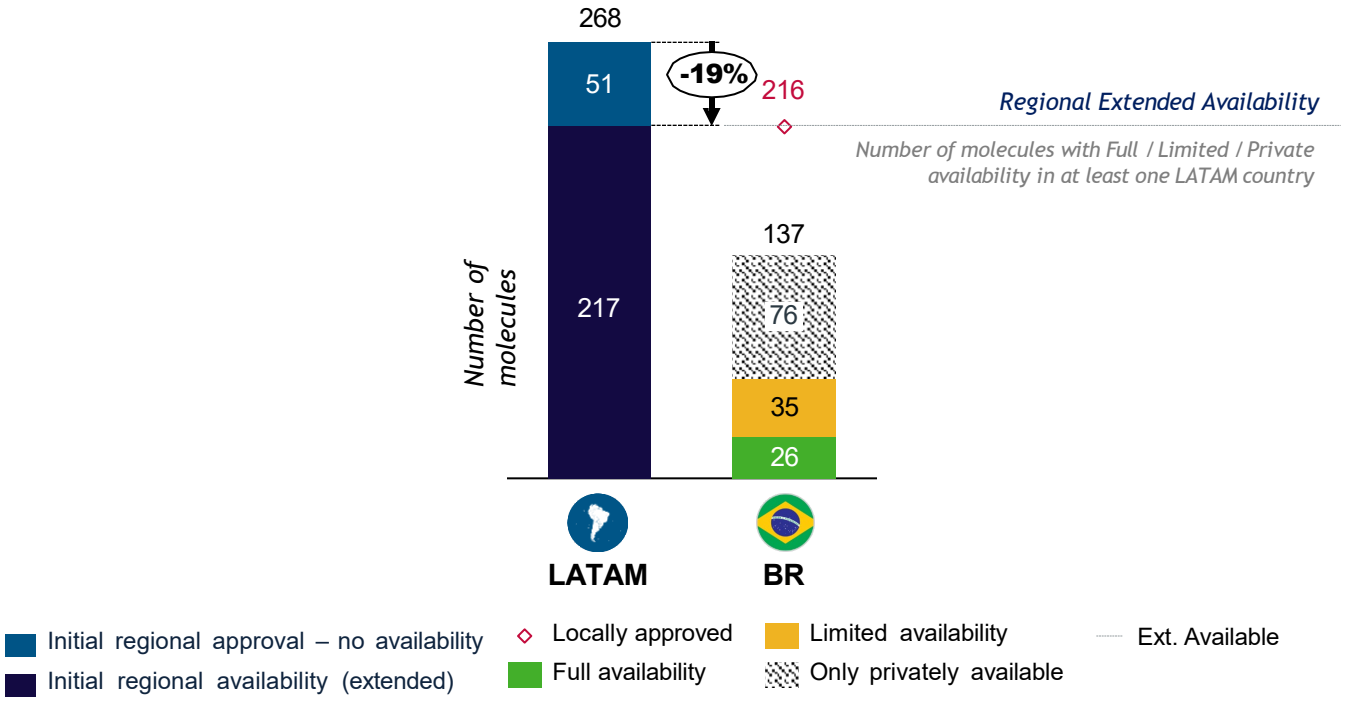
*See appendix for further detail

Acronyms: AR: Argentina; BR: Brazil; MX: Mexico; CO: Colombia; CL: Chile; CR: Costa Rica; PE: Peru; EC: Ecuador; PA: Panama; DO: Dominica n Republic; HTA: Health Technology Assessment

Brazil's availability lags compared to the approval

Strong approval rates contrast with limited public access and heavy reliance on private-sector availability in Brazil

Breakdown of Regional and Local Availability (2014 - 2025) — Combined



- There is an important gap between the approval and the extended availability, where only ~63% of the approved molecules have extended availability
- The composition of availability reveals a structural imbalance, where more than half of available therapies (~55%) are restricted to private-sector access, indicating that innovation is present in the market but not equitably distributed across the population
- Public system uptake remains constrained, as only 26 therapies achieve full availability, demonstrating that SUS faces significant limitations in scaling access to innovative medicines, driven by funding constraints, prioritization, and implementation capacity
- This dynamic results in systematic desynchronization between the innovation entry and general patient access. The country allows by its approval system to attract new therapies but fails to integrate them into the general health system

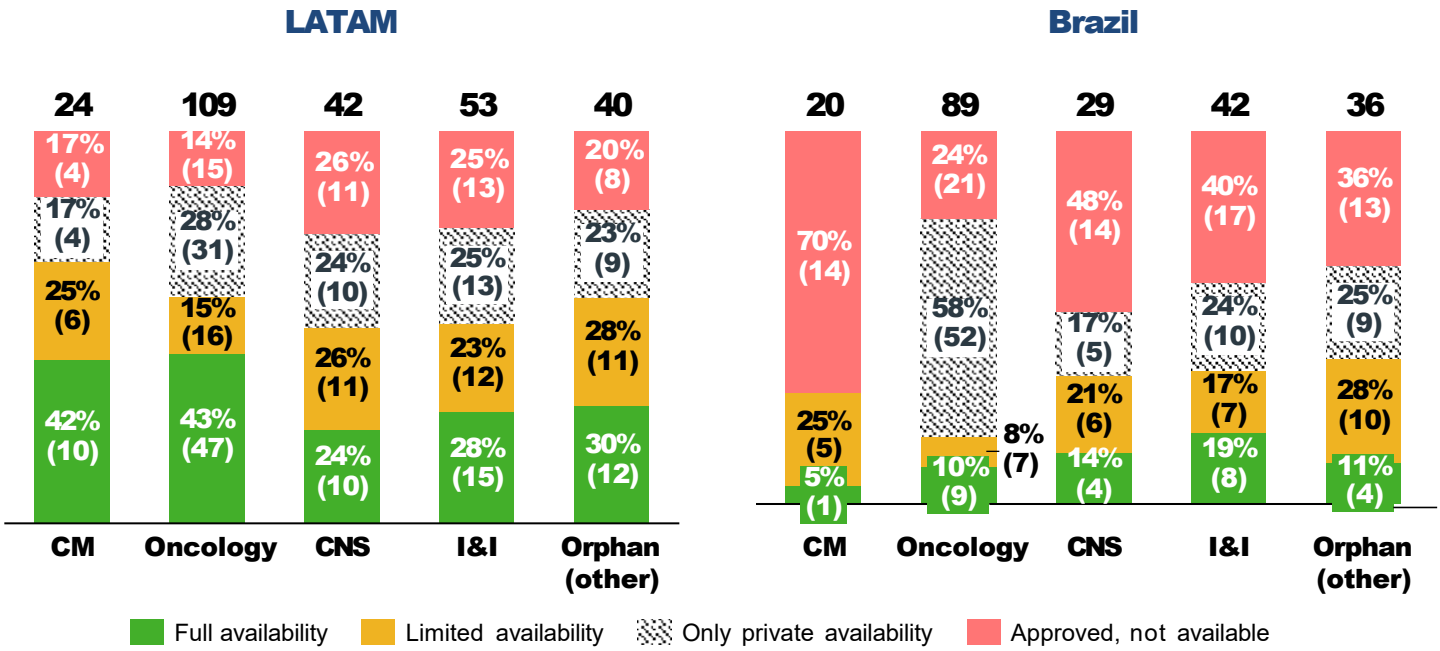
In Brazil, strong regulatory performance enables early access to innovation but limited public funding and system fragmentation results in restricted availability and a high reliance on private-sector access

Acronyms: SUS: Sistema Único de Saúde; BR: Brazil

Significant differences also exist by therapeutic area

Brazil, does not follow the regional trend, where CM & Oncology lead on full availability; in the local context, these therapeutic areas lag

Regional and Local Availability Status by Therapeutic Area



- Brazil exhibits a more constrained access profile across all therapeutic areas compared to LATAM, with significantly lower full availability levels, particularly in CM (5% vs. 42%) and Oncology (10% vs. 43%), highlighting systemic limitations in translating approvals into access
- In cardiometabolic therapies, Brazil shows extreme access limitations, with 70% of approved treatments not available, indicating that even high-burden, high-volume disease areas are severely deprioritized or constrained within SUS, and overly dependent on the OOP sector
- Oncology presents a dual-access paradox in Brazil, where availability appears moderate, but is overwhelmingly driven by private-sector access (58%), in contrast to severely limited public system uptake, except via legal injunction
- CNS therapies remain highly constrained, with only 14% full availability and 48% not available, reflecting high uncertainty in a TA with quickly growing burden
- I&I and Orphan diseases show (relatively) better access, while still being fragmentated, showing better approval but still depending significantly on the private sector

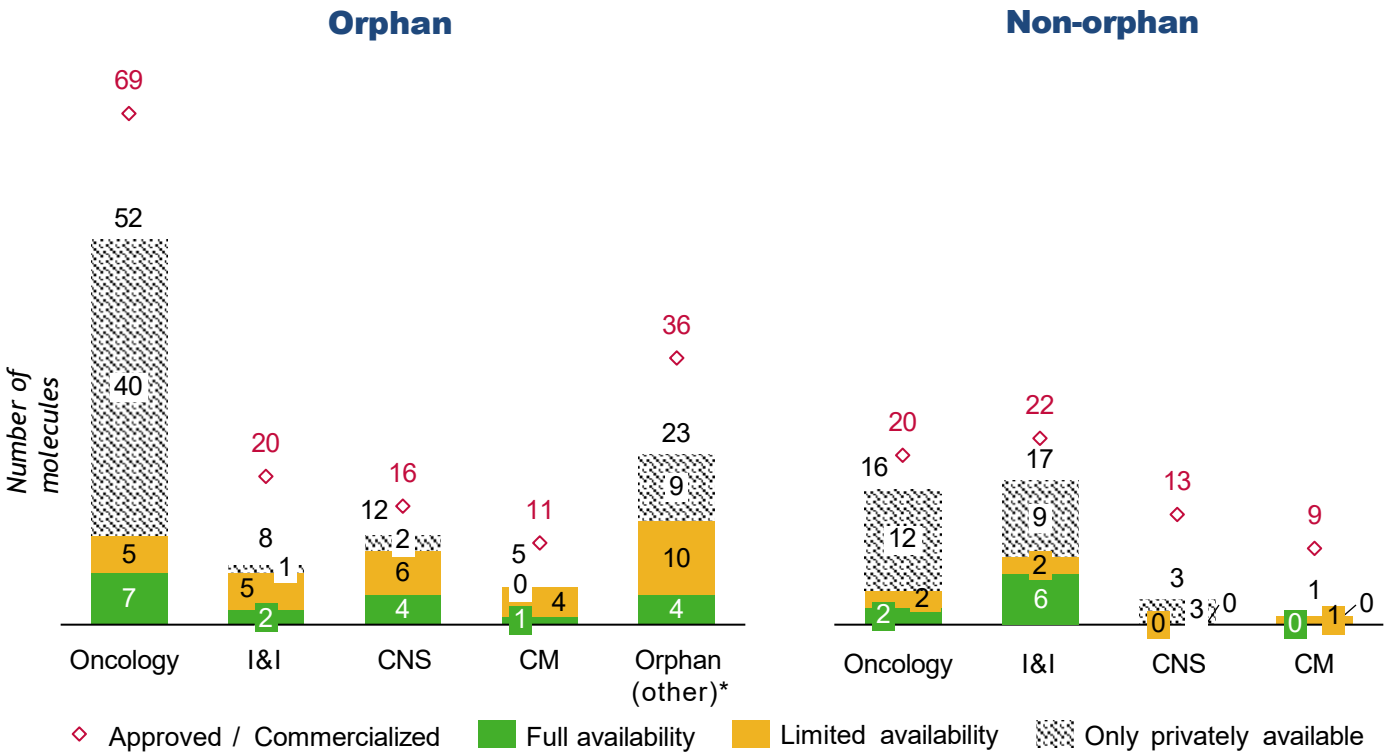
The biggest gaps in Brazil compared to the region are found in approved but not available; the impetus for regulatory submission and efficiency is present, but public access is the core bottleneck

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; SUS: Sistema Único de Saúde; OOP: Out-of-pocket

Orphan therapies show higher availability

Orphan therapies often rely on private access, while non-orphan therapies face stronger system constraints, in many cases as a result of larger potential budget impact

Breakdown of local availability (2025) – Orphan vs. Non-orphan by TA



- Orphan therapies represent the largest share of the approved treatments, particularly in oncology (69 approved orphan molecules vs. 20 non-orphan)
- Orphan therapies are significantly more reliant on private-only availability, suggesting that access to rare disease innovation is heavily dependent on private system channels, likely driven by three main factors:

a. Population size is limited for plans, resulting in lesser budget impact risk

b. ANS RoI lists infusion drugs as part of baseline coverage

c. Allows real-world use in the local population to substantiate broader, public access

- In contrast, non-orphan therapies show lower private-sector dependence, and notable general gaps between approval and availability, particularly in CNS and CM where full availability is minimal or absent, reflecting stronger system constraints driven by aggregate budget impact and treatment volume

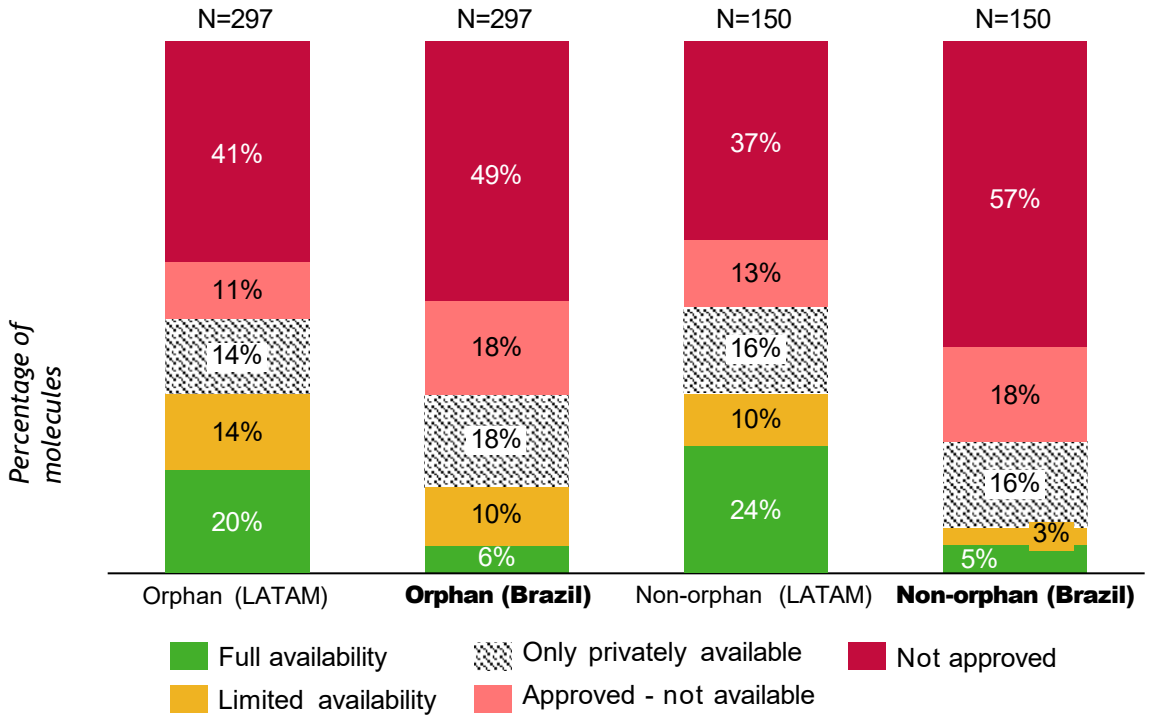
In Brazil, orphan therapies benefit from a larger innovation pipeline and greater private-sector uptake, while non-orphan therapies face stronger systemic constraints, yet both ultimately show low levels of full public availability

* Orphan (other) category considers orphan molecules that are not also part of any of the other TAs
Acronyms: I&I: Inflammatory and Immunology; CNS: Central Nervous System; CM: Cardiometabolic; TA: Therapeutic Area

Availability varies by therapeutic area

While orphan drugs show lower availability globally, Brazil demonstrates markedly reduced access across both orphan and non-orphan therapies, with minimal conversion into full availability

Initial Regional and Local Availability (2014 – 2025) – Orphan vs. Non-orphan



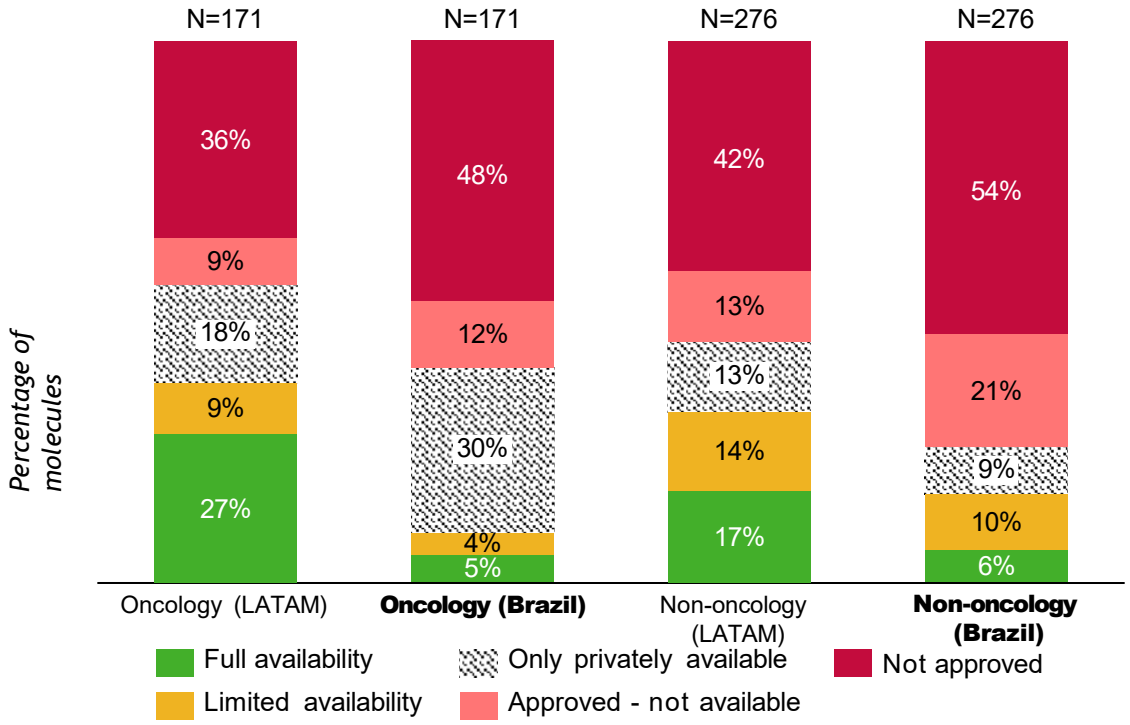
- Brazil exhibits consistently low full availability across both orphan and non-orphan therapies, with only 6% (orphan) and 5% (non-orphan) achieving full access, significantly below LATAM benchmarks (20% and 24%, respectively)
- The biggest gap between the general LATAM Benchmark and Brazil, is noted on the Non-orphan drugs, where there is a ~20% difference between the Not-approved medicines.
- Orphan therapies in Brazil show slightly better performance than non-orphan in availability terms limited (~10%) or private-only (~18%) availability, resulting in extended availability difference of 34% vs. 24% respectively, highlighting the heightened challenges of covering medicines for broad populations
- Across both categories, the distribution of access indicates that availability is a bottleneck in the country, and more so for innovative medicines that are more likely to address the broader population, and in many cases, much higher disease burden

Brazil underperforms across both orphan and non-orphan therapies, indicating that access challenges are not driven by therapeutic complexity alone, but by structural limitations in funding and system capacity

Oncology lags behind non-oncology in Brazil in full availability

Oncology in Brazil lags slightly in full availability vs. non-oncology; however, extended availability is significantly higher driven by region-topping private access

Initial Regional and Local Availability (2014 – 2025) – Oncology vs. Non-oncology



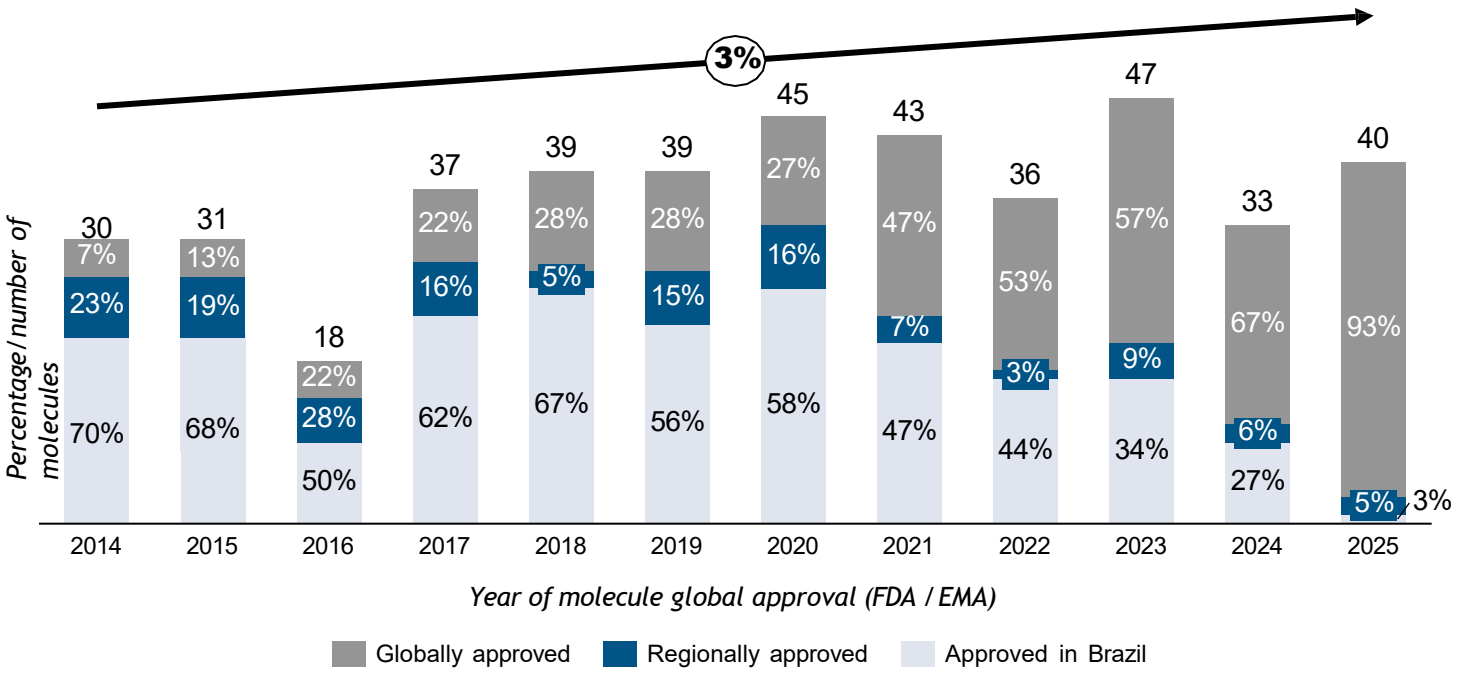
- The availability of oncology therapies is largely driven by private-sector access, with 30% of treatments available only privately, masking limited integration into the public system and limiting access to the general population
- Public access is severely deficient, with just 9% achieving it; the overdependence on the private sector and barriers in reaching and sustaining funding decisions for oncologics is a major challenge for the healthcare system, and results in high degrees of legal/administrative processes
- A substantial share of non-oncology therapies (~21%) remain unavailable despite approval, highlighting persistent bottlenecks in decision-making, pricing negotiations, and public funding allocation
- Compared to LATAM, where oncology achieves significantly higher full availability (~27%), Brazil stands out as an underperformer in translating oncology innovation into access, despite comparable or stronger regulatory throughput

In Brazil, oncology benefits from strong innovation inflow but underperforms in full access, with limited public uptake and a heavy dependence on private-sector delivery

New medicines increase, approvals are lagging behind

Significant time-lag effects and widening gaps limit the translation of global innovation into regional and Brazil market availability

Global vs. Regional vs. Local Approved Therapies (2014 - 2025) – Combined



- Regional approval rates remain consistently high for older cohorts but show a pronounced decline for more recent approvals, falling from a strong range of 72–93% between 2014 and 2020 to just 33% in 2024 and 8% in 2025
- Brazil follows a similar downward trajectory in approvals, consistently driving the regional trend, though with discrepancies ranging from 23% difference, showing its standing as a regional first-to-approval market
- The proportion of therapies that remain exclusively at the global approval stage has increased markedly over time, rising from 7% in 2014 and 13% in 2015 to 57% in 2023, 67% in 2024, and 93% in 2025, reflecting a widening gap between global approvals and their translation into downstream approval
- A clear time-lag effect is evident, as therapies approved in earlier years have had sufficient time to expand into regional markets and Brazil, reaching 93% regional and 70% Brazil availability for 2014 cohorts, whereas more recent approvals show substantially lower penetration due to shorter time since launch
- Furthermore, over time the “ceiling”, that is the peak level of approvals in the region for globally approved medicines, is lowering with a very clear downward trend over time, even for the medicines in mid-late lifecycle, indicating compounding challenges to launching in the region

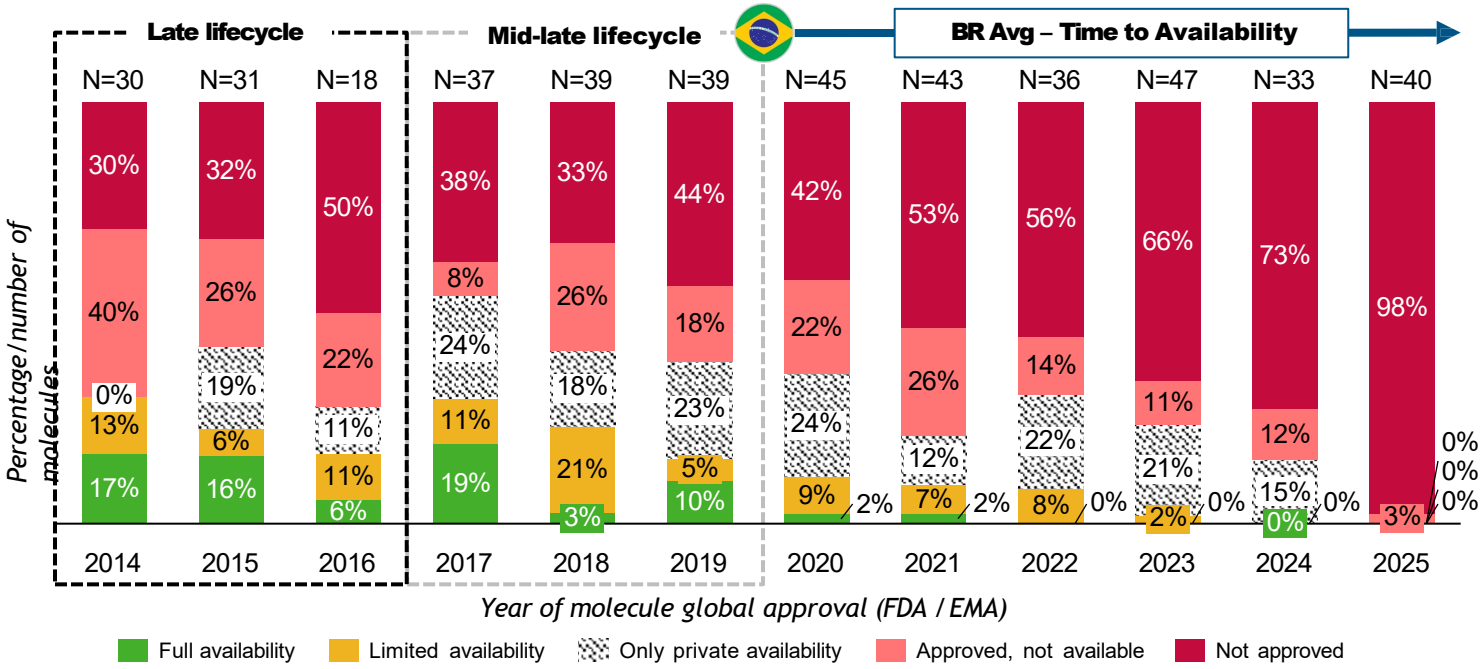
Approval rates are declining in the region, whilst global approvals are increasing; the gap will continue to widen without concerted action

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Even for older technologies, public access is highly challenging

Newer molecules are highly concentrated in not approved or low-access categories, public access takes time to reach in Brazil

Broadest Molecule Availability Status Over Time (2014 - 2025) – Brazil Combined



- Full availability remains consistently low across all cohorts and declines in recent years, dropping from 17% in 2014 and 19% in 2017 to just 3% in 2018 and 0% from 2022 onward, indicating persistent challenges in achieving broad access
- The share of not approved molecules increases sharply for newer cohorts, rising from 30–32% in 2014–2015 to 66% in 2023, 73% in 2024, and 98% in 2025, highlighting the challenges in reaching consensus on both submission and approval
- Approved but not available therapies also represent a substantial share, particularly in earlier cohorts, peaking at 40% in 2014 and remaining notable in years such as 26% in 2021 and 14% in 2022, suggesting delays beyond approval
- Limited and only private availability together constitute a meaningful portion of access but show volatility over time, with no clear upward trend, indicating inconsistent pathways to partial access
- The overall distribution shifts toward lower access over time, with recent cohorts increasingly concentrated in not approved and unavailable categories, pointing to a growing backlog and widening access gap despite ongoing innovation

"These technologies being incorporated are older, and I don't know how we can get to the newer ones; there's a backlog."

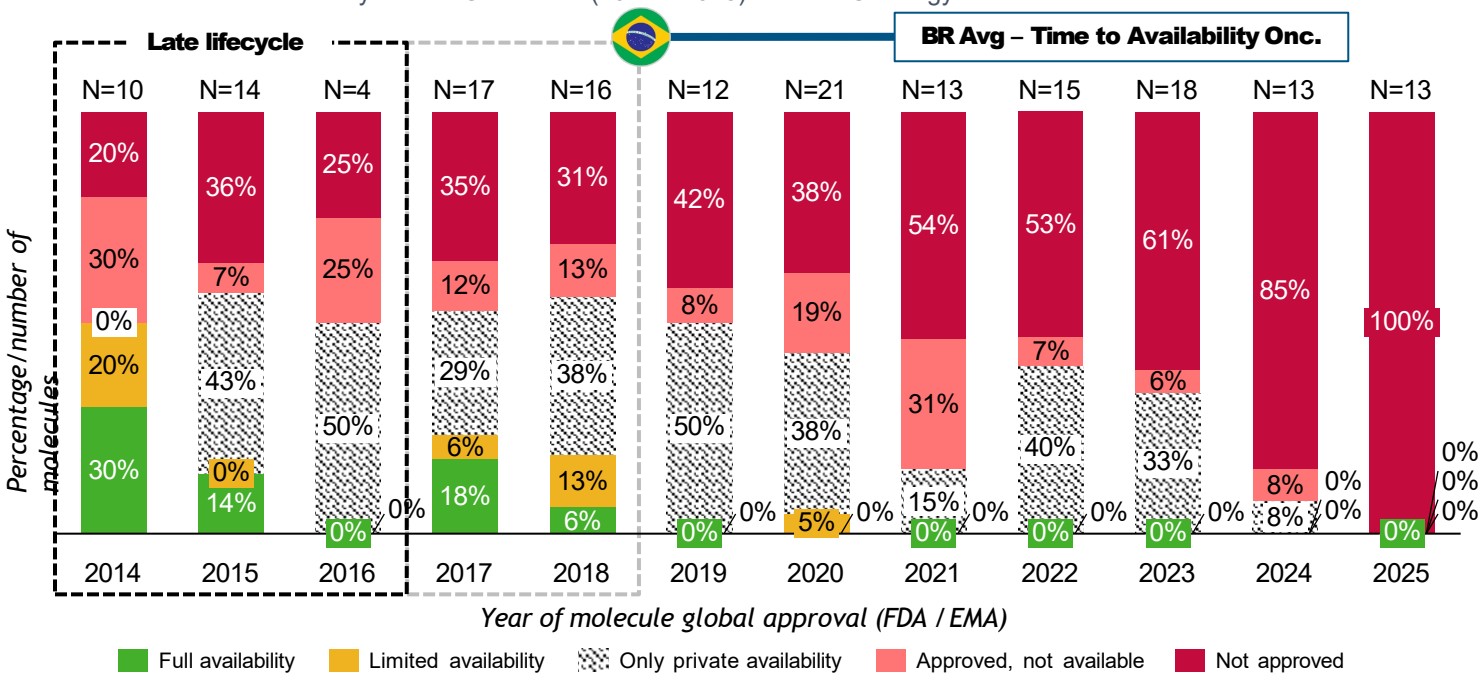
- ex-Minister of Health

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Oncology private sector access is strong, but public is very slow

Approvals drop sharply after 2020, with fewer than 50% of oncology drugs approved since 2021, with private sector playing a key role in supporting access for new technologies

Broadest Molecule Availability Status Over Time (2014 - 2025) – Brazil Oncology



- Full availability of oncology molecules in Brazil remains very limited and declines over time, falling from 30% in 2014 to 18% in 2017, 6% in 2018, and 0% from 2019 onward; older technologies are the only ones that are able to secure CONITEC recommendation, highlighting the protracted time to a decision, as well as the challenging nature of assessment, with high uncertainty for laboratories
- The share of oncology molecules that are not approved rises sharply in recent years, increasing from 20% in 2014 to 54% in 2021, 61% in 2023, 85% in 2024, and 100% in 2025, highlighting major barriers for newer oncology therapies
- Private-only availability represents an important access pathway, accounting for 43% in 2015, 50% in 2016 and 2019, and 40% in 2022, suggesting that many products reach patients only through private channels rather than broad public availability
- Approved but not available molecules remain a meaningful share of the oncology pipeline, especially in earlier and intermediate cohorts, reaching 30% in 2014, 25% in 2016, 19% in 2020, and 31% in 2021; the gap is likely driven by orals or injectables which face additional hurdles to reach even the private sector vs. IV
- Access to oncology innovation in Brazil has shifted away from broad availability toward restricted or absent access, with recent years showing minimal progression to full availability and a growing concentration of molecules that have not yet reached patients through the healthcare system

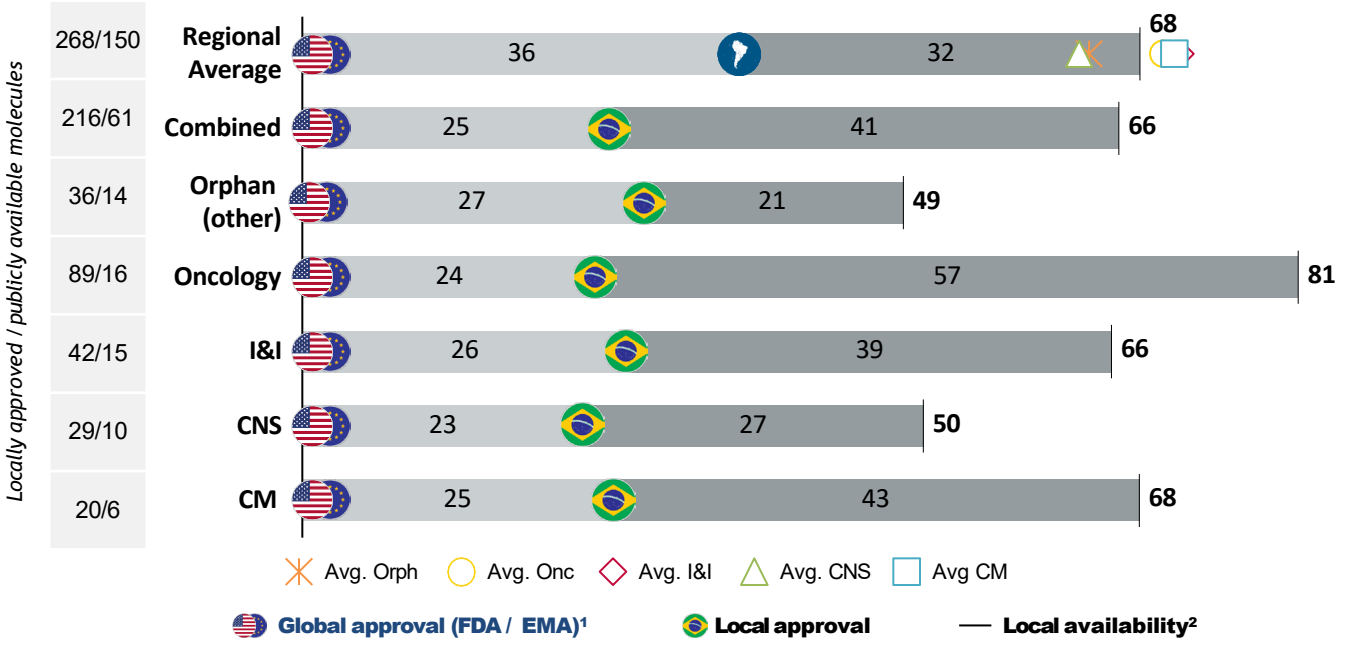
Access to oncology molecules in Brazil has worsened over time, with newer cohorts increasingly concentrated in not approved or restricted-access categories

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency

Access is a long and fragmented process

The time to availability in Brazil averages 5.5 years, with a time to approval of 2.1 years and a time to availability of 3.4 years

Time to Availability from Global Approval (2014 - 2025) – Brazil Combined



[1] Global approval date considered the earliest date between FDA or EMA
[2] Considering molecules with Full and/or Limited Availability

- Total time to availability in Brazil reaches ~66 months (~5.5 years), closely aligned with the regional average (68 months), confirming that patient access remains significantly delayed despite earlier innovation approvals in Brazil
- Brazil benefits from relatively faster regulatory approval timelines (25 months vs. 36 months regional), which is of particular note given the volume of submissions is also the highest of the region, making Brazil the regulatory reference in the region
- This advantage is almost completely offset by prolonged post-approval delays (41 months vs. 32 months regional), indicating that the majority of access delays occur after approval, driven by reimbursement, pricing, and implementation barriers
- The most significant delays post approval correspond to the oncology medicines, despite having a quick local approval time, the total time to availability exceeds the local average by ~1.3 years
- In contrast other therapeutic areas, Orphan (49 months) and CNS (50 months), are strikingly quicker to availability

Brazil gets innovative medicines approved relatively quickly, but struggles to deliver them, with most of the delay occurring after approval

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology

Timelines lengthened in 2026, driven by post-approval delays

While regulatory timelines remain stable, delays in availability are increasing in Brazil, particularly in high-budget-impact therapeutic areas, reinforcing system strain beyond approval

Time to Availability from Global Approval vs. 2025 – By TA in Brazil

	Approved	Available	Total
Regional average	-5.6%	+9.4%	+1.5%
Combined	-	+4.9%	+3%
Orphan (other)	-3.7%	-38.1%	-
Oncology	-	+3.5%	+2.5%
I&I	+3.8%	+7.7%	+9.1%
CNS	-	-3.7%	-
CM	-	+18.6%	+11.8%

- Brazil shows a +4.9% increase in time to availability vs. 2025, resulting in a +3% overall delay, which equates to approx. 2 months of additional wait time for patients to access treatments compared to the year prior, driven by prolonged access decisions
- This pattern mirrors the regional trend, where approval timelines improved (reduced by 5.6%) but availability timelines worsened (increased by 9.4%), highlighting a region-wide tendency toward regulatory efficiency, but accumulating access bottlenecks
- Delays are not uniform across therapeutic areas, with: CM therapies (+18.6%) showing the largest increase, reflecting high-volume budget pressure and prioritization constraints; I&I (+7.7%) and Oncology (+3.5%) also experiencing deterioration, evidencing chronically evolving systemic strain
- In contrast, Orphan therapies (-38.1%) and CNS (-3.7%) show improvements, suggesting targeted prioritization or lower budget impact enabling faster access in select segments
- There are isolated improvements but the overall trend indicates that system capacity is not keeping pace with innovation inflow, resulting in slower transitions from approval to availability

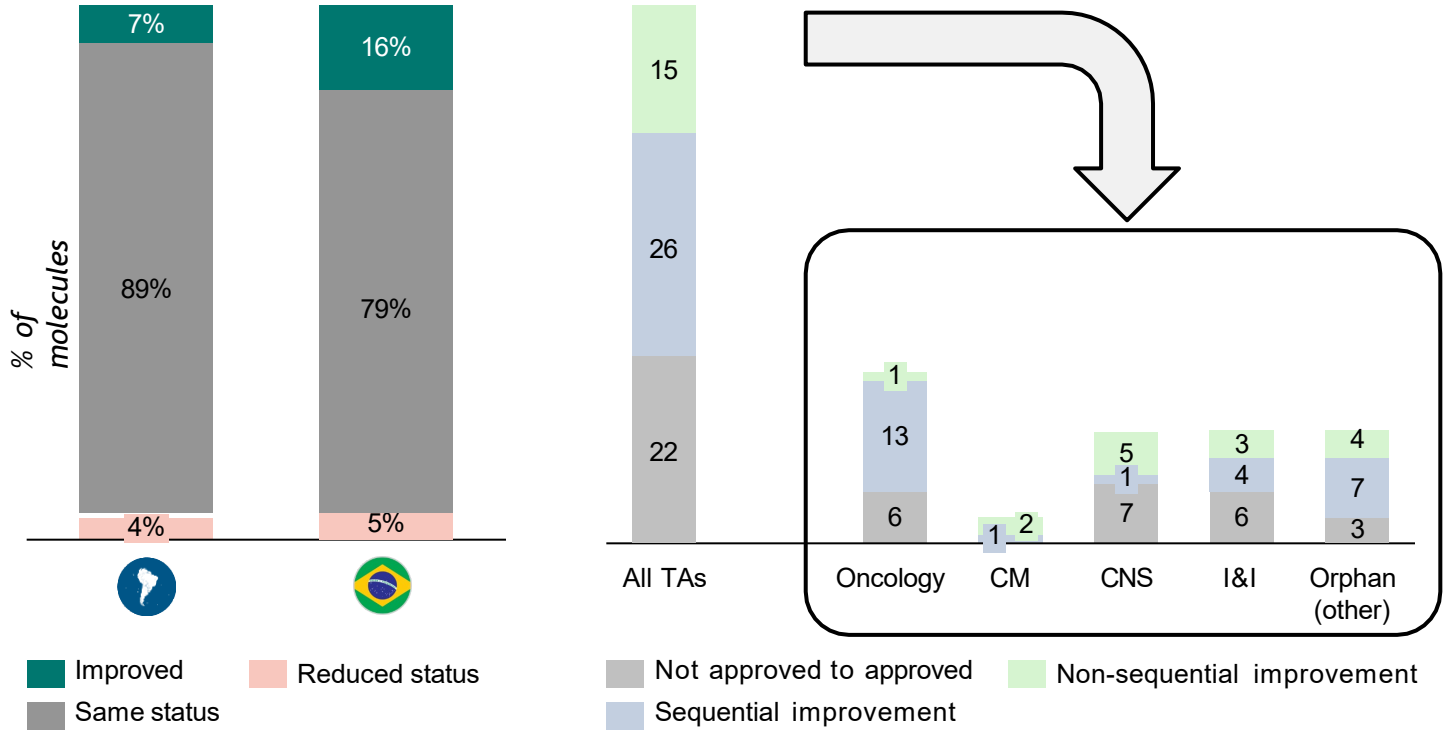
In Brazil, access timelines are increasingly delayed after approval, with system constraints and budget pressures slowing the transition from innovation to patient access, particularly in high-impact therapeutic areas

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology

Brazil's improvement rate doubles LATAM's

Brazil shows notable access improvements compared to 2025 (existing definition) with a relatively even spread across TAs, however much is driven by approvals, and private access

Improvement Index Argentina (2026 vs 2025)



- Brazil outperforms the regional average in access progression, with 16% of molecules improving vs. 7% in LATAM; breaking from the incremental progress in the region, and potentially showing a shift to a faster pace of change
- Despite these gains, most molecules (~79%) remain in the same access status, with many remaining in the private sector only, highlighting a structure where most molecules are not scaling to the broader population, but can quickly reach approval and/or private sector access
- A portion of molecules (~5%) experienced reduced status, consistent with the regional benchmark (~4%); this can represent molecules that have become obsolete due to clinically superior options becoming available, competitive dynamics, etc.
- Across the therapeutic areas, more improvements are made in oncology, the least in CM, and relatively consistent patterns in other disease areas

Brazil is making measurable progress in access, but the pace and scale of improvement remain insufficient to overcome systemic constraints, with most therapies seeing little or no change in real-world availability

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology

Recent system reforms are creating tangible opportunities

Targeted policy updates, stronger processes, and procurement reforms are beginning to emerge and may translate into broader, more predictable patient access

Recent Health Reforms in Brazil

Brazil has made significant changes in policy that will change the access dynamic

- CMED pricing policy update
- Updates to the National Cancer Care Policy (Política Nacional de Prevenção e Controle do Câncer)
- Changes to managed entry agreements
- Themes 6 and 1234 related to CONITEC's role in legal injunction decisions

- Pricing and HTA integration is becoming more sophisticated, but restricted; the CMED reform (Resolution 3/2025) introduces several changes including: an expanded number of reference countries to 14, new categories (e.g. "biosimilars", incremental innovation), greater requirements for disclosure of HTA studies and risk-sharing agreements, shifting towards a more rigorous and complex process to demonstrate value

- Themes 6 and 1234 further restrict the potential for legal injunction decisions in favor of patients where CONITEC decision is not available or a treatment is not recommended, though in practice it remains to be seen the extent of the impact

- There are specific changes, such as updates to the National Cancer Policy that drive centralized purchasing, creation of a dedicated oncology component in the budget, and broader use of legally-binding clinical guidelines (PCDTs) to support access

- The introduction and formalization of managed entry agreements, supported by legal frameworks such as Bill 667/21 reflect Brazil's gradual move towards value-based procurement mechanisms; these agreements include policy regarding financial discounts to outcome-based risk-sharing, allowing to mitigate uncertainty while enabling access. This aligns with international best practices; however, the mechanism remains limited in scale

Brazil's reforms reflect a transition toward a more structured, value-based access system; however, increased management and pricing regulation could amplify delays, whilst creating further opportunities for novel technologies

Sources: Global Health Expenditure Database, International Trade Administration, OECD
Acronyms: NHA: National Health Accounts; CMED: Câmara de Regulação do Mercado de Medicamentos; 667/21 – Lei de Acordo de Compartilhamento de Risco em Saúde no Brasil; HTA: Health Technology Assessment

Brazil's ANVISA has gained global recognition

Brazil's regulatory framework is aligned with international standards and increasingly participates in global reliance mechanisms, strengthening its role in regional innovation access

Global Reliance of Brazil's Health Agencies

Global Reliance

ANVISA is widely recognized as a mature regulatory authority in Latin America, with strong technical capacity and alignment with international regulatory standards

- Brazil plays a key role in regional regulatory processes and reliance initiatives, supporting more efficient approval pathways and positioning the country as a leading gateway for innovation in LATAM
- Brazil has a strong reliance framework whereby it can accelerate approvals by reducing duplicative work realized by Equivalent Foreign Regulatory Authorities (AREEs), primarily US-FDA, EU-EMA, UK-MHRA and Health Canada
- Furthermore, Brazil is active in its global collaboration via International Council for Harmonization (ICH), and Project Orbis (for oncology medicines)whereby it is a contributor in assessments as well as a participant benefiting from parallel reviews and other mechanisms
- Brazil (ANVISA) is also recognized by PAHO/WHO as a National Regulatory Agency of Regional Reference (NRAr), indicating the consensus in the international community on the advanced level of maturity of the agency, and enabling other countries in the region to fast-track approvals by relying on the evaluation of ANVISA

Brazil's regulatory system is recognized as mature, and its participation in international collaboration programs cements itself as the regional reference

Acronyms: ANIVISA: Agência Nacional de Vigilância Sanitária; CONITEC: National Committee for Health Technology Incorporation; NRAr: National Regulatory Authorities of Regional Reference

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Local trade associations also supported in the development and validation of the study

AMIIF, MX

CAEME, AR

AFIDRO, CO

CIF, CL

FEDEFARMA, CAC

INTERFARMA, BR

ALAFARPE, PE

IFI–Promesa, EC

Definitions and additional notes on methodology

Assumptions and rules to identify a NAS

- A NAS must be an active moiety and therefore cannot be a purified biologic entity (e.g., biosimilar, bio-betters, certain tissue products
- If the new approval is a combination, it needs at least one new compound in the product
- The NAS may be a pro-drug (i.e., a substance which is inactive when administered and which requires metabolism to produce an active metabolite). In such case, the active metabolite may not be novel. However, provided that the pro-drug is novel (i.e., not previously approved by any regulatory authority and not available for commercial sale), the pro-drug would be a NAS
- A different ester form of an existing substance would also not be precluded from consideration for NAS status
- New salts, polymorphs, enantiomers, isoforms, solvates, hydrates, crystalline forms, or other noncovalent derivatives of previously approved substances are not NASs unless they are deemed to be by a regional or national regulatory authority

Selection of NAS molecules

1. NAS with FDA/EMA approval 2014-2025 in relevant TAs
2. Global launch rest of world - (without US launch): Products that are typically not exposed to the global market e.g., homegrown PD-1s in China, endemic response in Africa etc.
3. Pandemic response - outbreaks (e.g., COVID), and respective treatments may be subject to exceptional routes to access and procurement dynamics
4. Vaccines - also have different routes to access, confounding comparison; FIFARMA Time to Vax study in development to assess these separately
5. Other non-comparable agents e.g., imaging/diagnostics - agents not directly used in treatment and also not directly comparable
6. Withdrawn/not launched - typically a repeal of conditional approval based on not meeting evidence requirements and resulting in global withdrawal/or not launched

	Overview of additional TAs selected		
	I&I		CM
ATC2 Examples**	L4, M1, D5, A7	N3-7, L04	B1, C2, C10, A10
Class Examples	ILis, JAKis	CGRPis, antiamyloid mAbs	PCSK9i, GLP1s, GH
Product Examples	Skyrizi, Olumiant, Cibinqo, Ultomiris, Tremfya	Leqembi, Zurzuvae, Nurtec, Ubrelvy	Ozempic, Ngenla, Repatha
Indication Examples	RA / CD / UC / PSO / PSA	AD / MS / ALS / DMD	HF / Diabetes / GHD

Notes on sources and validation process

THIS REPORT IS BASED ON THE SOURCES DETAILED BELOW

IQVIA NRC/ MIDAS™ is a unique platform for assessing worldwide healthcare markets. It integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, tracking virtually every product in hundreds of therapeutic classes and provides estimated product volumes, trends and market share through retail and non-retail channels. MIDAS data is updated monthly and retains 12 years of history. IQVIA MIDAS was used by each local IQVIA team to provide the existing data

PUBLICLY AVAILABLE INFORMATION for each market was incorporated in the study from agencies and regulatory bodies

LABORATORY INTERNAL DATA was asked via a Smartsheet survey and collected from each of the manufacturers included in the study, as well as via interviews to understand underlying dynamics

LOCAL TRADE ASSOCIATION DATA was collected from associations and validated, in addition to the development of the definitions for their respective countries

Former **Ministry of Health stakeholders** were interviewed across a number of countries in scope to provide additional perspective and validation

THE DEVELOPMENT OF THE REPORT FOLLOWS A PROCESS OF MULTI-STAKEHOLDER INPUT AND VALIDATION

The initial selection of molecules as described on page 20 is made the core IQVIA project team and validated by FIFARMA

Definitions for availability are developed/updated by the local IQVIA consulting teams and validated by local trade associations

The approval/availability data is then gathered by IQVIA local consulting teams leveraging the data sources outlined (to the left)

This data is validated by IQVIA and FIFARMA and, in a confidential manner, shared to the respective, marketing-authorization laboratories for validation and complementing

IQVIA local consulting teams perform a final validation of the data and IQVIA core project team performs the relevant analyses

IQVIA core project team develops the preliminary report for final validation by the FIFARMA and local trade organization representatives prior to publication

For local country reports, trade associations perform a further validation prior to publication

Patient W.A.I.T. Indicator & Root Causes 2026 – Brazil

FIFARMA | IQVIA

Measuring availability and understanding the barriers to access to innovative medicines

The FIFARMA Patient W.A.I.T. Indicator 2026 – Brazil is the fifth edition of this study that measures the availability of innovative medicines in the country and explores the root causes behind access delays. This year's study includes 447 innovative molecules approved globally between 2014–2025 across 5 therapeutic areas and orphan drugs.

Key Takeaways

Low Availability

Only 19% of innovative molecules are fully available in Brazil (public and private sectors).

Long Time to Access

Median time to availability
Public sector: 66 months (5.5 years)
Private sector: 24 months (2 years)

Modest Improvement

Improvement index 2024–2026
16% for the public sector
41% for the private sector

Patient Impact

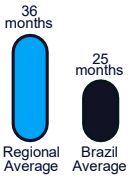
Delays in access limit treatment options and contribute to worse health outcomes and productivity losses.

Availability Snapshot (2026) Molecules approved globaly

Status	Molecules	%
Not available	231	51.7%
Out of pocket	79	17.7%
Private	76	17.0%
Limited availability	35	7.8%
Full availability	26	5.8%
Total	447	100%

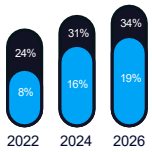
More than half of innovative molecules (51.7%)are not available to Brazilian patients.

Time to Approval by the Local Authority



Brazil presents an approval time of 25 months, compared to the regional average of 36 months

Time to Availability (Median Months)



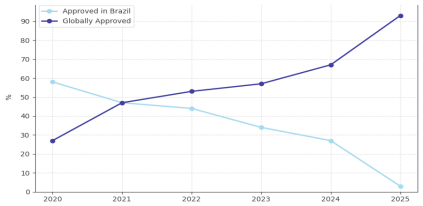
Full availability improved, **but from a low baseline.**

Availability by Therapeutic Area (2026)

Therapeutic Area	Public Sector	Private Only	Extended Availability (public+private)
Oncology	18%	58%	76%
Inflammation & Immunology	36%	24%	60%
Central Nervous System (CNS)	35%	17%	52%
Cardiometabolic	30%	0%	30%
Orphan Drugs	39%	25%	64%

Oncology and orphan drugs show higher availability, while Cardiometabolic and CNS remain among the most challenging areas.

Approval of Innovative Medicines (2020-2025)



Public spending in Brazil remains lower than the recommended 6% GDP shared by WHO and the OECD average, but remains in line with its LATAM peers, indicating structural underfunding

Root Causes: Main Barriers to Access

These structural factors create delays and prevent patients from accessing innovation in a timely manner.

Regulatory & HTA Complexity
Multiple assessment bodies, lack of alignment and transparency,and evolving HTA criteria.

Pricing & Budget Constraints
Insufficient and inflexible budgets and challenges in value assessment and price negotiations.

Procurement & Supply Chain
Centralized purchasing, lengthy tender processes and local uncertainties.

Inequity of Access
Large disparities between regions and between public and private healthcare.

Data & Monitoring Gaps
Limited real-world data and monitoring to support decision-making and track access.

Opportunities to Improve Access

Collaborative, multi-stakeholder action is essential to accelerate patient access to innovative medicines in Brazil.

Align & Streamline Processes
Harmonize requirements across agencies and increase transparency and predictability.

Strengthen Value-Based Decisions
Adopt sustainable funding models and incorporate health technology value and outcomes.

Modernize Procurement
Simplify and accelerate tender processes and improve planning and supply chain management.

Promote Equity
Expand access programs and reduce regional disparities within the public health system.

Invest in Data & Monitoring
Build robust data infrastructure to inform and monitor access and outcomes.

Better data. Better decisions. Better access. Innovation only transforms lives when patients can access it.

Source: FIFARMA & IQVIA. (2026). FIFARMA Patient W.A.I.T. Indicator 2026: Brazil.

Learn more: w.fifarma.org

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