White Paper – Summary

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

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Table of contents

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

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:

Based on public and IQVIA data (MIDAS / NRC, hospital audits, gov't sites, etc.)

Aligned with FIFARMA, local trade assoc., e.g., Interfarma, AFIDRO, AMIIF, etc.

Participation from laboratories via data validation, interviews, and project steering

Interviews with ex ministers of health and other high-level MoH officials

Added in 2026

Multiple formats and cuts of data (local, by TA)

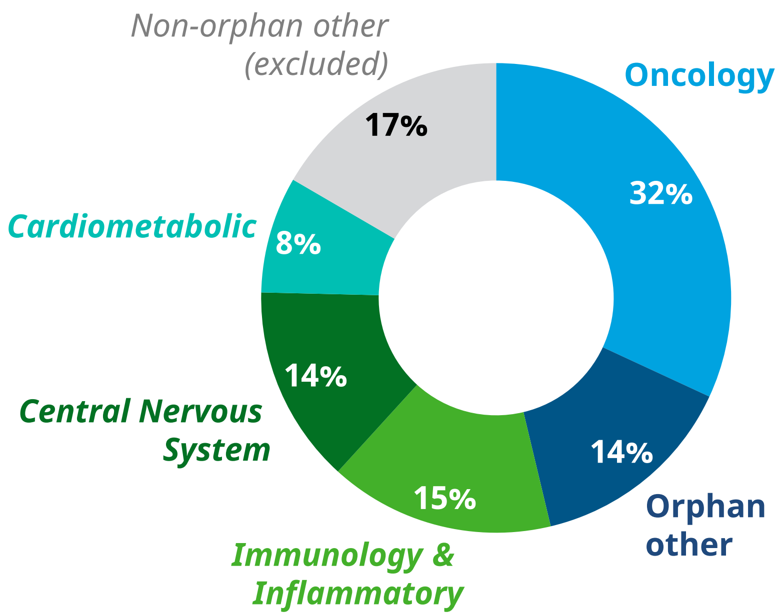
"It's an optimistic view still, there are more challenges for real-life access than what we see here."

- ex-Minister of Health

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 2025



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

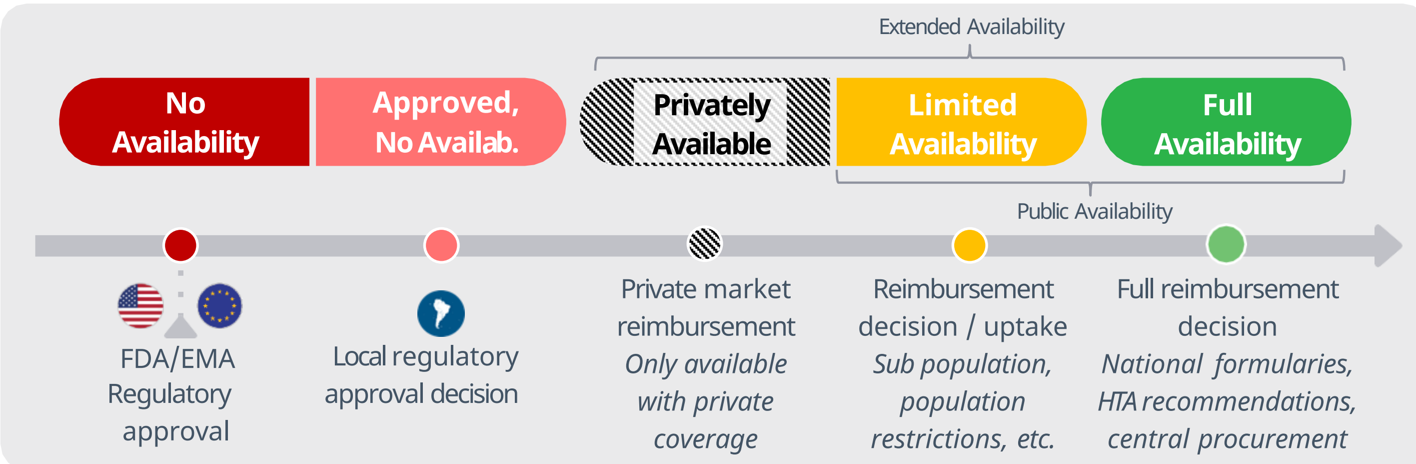
Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

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

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

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

Methodological considerations

Each geography in scope has a local definition of availability such that, to the extent possible, results can be compared regionally

		AR	BR	CL	CO	CR	DO	EC	MX	PA	PE
Availability Definition	Full	PAMI/ SURGE or PAMI / PMO	CONITEC and centralized purchases	Ley Ricarte Soto or GES	PBS-UPC	CCSS (LOM)	PBS-SISALRIL	Essential list e.g., MSP, IESS	Compend-ium, and federal inst. purchases	CSS and ION (LOM)	PNUME, and RENETSA/ RM purchases
	Limited	1+ country formulary and broad coverage by OSN / prepaid	CONITEC, no centralized purchasing	Limited FONASA reimb-ursement, special programs	ADRES / MIPRES	Special purchases	DAMAC LOM	Typically exception processes	De-centralized form-ularies	Special Purchases	Typically exception processes
	Private	Broad prepaid coverage	ANS ROL placement	CAEC, ISAPREs	n/a	Prepaid plans	Prepaid plans	n/a	Large private form-ularies	Prepaid plans	n/a
Data	Public	ANMAT, SURGE Drug Banks	CONITEC, ANVISA, ANS ROL	ISPCH, MOH public data, tenders	INVIMA, MinSalud circulars	MOH, CCSS	SISALRIL, PDSS, DAMAC	MSP, IESS	COFEPRIS, Compend-ium, INEFAM, tenders	MOH, CSS, ION	DIGEMID, PNUME, IETSI, INEN
Caveats		Data coverage for sub-national plans not compre-hensive	Limited availability definition adjusted to reflect stricter criteria	Private coverage data is highly limited	n/a	Public data limited, relies on IQVIA expertise and laboratory part-icipation	Public data limited, relies on IQVIA expertise and laboratory part-icipation	n/a	n/a	Public data limited, relies on IQVIA expertise and laboratory part-icipation	n/a

Definitions were aligned on and refined by the working group of local trade association representatives, IQVIA local consulting teams, and FIFARMA; full availability definitions can be found in the appendix

Where not otherwise stated, date of sustained sales (after 3mos with country-specific thresholds) was used to indicate time to reimbursement

Acronyms: PAMI: Programa de Asistencia Médica Integral; SURGE: Sistema Único de Reintegros por Gestión de Enfermedades; PMO: Programa Médico Obligatorio; OSN: Obras Sanitarias de la Nación; ANMAT: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica; ANS ROL: Agencia Nacional de Saúde list of procedures of mandatory reimbursement; CONITEC: National Committee for Technology Incorporation; ANVISA: Agencia Nacional de Vigilancia Sanitaria; GES: Garantías explícitas en Salud; FONASA: Fondo Nacional de Salud; ISPCH: Instituto de Salud Pública de Chile; CAEC: Cobertura Adicional para Enfermedades Catastróficas; ISAPREs: Instituciones de Salud Previsional; PBS-UPC:Plan De Beneficios En Salud Con Cargo A La UPC; ADRES: Administradora de los Recursos del Sistema General de Seguridad Social en Salud; INVIMA: Instituto Nacional de Vigilancia de Medicamentos y Alimentos; CCSS: Caja Costarricense De Seguro Social; MOH:Ministry of Health; PBS-SISALRIL: Plan Básico de Salud - Superintendencia de Salud y Riesgos Laborales; PDSS: Plan de Servicios de Salud; DAMAC: Dirección de Acceso a Medicamentos de Alto Costo; MSP:Ministerio de Salud Pública; IESS:Instituto Ecuatoriano De Seguridad Social; COFEPRIS: Comisión Federal para la Protección contra Riesgos Sanitarios; INEFAM: Instituto Farmacéutico de México; CSS: Caja de Seguro Social; ION: Instituto Oncológico de Panamá; LOM: Lista Oficial de Medicamentos; PNUME: Petitorio Nacional Único de Medicamentos Esenciales; RENETSA:Red Nacional de Evaluación de Tecnologías Sanitarias; ANVISA: Agencia Nacional de Vigilancia Sanitaria; MOH:Ministry of Health; IETSI:Instituto de Evaluación de Tecnologías en Salud e Investigación; INEN: Instituto Nacional de Enfermedades Neoplásicas

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 2024 W.A.I.T. to 2025 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 2025, 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 metrics from the study

Time to Availability

Represents the length of time from both global and local market authorization until full or limited 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 (public or private), as of FDA/EMA approval
- Time to availability, post-marketing authorization, is 32 months on average between the countries in scope
- As with regional availability, wide disparities also exist between countries in terms of time to availability, with AR on the low end at an average of 63 months, and PA on the high end, with an average of 91 months
- Comparing across TAs, orphan and CNS drugs are typically the fastest to reach availability after local marketing authorization, although there is variability by country

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, though wide disparities exist between countries
- 34% of molecules have a degree of availability in the public market in at least one market, whilst a further 27% are only available with private coverage

Availability Over Time

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

- <50% of molecules from 2018 onwards have public availability in at least one country
- <50% of molecules from 2021 onwards are approved, driven by BR and AR

Improvement Index

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

- From 2024 to 2025, 89% of molecules did not change in availability status
- 7% of molecules improved availability status

Acronyms: AR: Argentina; PA: Panama; BR: Brazil; LATAM: Latin America; TA: Therapeutic Area; CNS: Central Nervous System1; FDA: US Food & Drug Administration; EMA: European Medical Agency

Key takeaways

Innovation is accelerating as disease burden evolves

Disease burden in LATAM is significant and changing; driving innovation toward more targeted and high-impact therapies to address these challenges

Access challenges are intensifying as innovation grows

Access is a key challenge, with difficulties that worsen year after year; reliance on fragmented, bottom-up pathways is increasingly inadequate

Structural underinvestment amplifies access inefficiencies

Low spending on healthcare and innovative medicines constrains capacity and creates inefficiencies, compounding delays and misalignment across the access pathway

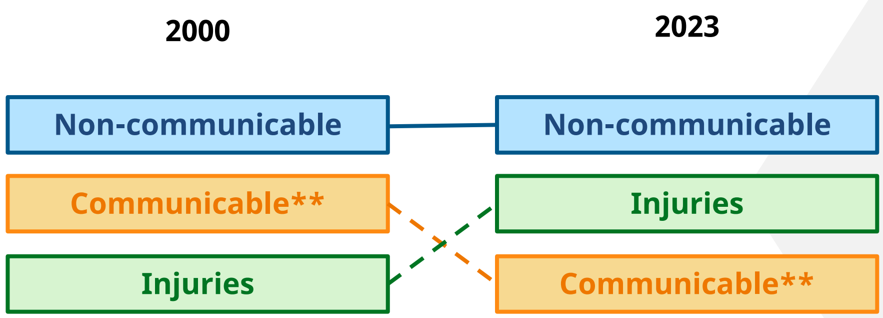
A window for transformation is emerging

Amidst global shifts and the rise of AI, a significant opportunity exists today to stimulate the pharmaceutical sector for growth and impact

Non-communicable diseases drive LATAM's health burden

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

Evolution of Disease Burden in Latin America - DALYs per 100,000



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

1	Cardiovascular disease
2	Neoplasms
3	Diabetes and chronic kidney disease
4	Musculoskeletal disorders
5	Respiratory infections and tuberculosis
6	Mental disorders
7	Other non-communicable diseases
8	Neurological disorders
9	Digestive disorders
12/13	Maternal and neonatal

- Non-communicable diseases (NCDs) now account for approximately two-thirds of global mortality and morbidity, with cardiovascular disease, neoplasms, and diabetes leading the burden.
- This shift has critical implications for healthcare systems and pharmaceutical needs. Unlike acute infectious diseases, NCDs are chronic in nature, requiring long-term management, often with multiple therapies over extended periods.
- 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 HTA 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.

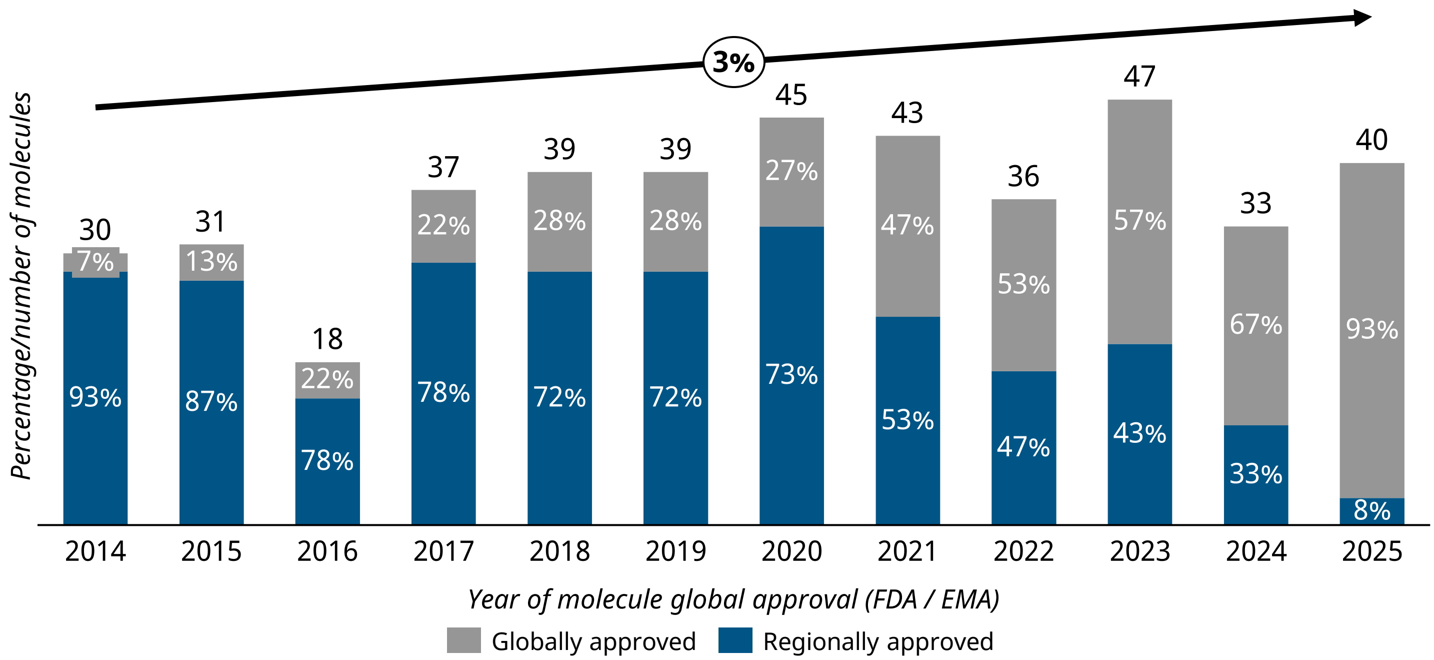
LATAM's disease profile justifies the focus on innovative medicines for NCDs, while the rising burden underscores the importance of timely access to novel therapies

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

In response, pharma innovation is increasing and evolving

There has been a 3% YoY increase in medicines globally approved, though after 2020 there is a drop in the number approved for LATAM patients

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



- Overall, globally approved molecules have been increasing, despite significant dips in approvals in 2024 and 2025
- From 2014-2019, the rate of initial regional approval is >70%, showing that given enough time, molecules are generally approved in at least one country in the region
- From 2019 to 2021, it drops from 72% to 53%, and then drops more quickly to 33% in 2024, and 8% in 2025
- Over the past decade, the number of novel medicines successfully completing pivotal trials and entering the global pipeline has continued to grow. However, before reaching patients, these therapies must navigate local regulatory systems, where the first major bottlenecks emerge in LATAM

- While global approvals have risen steadily, regional approvals remained flat until 2020 and then declined sharply. This divergence reflects broader delays in regulatory timelines and highlights growing difficulty for local agencies to keep pace with innovation, particularly after the pandemic, when resource constraints and operational disruptions further slowed progress

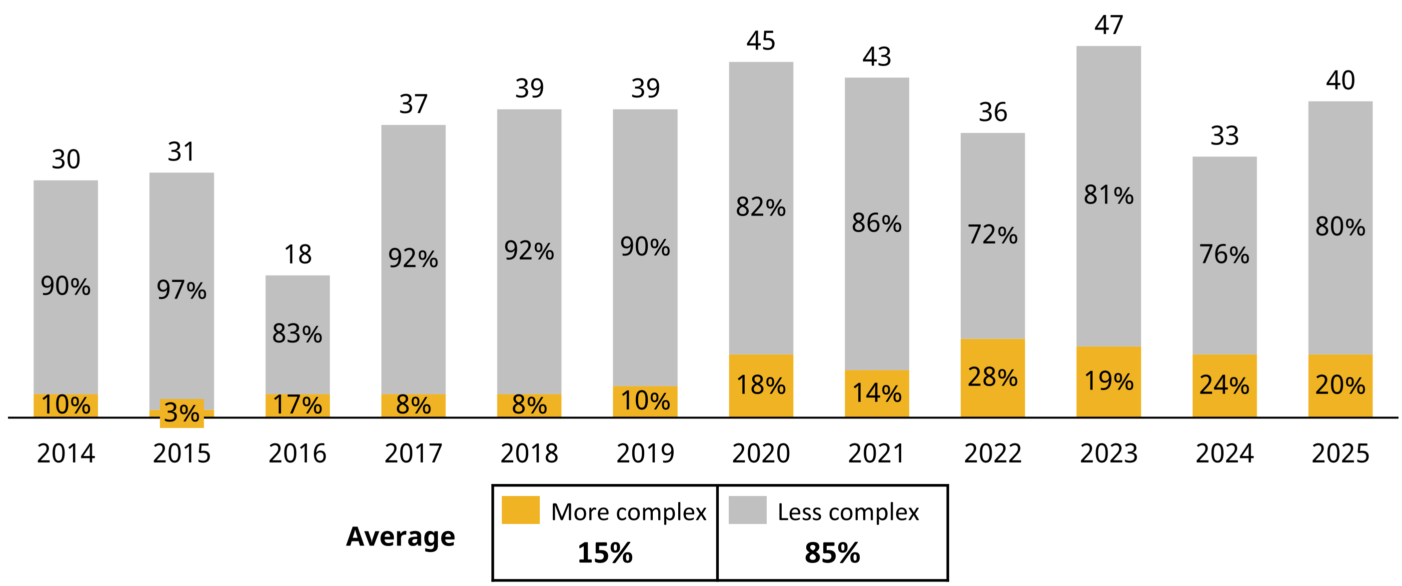
Regulatory agencies face increasing submission volumes, creating saturation and reducing efficiency; with increasing innovation and delays, comes the threat of compounding upon an existing backlog

Acronyms: YoY: Year over Year; FDA: US Food & Drug Administration; EMA: European Medical Agency; SoC: Standard of care

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

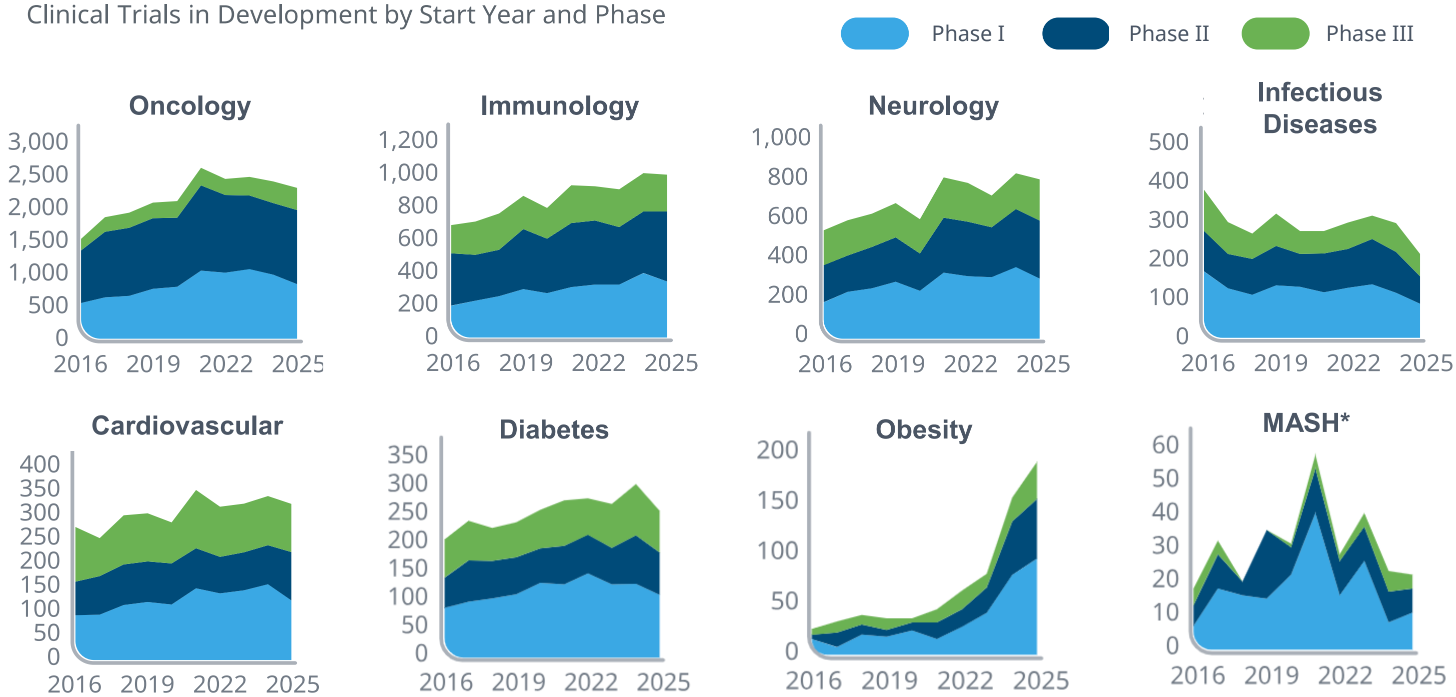
Rising therapeutic complexity requires evolution of regulatory and HTA frameworks in LATAM as well as renewed focus on technical capacity; without adaptation, complexity becomes an additional barrier

*Complexity categorization considers: Biologic or advanced therapy, Next generation therapy (e.g., nucleotide, RNAi, gene, cell, tissue therapy); Innovative therapy / first-in-class, Precision medicine (diagnostic required), Orphan population, Route of administration
Acronyms: HTA: Health Technology Assessment

A robust global pipeline signals sustained innovation and mounting system pressure

Clinical trials point to continued innovation, presenting a significant opportunity hat can only be unlocked if access bottlenecks can be alleviated

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

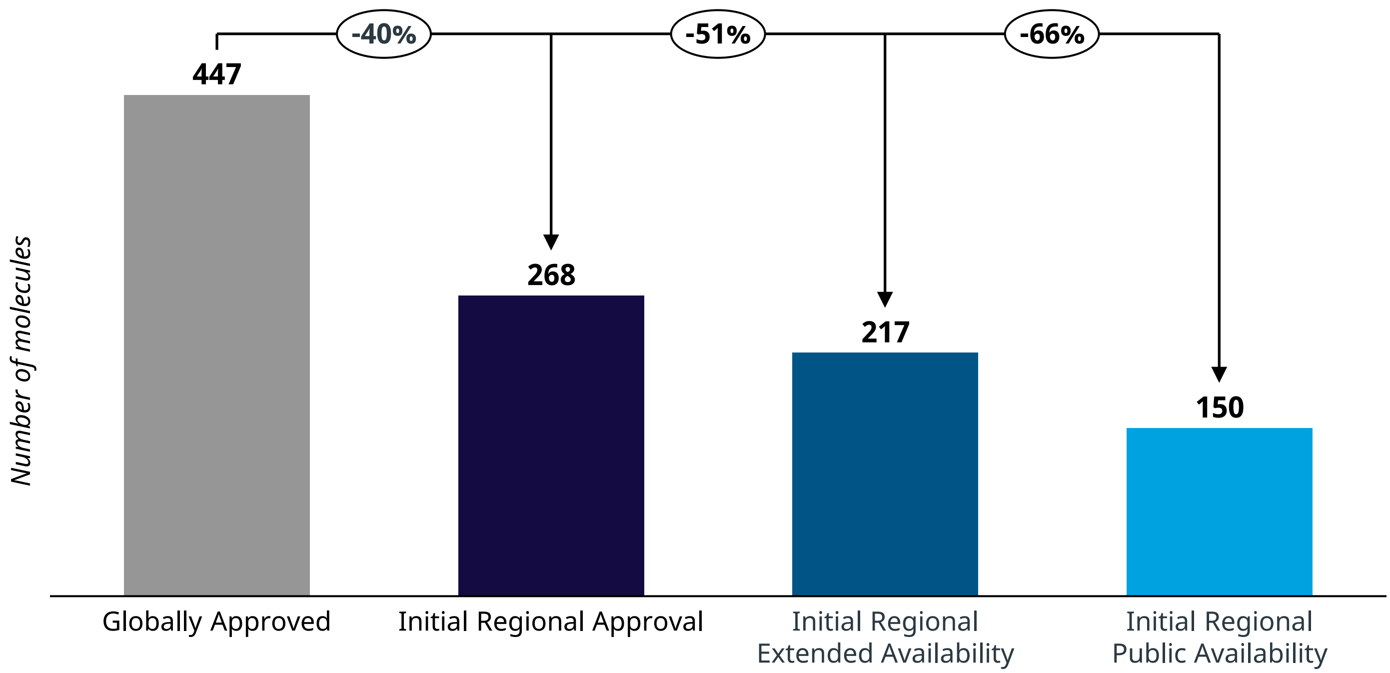
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

Sources: IQVIA – Global R&D Trends 2026

There are significant barriers to accessing innovation

Regional availability is broken down into subtypes, with <50% of molecules included in the study available in at least one country regionally considering either public or private coverage

Breakdown of Initial Regional 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
- Overall, there is a large gap between globally approved molecules and those that become available in the region in even just one country, reflecting review backlogs, HTA and pricing delays, and challenges in translating global approvals into local access
- Out of 447 molecules, 60% of these are approved for commercialization in at least one of the ten LATAM countries in scope
- 49% have extended availability, meaning these molecules have some level of availability between public (full or limited) and/or private markets in at least one country, often affected by timing of HTA decisions, pricing negotiations and reimbursements
- 34% of globally approved molecules are available publicly, whether that be limited or full availability, in at least one country in the region
- Drivers of lower rates of approval and availability include: regulatory backlogs and lengthy submission and review processes, HTA assessment timelines and pricing negotiations delaying extended availability, funding constraints and procurement processes limiting public-sector availability

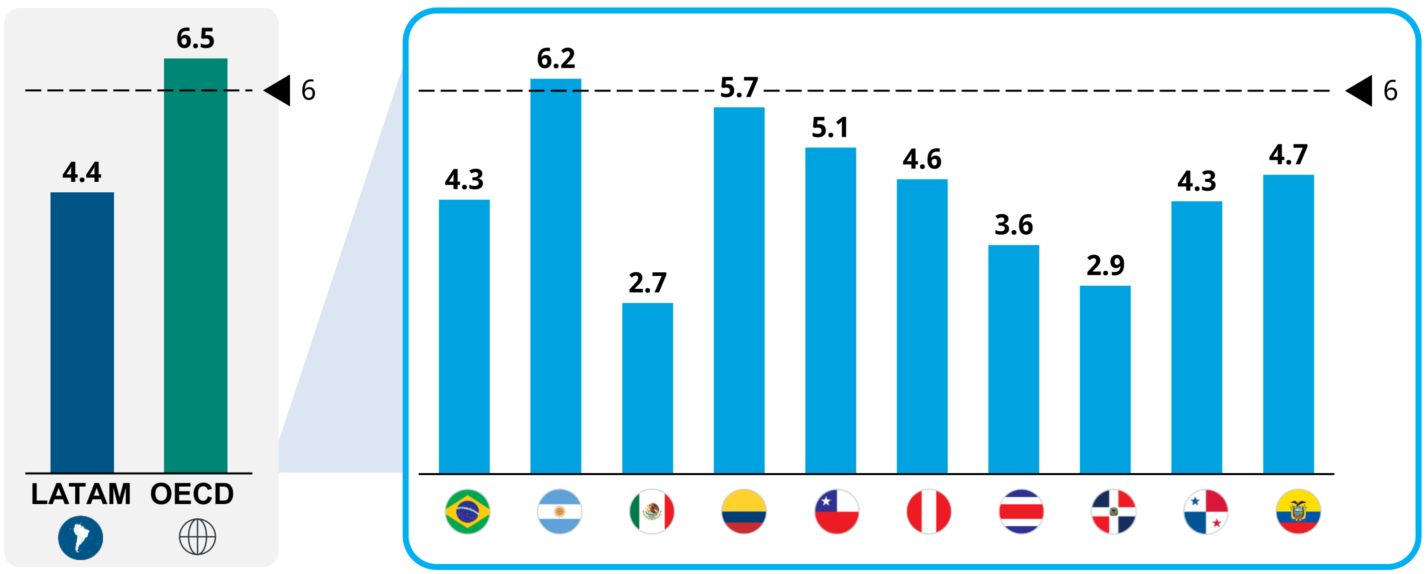
Patients across LATAM have access to almost half of the globally available innovative medicines in the private sector, that trend is worsened when looking at the public sector where the majority of patients are covered

Acronyms: HTA: Health Technology Assessment

LATAM’s health spending is below the OECD target

Public spending on health as a proportion of GDP remains below 6%—the benchmark recommended by the WHO—as well as below the average for OECD countries

Average Public Spending on Health (% of GDP)



- Public spending on health across LATAM remains materially below international benchmarks. WHO recommends that countries allocate at least 6% of GDP to health to ensure universal health coverage and adequate service delivery, while the OECD average stands at approximately 6.5%
- Most LATAM countries fall short of these thresholds, with some operating on budgets closer to 4–5% of GDP. Even among higher-income countries in the region, health spending as a share of GDP often lags behind global peers with comparable economic development
- This underinvestment has profound system-level consequences. Limited budgets constrain the capacity of regulatory/HTA agencies and procurement systems to evaluate and incorporate innovative medicines in a timely manner
- Chronic underfunding also affects workforce availability, infrastructure, and the ability to maintain robust supply chains and distribution networks. These structural weaknesses slow decision-making, reduce transparency, and create bottlenecks across the access pathway
- Over time, underinvestment in health is likely to translate into worse health outcomes, avoidable disease progression, and greater downstream healthcare costs

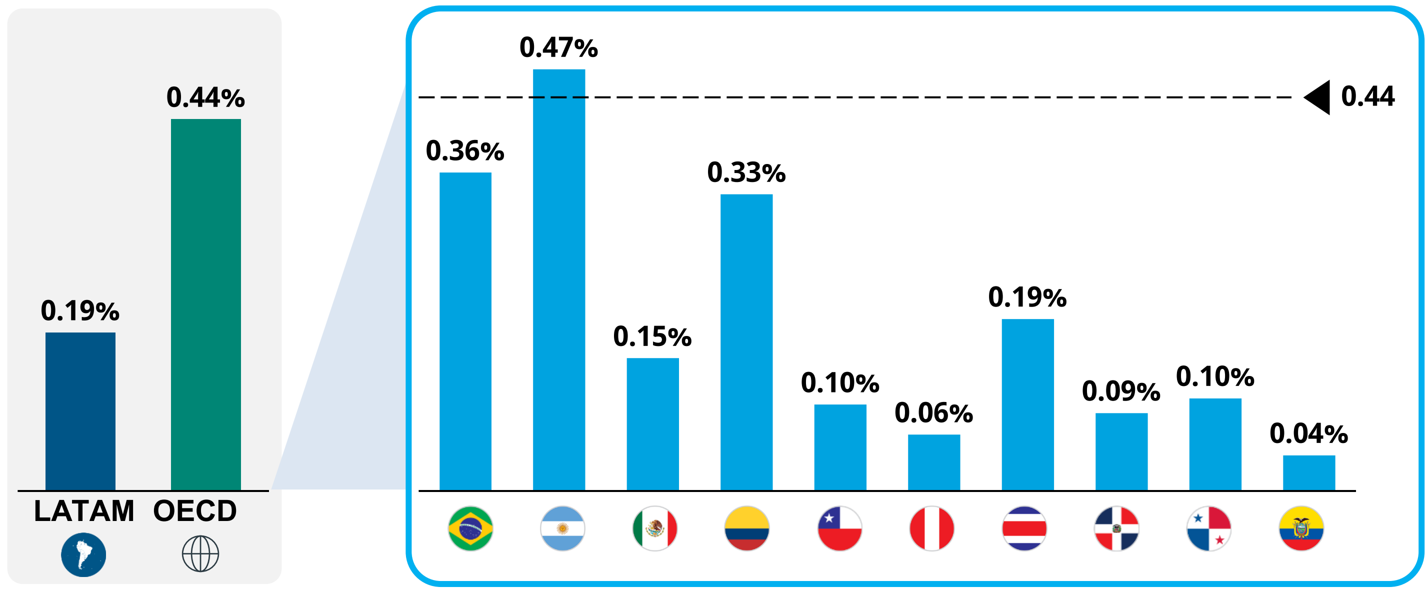
Underinvestment in health limits both system capacity and population reach, creating structural barriers to timely and equitable access

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

There is a similar trend for innovative treatments

Latin America falls even further behind the OECD, highlighting that the most innovative and high-value therapies face additional access barriers in the region

Average Public Spending on Innovative Treatments – WAIT (% of GDP)



- Public expenditure on innovative medicines in LATAM is materially lower than in OECD. On average, countries in the region allocate approximately 0.19% of GDP to innovative treatments, compared to around 0.44% across OECD nations
- This disparity reflects both overall lower health spending and conservative prioritization of budget allocation toward newer, higher-cost therapies. Variation within the region is also pronounced, with some countries investing closer to OECD levels while others dedicate a fraction of that share
- Low spending on innovative medicines directly constrains capacity to incorporate technologies; budget limitations force stricter prioritization, often favoring therapies with higher certainty or lesser budget impact
- Beyond immediate access, this also reflects challenges in aligning financing models with the realities of modern medicine, where value may be delivered upfront or over long-time horizons though with high uncertainty, and where traditional cost-effectiveness frameworks may inadequately capture broader benefits

"Health is not the priority; it is viewed more as a burden or an expense—rather than as it should be: an investment."

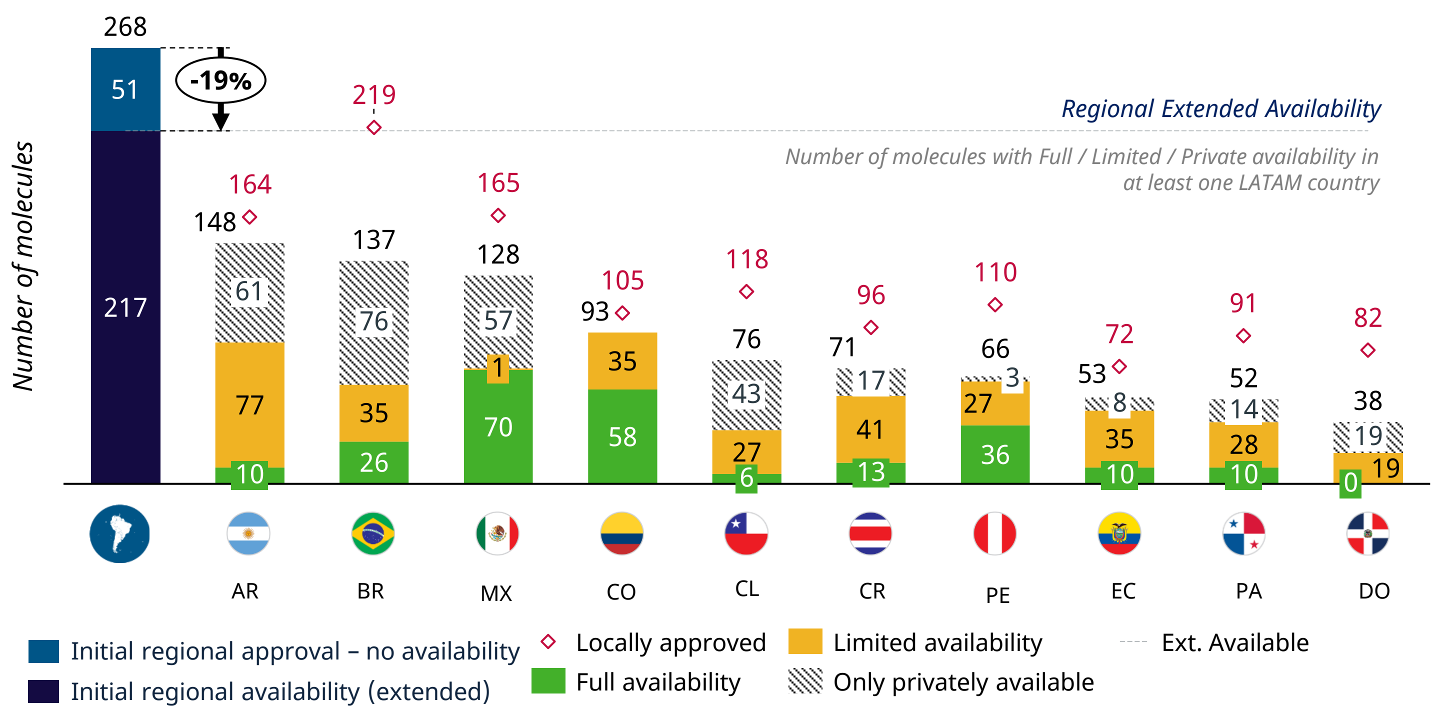
- ex-Minister of Health

Acronyms: OECD: Organization for Economic Co-operation Development

Availability rates vary widely by country

Brazil drives initial regional approval, Colombia has 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

*See appendix for further detail

- 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

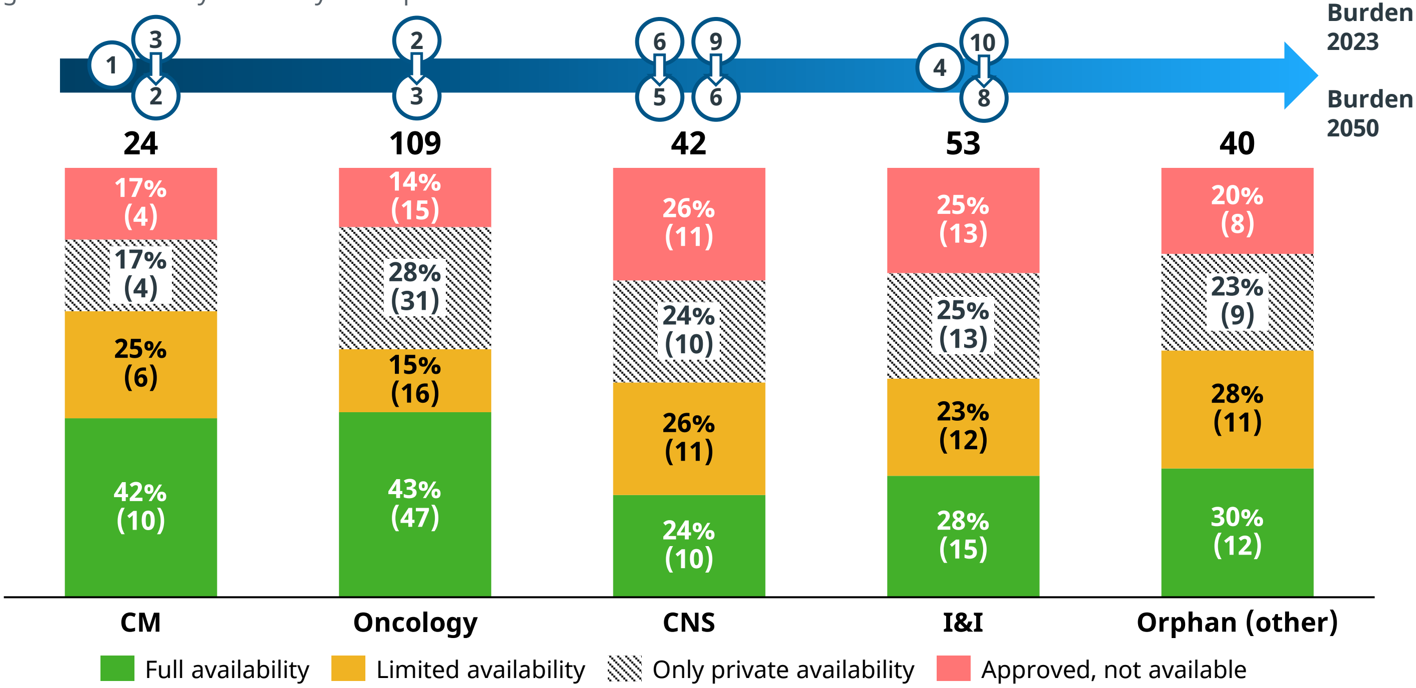
Patients face different challenges by country: where private coverage is high it affords better access but for a subset of patients, whereas where there is a high rate of public coverage, typically there are fewer molecules available, heightening inequalities

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

Significant differences also exist by therapeutic area

CNS and I&I exhibit lower full availability of approved treatments, while CM and oncology demonstrate broader access, even if a significant portion of oncology access is supported privately

Regional Availability Status by Therapeutic Area



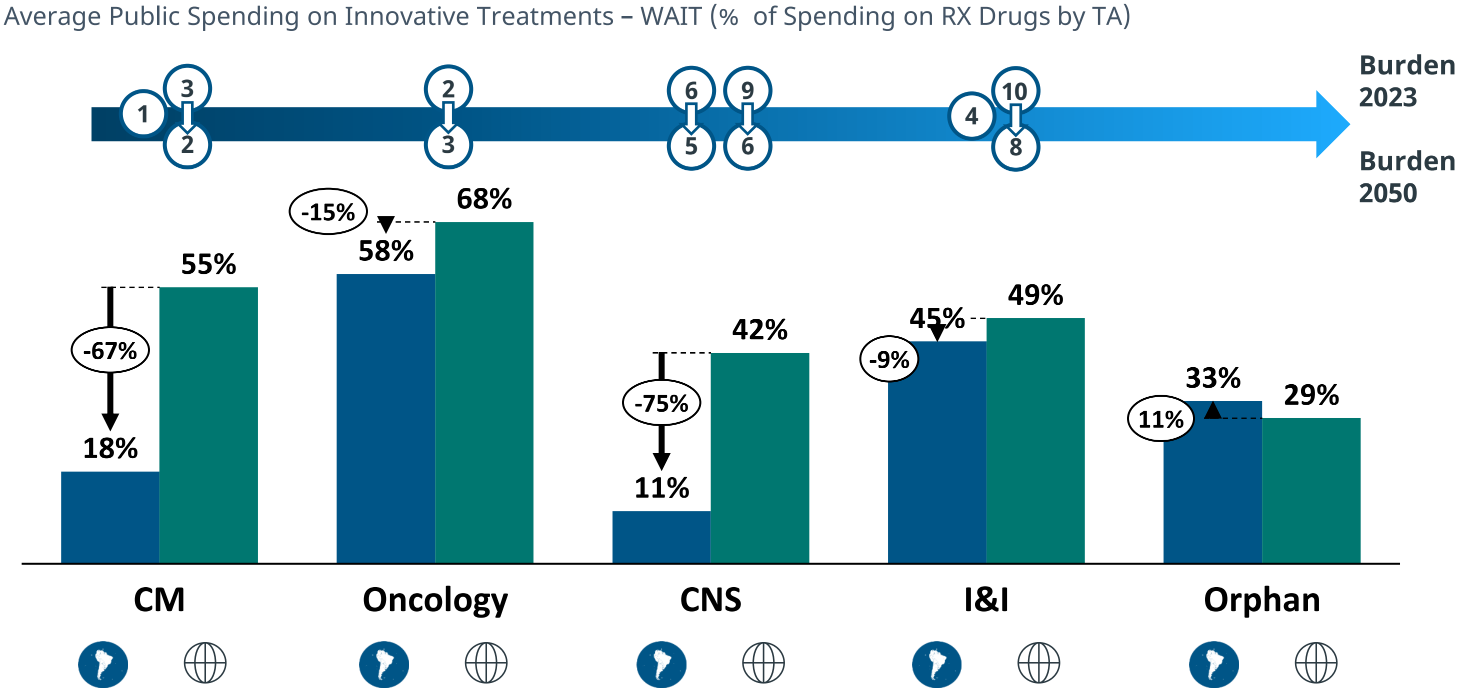
- Access varies materially by therapeutic area, with CM and Oncology showing the broadest access among approved treatments. Oncology has the highest full availability share at 43%, while CM is close behind at 42%, indicating relatively stronger conversion of approvals into access
- Oncology's stronger access profile is partly offset by a heavy reliance on private access. While Oncology has high full availability, 28% of approved treatments remain only privately available, suggesting that headline access overstates the extent of broad, equitable patient reach
- CNS and I&I lag in broad access, with lower full availability and a larger share of treatments remaining constrained
- CNS shows only 24% full availability, with the remainder spread across limited availability (26%), only private (24%), and approved but not available (26%); I&I performs somewhat better but still reaches only 28% full availability
- Orphan in the middle: meaningful progress, but broad access remains limited. Full availability reaches 30%, yet 48% of approved treatments are still either limited (28%) or approved but not available (20%), underscoring persistent access friction even after approval

Therapeutic area remains a major determinant of access: CM and Oncology show broader availability, but Oncology still depends heavily on private channels, while CNS and I&I continue to face more constrained access even after approval

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

The trend in public spending differs from that of access

Public spending in Latin America is lower—in some cases significantly so (CM/CNS)—compared to the OECD average, while the spending on orphan diseases is higher



- Public spending on innovative treatments in LATAM remains materially below OECD levels across most major therapeutic areas, reflecting constrained budgets and conservative prioritization
- In CM disease, LATAM public systems spend ~67% less than OECD countries, the widest gap observed. CNS disorders show a similar pattern, with LATAM at roughly 11% vs OECD's ~42%, underscoring limited public investment despite rising disease burden in these areas
- The gap narrows in oncology, where LATAM reaches approximately 58% compared with OECD's ~68%, and in I&I, where the region achieves roughly 45% vs ~49% in OECD markets
- Notably, orphan diseases represent an exception, with LATAM at approximately 33% vs OECD's ~29%, suggesting relatively stronger public commitment in select markets or therapeutic categories, though absolute availability for rare diseases remains limited as shown in prior analyses
- These disparities reveal how budget constraints and prioritization decisions shape which innovations reach patients. Therapeutic areas with the largest gaps represent major contributors to regional disease burden, yet public systems allocate proportionally less to their innovative treatments

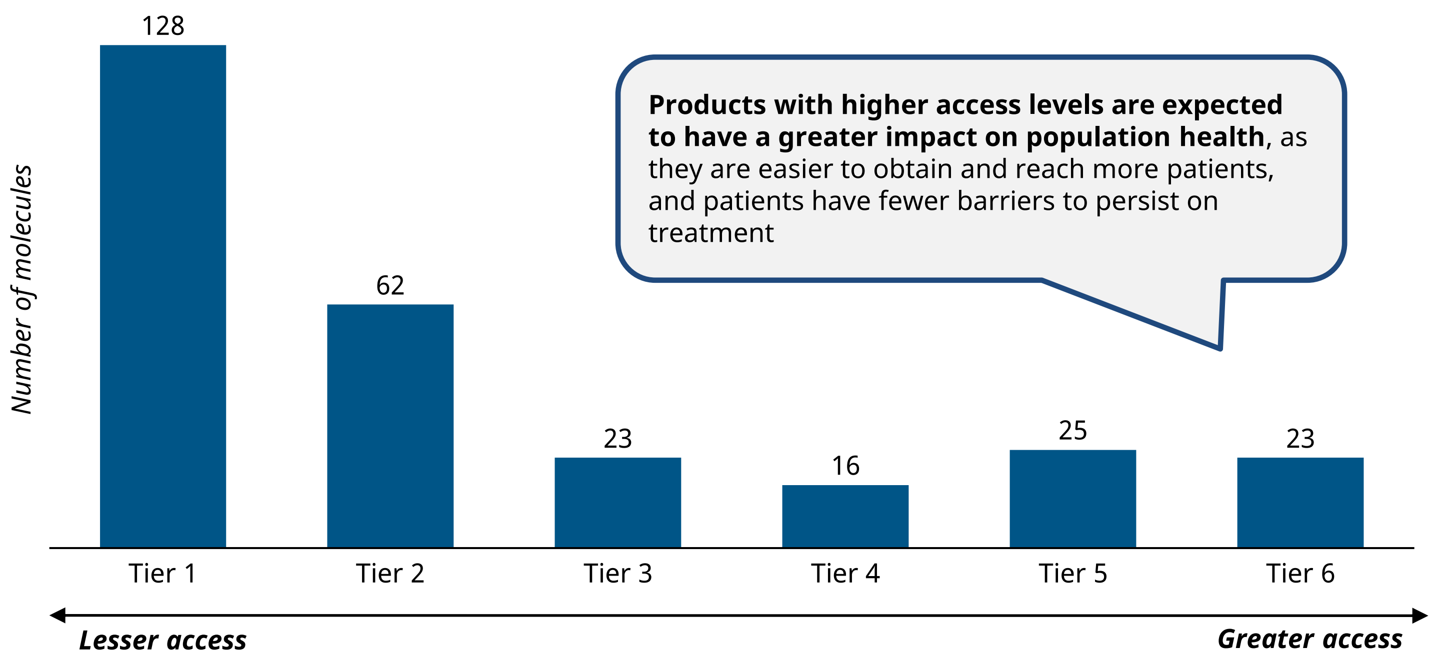
LATAM's TA spending gaps highlight misalignment between burden, innovation availability, and public investment priorities

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

Access is concentrated among a few molecules, limiting reach

Only a small subset of innovative molecules achieve broad access; the majority remain at lower access tiers, limiting real-world impact and deepening inequities

Access Level of Regionally Approved Molecules – WAIT 2026



- The access levels shown above reflect both a product's availability in a given country and said country's extent of healthcare coverage
- Access remains heavily skewed toward the lowest tiers, with Tier 1 alone containing 128 molecules, by far the largest concentration in the distribution and reflective of significant gaps in availability post-approval
- Tier 2 is the second largest group at 62 molecules, reinforcing that a substantial share of regionally approved products are available less-than fully, in a subset of countries (usually BR/MX/AR)
- The sharp drop from Tier 2 to Tier 3 (62 vs. 23 molecules) suggests that relatively few products transition from approval /private availability, into meaningful population-access levels in a critical mass of countries

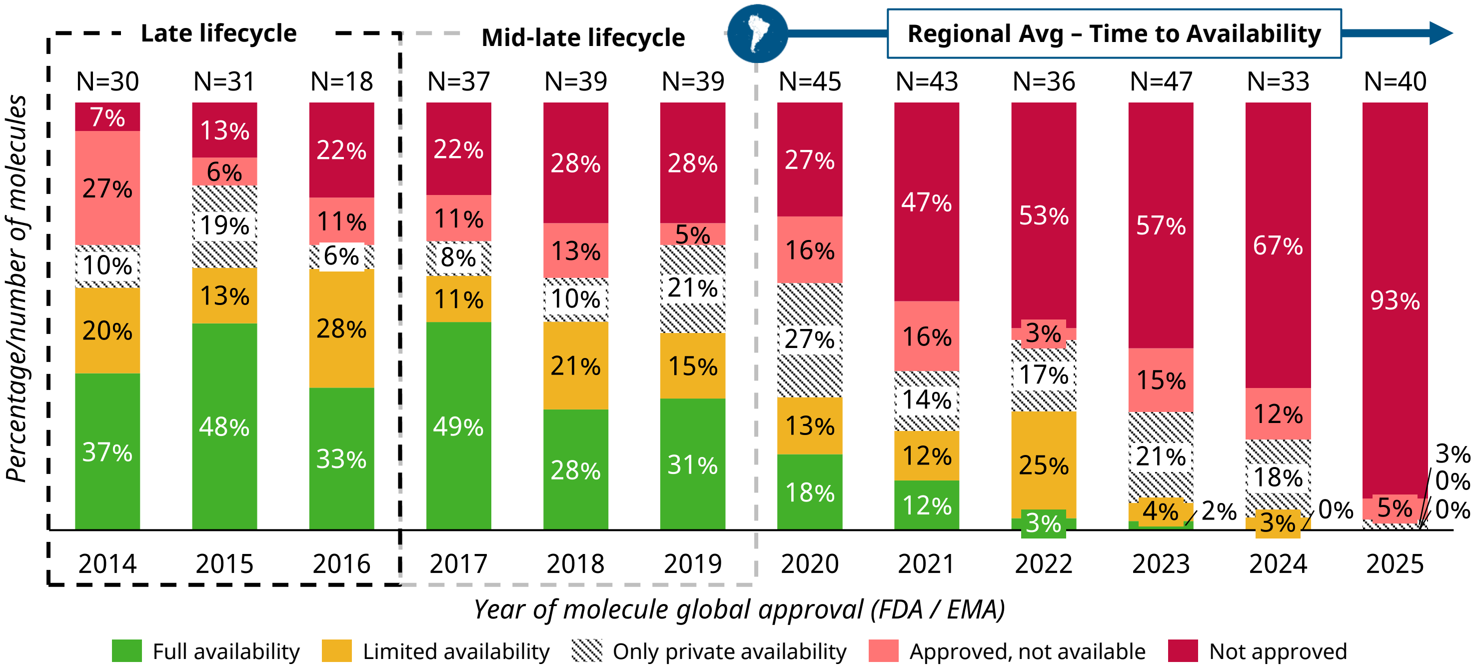
- Access level is not just a product level measure; it also reflects each country's healthcare coverage, meaning lower-tier concentration points to barriers to patient reach
- The real-world impact of innovation is likely constrained not only by whether a molecule is approved, but by whether it can move into the upper tiers where access becomes materially broader

The imbalance across tiers suggests that innovation is entering the region, but its effective reach remains concentrated among a narrower subset of molecules that successfully convert approval into broader access

Access focuses on medications launched before 2020

Regional availability drops drastically after 2020, with less than 50% medications available from 2021 onwards

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



- The overall trend, shows a general decrease in public availability and increase in molecules not approved from 2014-2025. Even older molecules have not achieved universal availability. Products approved between 2014–2018, now well beyond launch and clinical maturity, continue to show fragmented access, demonstrating that time does not automatically translate into broad availability
- The highest variability, besides molecules not approved, is derived from broad public availability ranging from 49% for molecules that received global approval in 2017 where it's at its highest, to 0% in 2024 and 2025, highlighting the significant hurdles in reaching the broader population
- Private availability and limited availability percentages do not have such wide ranges at a regional level, with only privately available molecules ranging from 6% in 2016, to 27% in 2020, and limited availability ranging from 0% in 2025 to 28% in 2016, though this trend varies significantly between countries
- Systems are not catching up to past innovation peaks, the sustained presence of older molecules in lower access tiers points to a growing backlog, where newer launches accumulate on top of unresolved access gaps

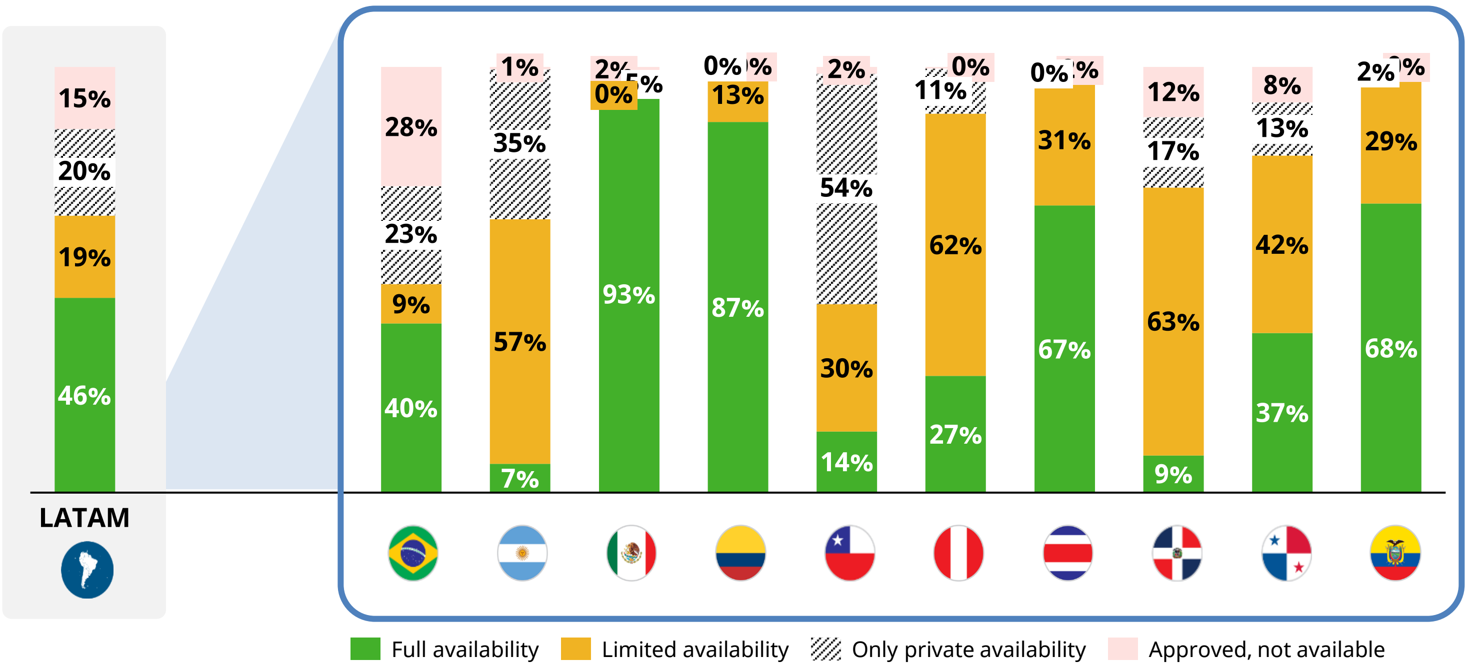
"These technologies being incorporated are older, and I don't know how we can get to the newer ones; there's a backlog."

- ex-Minister of Health

There is disproportionate public spend by availability status

Public expenditure should be highly concentrated across public-availability status, however in some countries the spend on molecules not publicly available indicates high use of legal injunction

Public Expenditure on Innovative Treatments – WAIT 2026 by Availability Status (% of Total Expenditure)



- In a well-functioning access system, public spending on innovative medicines would be concentrated in categories with full or broad availability, reflecting coordinated decision-making and transparent reimbursement. However, across LATAM meaningful public expenditure is observed even in lower availability tiers. This suggests that spending does not flow exclusively through planned, formulary-based channels but also occurs widely through alternative access pathways

- Alternative mechanisms (e.g., patient groups, judicial orders, exception protocols) can enable access outside formal frameworks, creating unpredictability and lacking traditional transparency, cost control, and equity safeguards. Over time, susceptibility to these pathways can undermine budget planning, distort prioritization, and delay systemic reforms; it is also a highly inefficient spend

- This misalignment also reflects inefficiencies. It unveils a paradox where systems are funding innovation but not capturing it within official metrics or governance structures, limiting accountability and making it difficult to assess if spending achieves intended health outcomes

"When spending is insufficient, it becomes inefficient."

- ex-Minister of Health

The challenges associated with low investment are varied

Limited resources cause significant gaps in health systems in the region, which in turn lead to drawn-out processes as a result of saturation, and insufficient means to handle high uncertainty

Key Challenges Associated with Underinvestment

Institutional Capacity

01

"Processes are reduced to mere documentation; it is not a real, technical evaluation."
- ex-Minister of Health

Consistency/ Coordination

02

"We don't know where the process stands, when to expect a response, or whom to contact... we're stuck."
- Access Director, Int'l Lab

Competitivity

03

"Submitting entails investing in personnel, production, and HCPs —only to then have to fight for its incorporation into clinical guidelines and then on top of that, infrastructure isn't there... Given such uncertainty, it's tough to reach patients."
- Access Director, Int'l Lab

- Low investment in health systems generates cascading challenges across three interconnected dimensions. Institutional capacity is constrained by limited human resources with uneven experience and expertise to carry out processes, alongside digital infrastructure still under development. This undermines the ability to manage rising volumes, assess complex evidence, and make timely, evidence-based decisions. The result is prolonged review cycles, inconsistent evaluations, and growing backlogs that delay access

- Consistency and coordination are weakened as underinvestment limits transparency around evaluation criteria and decisions and reduces structured interaction among ecosystem actors, fragmenting pathways and increasing uncertainty for patients and stakeholders. The lack of clear pathways complicates planning and undermines trust in the ability to deliver equitable access

- Competitiveness is undermined when commercialization conditions remain risky or unpredictable. Opaque processes, uncertain timelines, and constrained budgets dampen incentives and capacity to invest, prompting delayed launches, narrower indications, or market deprioritization

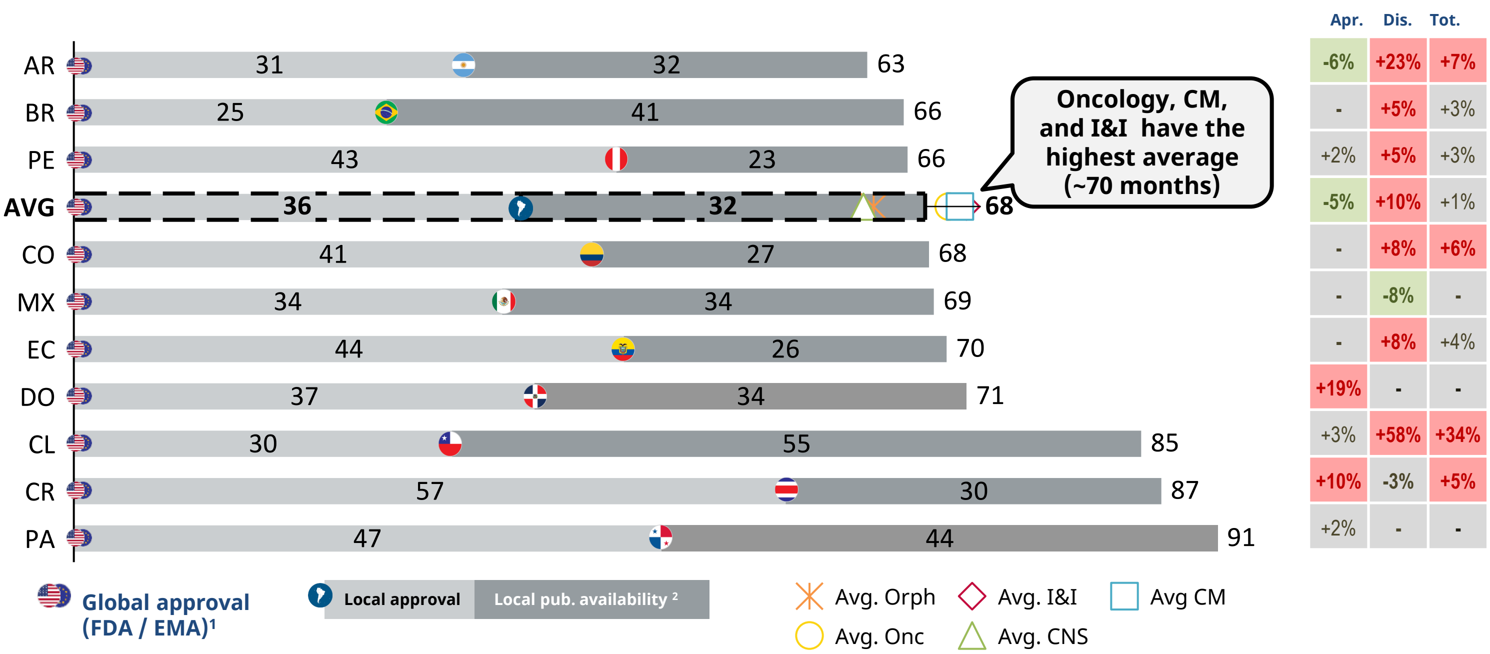
- Together, these dynamics reinforce a cycle in which low investment diminishes capacity, coordination, and confidence, constraining access today and discouraging the investment needed to improve access tomorrow

Low investment weakens institutions, fragments processes, and deters innovation participation, compounding delays and limiting patient access

Access is a long and fragmented process

The time to availability averages 5.7 years, with a time to approval of 3 years and a time to availability of 2.7 years

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



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

- The average time to local approval is 36 months, 3 years after global regulatory approval (first of FDA or EMA), though this does not consider at what time the laboratory filed a submission
- Wide disparities exist across countries in both approval and availability timelines, although in total, most of them are close to the average of 68 months for the region, with only Panama as an outlier at 91 months reflecting uneven system readiness and access processes
- The average time from local approval to first availability is 32 months, or ~2.6 years; this considers between the date of local approval and the date of first availability (public or private), and only considers the first indication
- Countries differ greatly in time to availability after local approval. Peru sees formulary listing relatively shortly, at an average of 23 months, whereas Chile and Panama are toward the high end, above 3.5 years
- Though both approval and availability timelines vary by country, overall time to availability ranges from approximately 5- 6 years across the region
- Differences in regulatory capacity, process maturity, funding, and purchasing delays likely contribute to this fragmented pathway

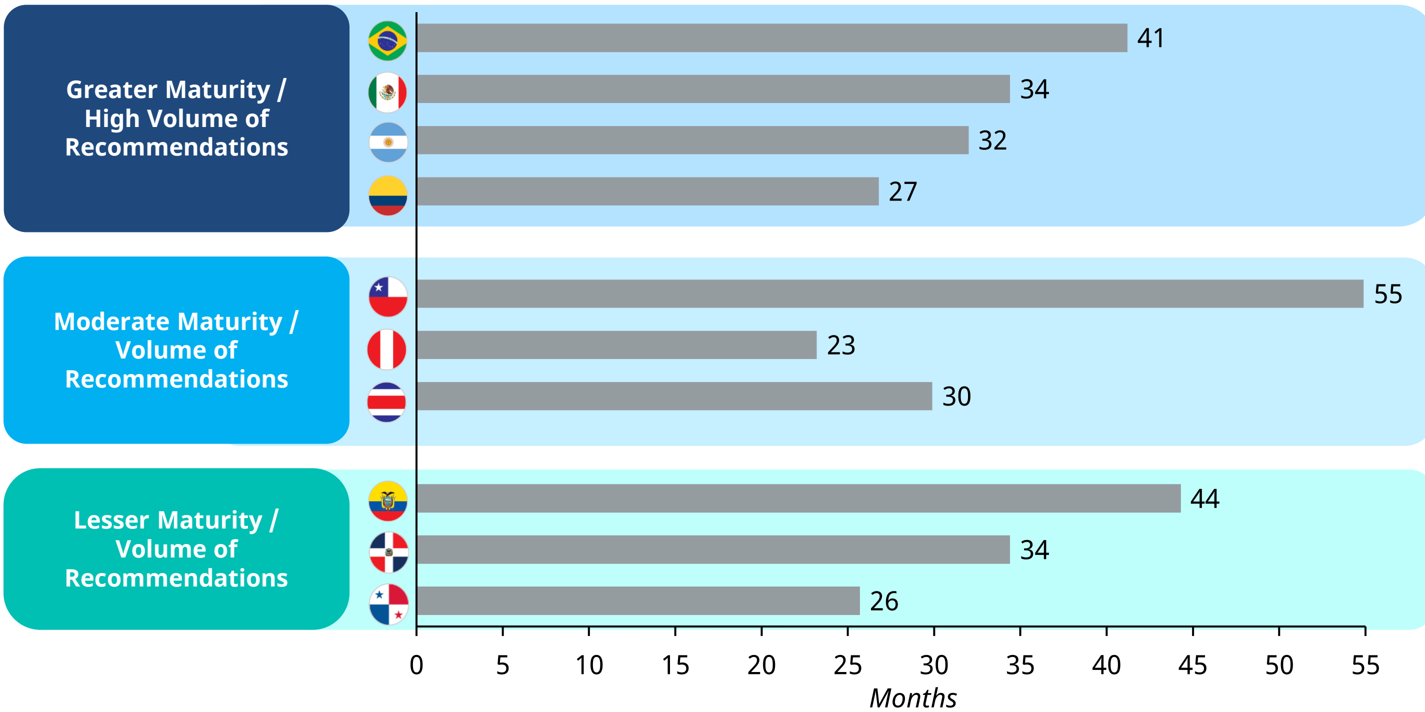
First availability captures only a small part of the patient experience, as for many molecules it marks access to only an initial indication and often only for a limited subset of the broader eligible population

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

Saturation results in longer processes

The maturity of HTA improves consistency, but may slow down access if adequate resources are not available

Time to Availability Based on the Maturity of Evaluation Processes



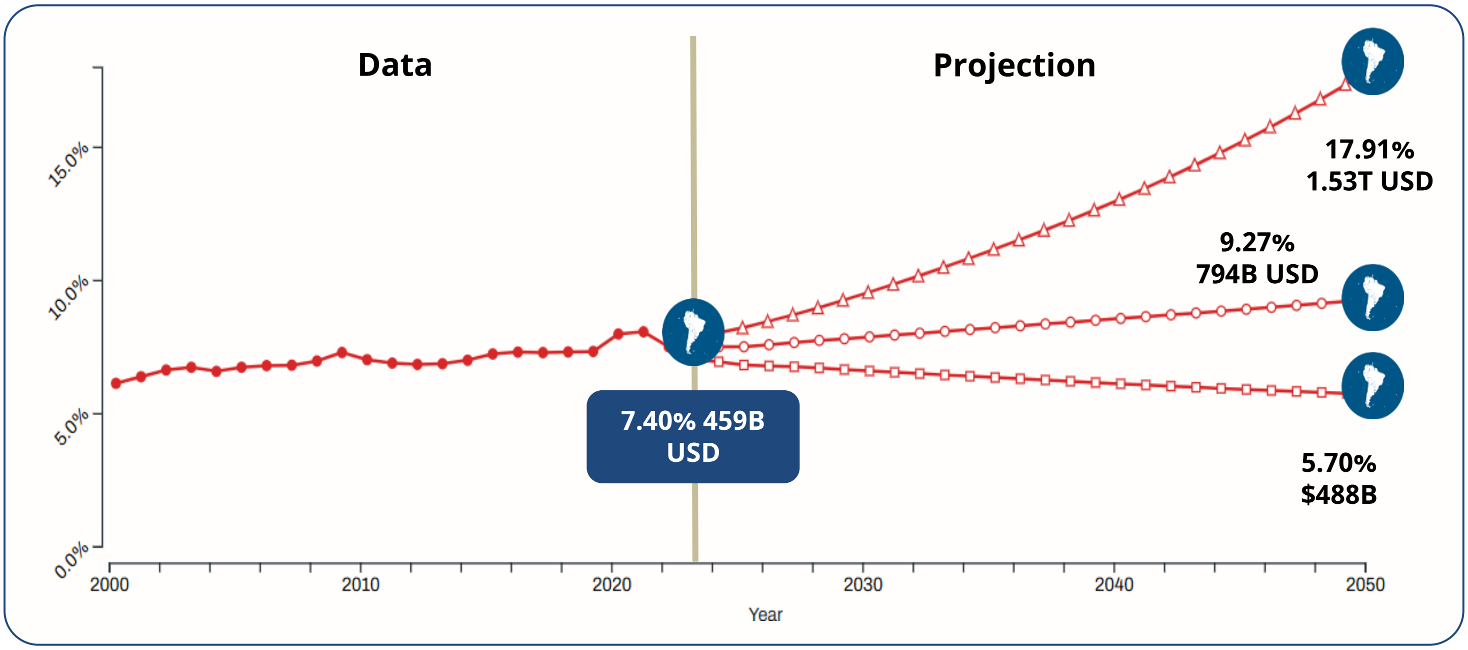
- The relationship between innovation volume and timelines is mediated by a system's maturity, specifically, design and resourcing of its processes
- More mature systems (i.e., longer track record) typically employ formalized review structures, clear criteria, and standardized pathways that reduce subjectivity and improve transparency. However, processes may become bottlenecks when capacity does not scale with demand, leading to backlogs and extended wait times despite procedural rigor
- In contrast, less mature systems, characterized by less structured processes, may achieve faster initial decisions in some cases. However, it often comes at the cost of consistency, transparency, and predictability. Over time, these systems may struggle to manage complexity or rising volumes, leading to delays or stagnation without procedural safeguards that mature frameworks provide
- This dynamic highlights a critical trade-off: maturity brings rigor and equity, but without adequate resourcing it can slow access; informality may enable short-term speed, but undermines long-term sustainability
- Addressing saturation in mature systems requires investment in capacity, expanding personnel, upgrading information systems, and optimizing workflow prioritization. For less mature systems, the path forward involves strengthening governance and process design to balance speed with consistency and transparency

Maturity enables rigor but can delay access under saturation; optimizing capacity, prioritization, and process design is key to balancing both

The growing burden of disease creates divergent scenarios

The baseline forecast projects an increase in health expenditure to 9.27% by 2050 in the region

Total Health Expenditure for All Causes (Expenditure as % of GDP - (2000-2050)



- Health expenditure in LATAM is projected to rise substantially over the coming decades, driven by aging populations, rising non-communicable disease prevalence, and increasing uptake of innovative treatments
- Under a baseline scenario, which assumes current policy trajectories and moderate investment growth, health spending as a share of GDP is expected to increase from ~7.4% today to ~9.3% by 2050. However, this trajectory is sensitive to policy and system design choices
- An alternative lower scenario, reflecting constrained budgets and limited innovation uptake, would see spending stabilize near 5.7% of GDP, while a higher scenario, incorporating universal health coverage expansion and broader access to innovation, could push spending toward 17.9%

- In the near term (2025–2030), systems will face pressure from complex, high-cost therapies amid tight budgets and political volatility. Without capacity-building, bottlenecks will intensify and access gaps widen
- In the mid term (2030–2040), rising chronic demand will require aligned financing and capabilities. Failure to plan risks fiscal stress and deepening inequities
- In the long term (2040–2050), sustainability will depend on maturity and spending efficiency. Optimized processes and integrated innovation will achieve better outcomes per dollar

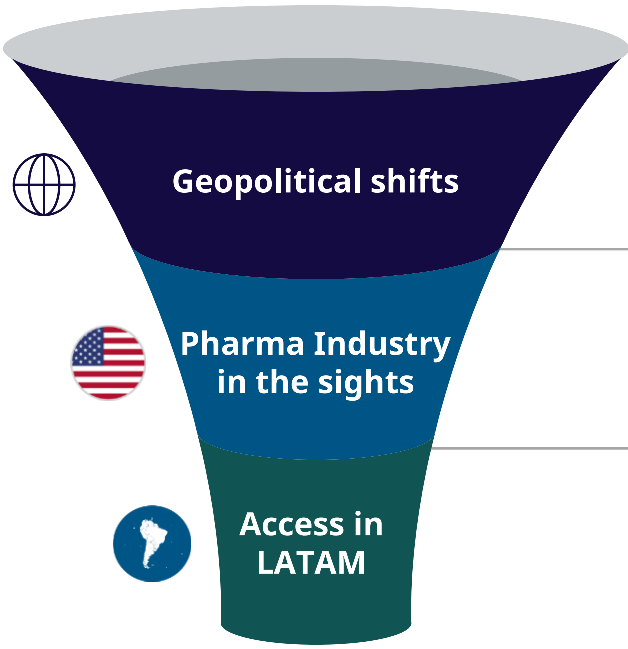
Increasing investment in systems is critical to avoid exponential growth in future expenditure; sustainability depends on governance, prioritization, and efficiency to align investment with impact

Acronyms: GDP: Gross Domestic Product

2025 & 2026 have brought significant change, and opportunity

Amidst global changes, the opportunity in the region can be repositioned to attract investment and stimulate the sector

Key Recent Market Changes Influencing the Pharmaceutical Landscape



2025: A New Global Geopolitical Order

Pressure on Global Drug Prices

A Different Approach for LATAM

- The global landscape is undergoing significant transformations which are prompting stakeholders to reassess dependencies and diversify supply, creating opportunities for LATAM to position itself as a strategic partner
- At the geopolitical level, recent US policy changes have marked the end of the post–Cold War and altered the industry's status quo through tariffs and withdrawal from key international bodies. This introduces volatility into global trade and supply chains, but also opens space to reassert strategic autonomy and negotiate new partnerships
- At the same time, the pharmaceutical industry faces intensified scrutiny, with a global lens on R&D spending and the "Most Favored Nation" approach exerting downward price pressure in developed markets, prompting companies to reassess launch sequencing and pricing strategies
- While LATAM is not explicitly referenced in MFN frameworks, it is receiving increased attention within broader National Security Strategy discussions, particularly around resilience and nearshoring. As laboratories seek alternatives to mitigate MFN impacts, the region is gaining relevance for differentiated pricing, partnerships, and investment
- These shifts create openings for LATAM countries to position themselves strategically, leveraging regulatory maturity, market size, and geographic proximity to attract investment and negotiate more favorable access terms

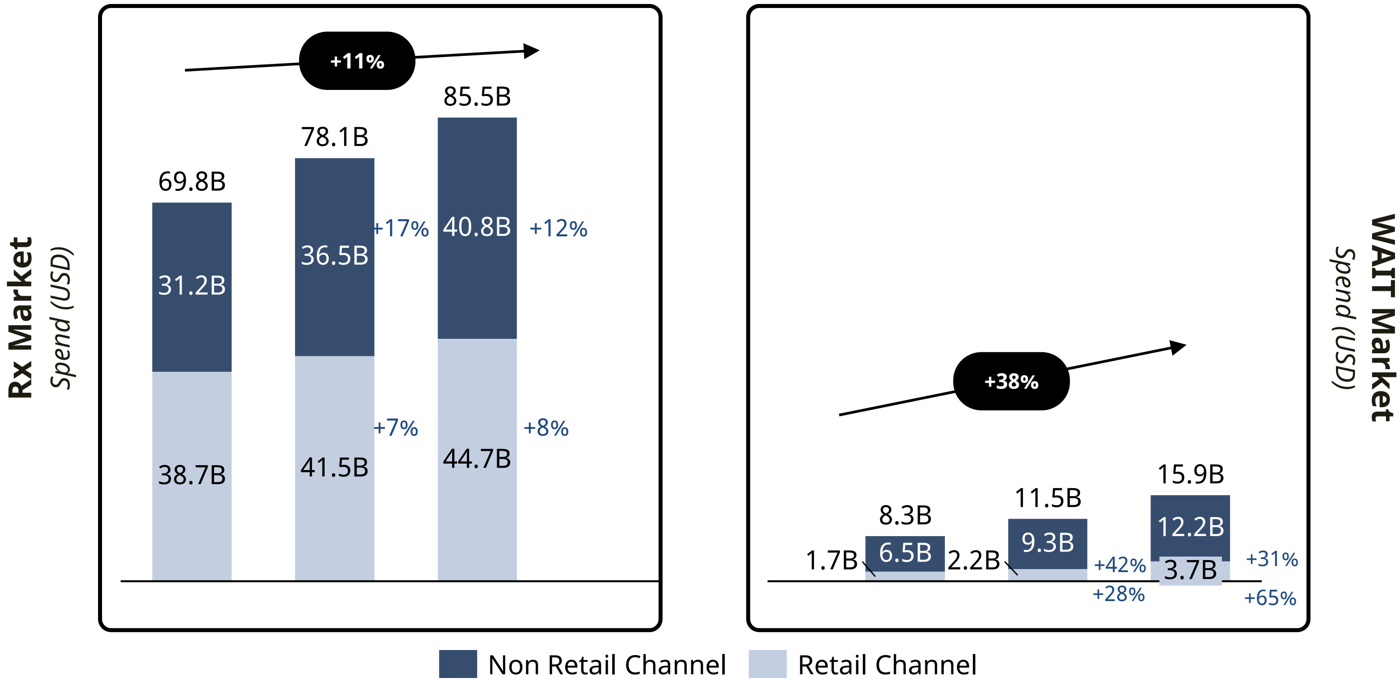
Global shifts in developed markets are reshaping pharma strategies, creating an opportunity to improve LATAM's positioning in the global pharma sector

Acronyms: R&D: Research and Development; MFN: Most Favored Nation

There has been growth in spending over the last three years

Spending on innovative treatments has increased considerably over the past two years, with institutional purchases assuming greater significance

Prescription Rx and WAIT Market Spend – MAT Oct 2025



- Pharmaceutical spending across LATAM has grown significantly, reflecting increased incorporation of innovative therapies and evolving treatment paradigms. Total prescriptions expenditure has risen 11%, while spending on medicines in the WAIT cohort has grown almost 40% over 3 years
- Much of this growth is driven by non-retail, institutional channels, rather than traditional retail pharmacy. This shift reflects the nature of recent innovation (e.g., biologics, specialty therapies) which are administered in controlled settings and managed through centralized purchasing
- The entry of high-cost biologics, precision oncology agents, specialty immunomodulators, and advanced therapies is starting to shift the composition of spending, though it is still a recent trend with older technologies dominating

- The implications are multifaceted. On one hand, rising spending signals improving access to innovation and greater willingness by payers to invest in newer treatments. As budgets expand to accommodate costly therapies, systems must ensure that spending growth is matched by governance capacity, monitoring and administration to ensure spend is strategically administered to maximize benefit, and continue expansion

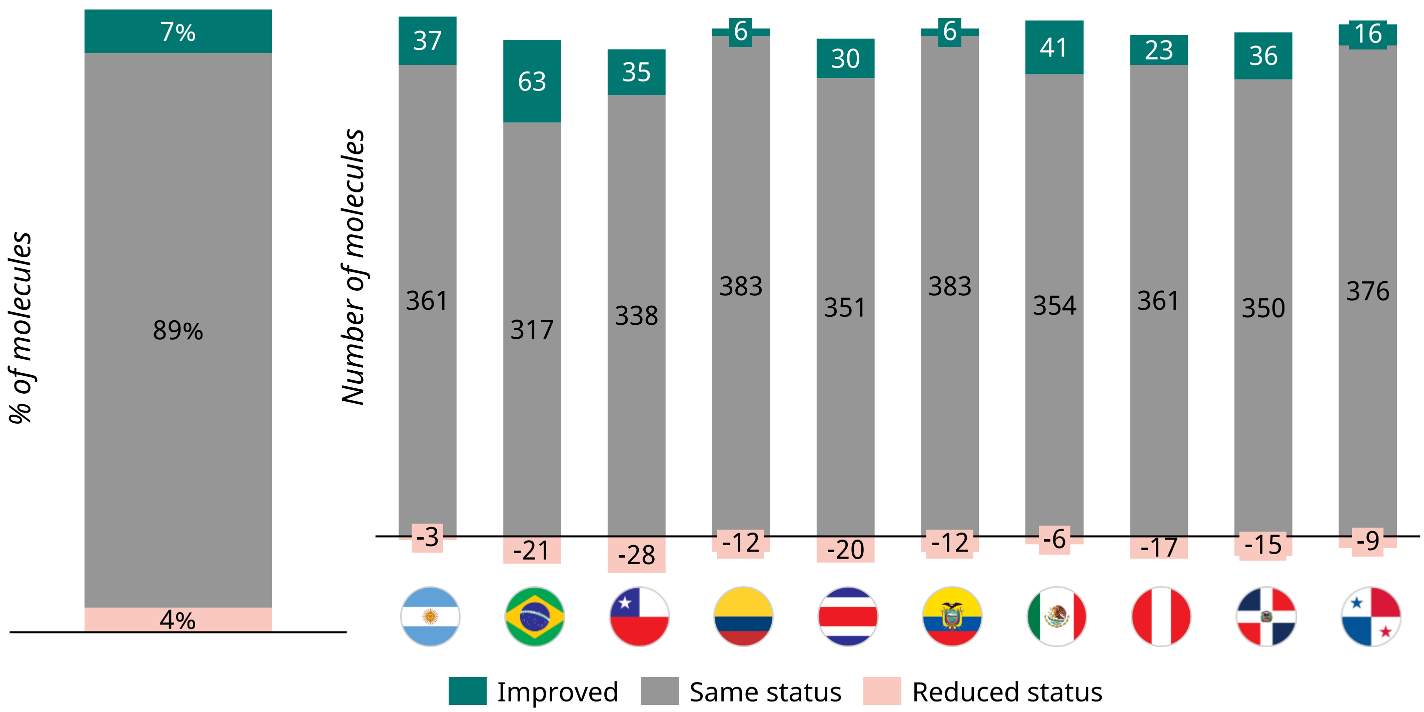
Rising innovative treatment spending signals progress but demands governance, prioritization, and equity to ensure sustainable, broad patient impact

MAT Oct 2025 – USD Fixed Price (Brasil, Mexico, Colombia, Chile, Costa Rica, Peru, Dominican Republic, Panama) and USD Mix Price (Argentina); Acronyms: MAT: Moving Annual Total; Sources: Fifarma – Drug Spend

Improvement index

7% of molecules advanced in access compared to 2024-2025; BR and MX R stood out in terms of improvements, together with CR/DR while CO shows a noticeable slowdown from previous years

Improvement Index by Country (2026 vs 2025)



- Overall, movement between availability status classifications varied by country, with Brazil leading in access expansion with 63 improvements
- Mexico and Argentina saw a consistent upward trajectory with a high net access gain as political continuity and traction allow for incremental gains
- Costa Rica and Dominican Republic, especially considering the size of the markets, saw considerable gains too, approaching larger markets in terms of net improvement
- Colombia and Ecuador saw near-stagnant progress, reflective of broader systemic challenges that divert attention and political will to healthcare

- Reductions typically reflect changes in access and/or purchases due to competition, redundancies as newer technologies or generics/biosimilars become available, and on occasion, withdrawals from manufacturers

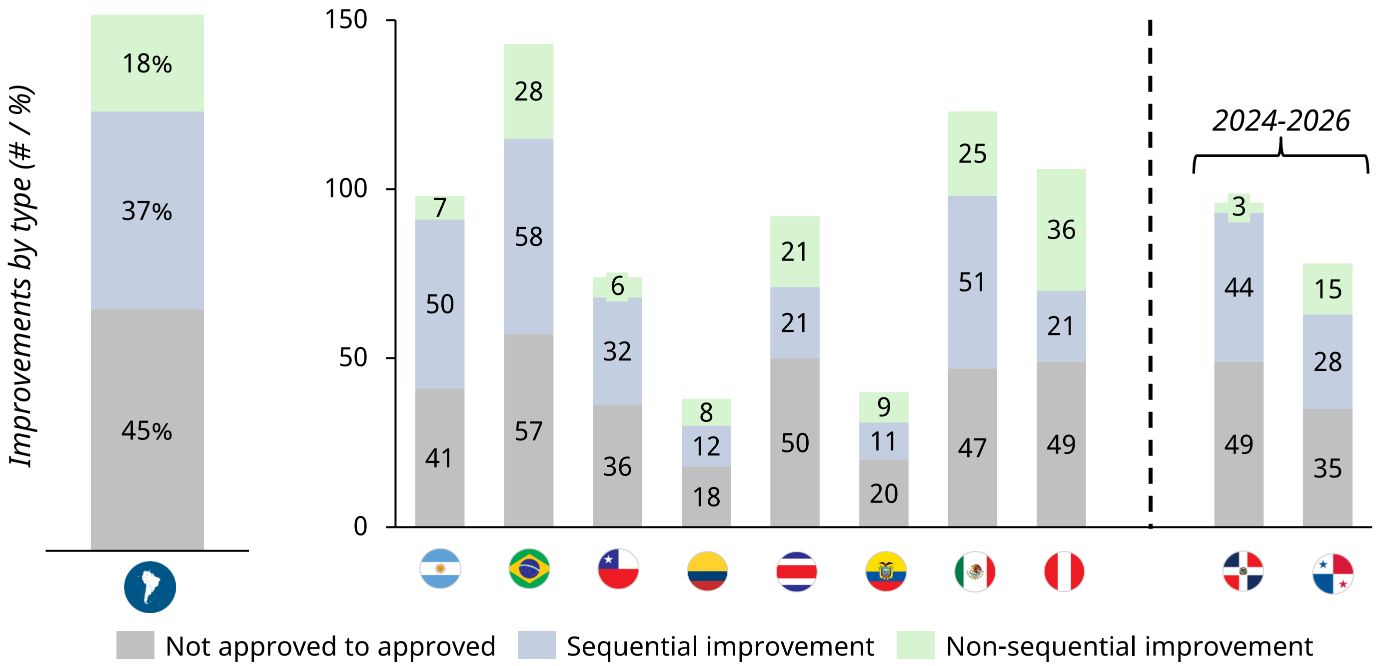
With increasing clinical innovation, regulatory and HTA agencies may have increasing backlogs of assessments, compounding challenges for patients in gaining access to innovative molecules

*See local definitions for further detail

The improvements are primarily sequential

Over 80% of the observed improvements consist of new approvals or sequential access changes, demonstrating a "bottom-up" approach

Cumulative Improvement Index (2023-2026)



- Access improvements in LATAM follow a consistent pattern with most progress coming from new regulatory approvals and sequential movements through availability tiers (bottoms-up)
- Between 2023 and 2026, cumulative improvement has been steady and increasing, with an average of 37% of gains attributable to sequential transitions e.g., approved, not available to privately available, or privately available to limited public availability
- Initial approvals account for ~45% of improvement, reflecting the entry of newer molecules. Non-sequential jumps, remain rare and are concentrated in select markets like Mexico and Peru, where policy interventions or centralized procurement enabled accelerated inclusion
- While sequential processes can provide governance rigor and allow for incremental evidence generation, they also extend timelines
- The cumulative strengthening of improvement over time suggests that systems are gradually incorporating more molecules, though the pace remains slow relative to innovation volume. For manufacturers and patients, this underscores the importance of understanding pathway structure and engaging early across stakeholders to facilitate progression and avoid prolonged periods in lower availability tiers

“With better access, we can manage much of the burden far better; otherwise, it will spiral out of control…”

- ex-Minister of Health

Investment must underpin key activities to drive improvement

It is possible to advance toward a more sustainable state of access by taking these measures today, and striving toward a leap in access as opposed to incremental improvements

Key Strategies Towards Innovation and Access in LATAM

Collaboration

Seek collaboration across countries, sectors, and institutions

Integration

Evaluate current processes and opportunities involving AI

Planning

(Re)-frame vision & roadmap for the future, clearing the backlog

- A path toward more sustainable access is emerging, grounded in three strategic pillars: collaboration, integration, and planning. These levers, if pursued with intent and coordination, can strengthen institutional capacity, improve process efficiency, and align stakeholder interests in ways that translate global shifts into tangible health gains
- Collaboration offers opportunities to pool expertise, share learnings, and coordinate action across borders and sectors. Regional mechanisms (e.g., PAHO, RedEtsa) provide platforms for harmonizing regulatory standards and coordinating procurement. Strategic public-private partnerships can attract investment, accelerate local manufacturing, and enable innovative financing models. Greater integration of the local innovation ecosystem amplifies capacity and creates a virtuous cycle of innovation uptake and reinvestment
- Integration of emerging technologies, particularly AI, presents efficiency opportunities. Use cases in regulatory assessment and HTA can reduce timelines and resource burdens. It also enables re-evaluation of latent opportunities, such as risk-sharing agreements, which can align incentives while managing uncertainty
- Planning is foundational. Immediate interdisciplinary dialogue can break down silos and improve coordination. Reducing short-term saturation through prioritization of technologies and initiatives will prevent backlogs. In the long-term, targeted investments will optimize system potential to manage future innovation waves

Sustainable access advances through collaboration, integration, and planning that reduces saturation and attracts investment

Acronyms: AI: Artificial Intelligence; PAHO: Pan American Health Organization; RedEtsa: Health Technology Assessment Network of the Americas

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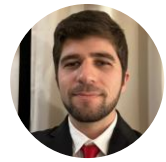
IQVIA Project Team



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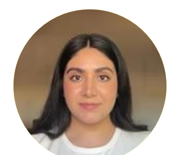

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Local trade associations also supported in the development and validation of the study

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	**CNS**	**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 HTA 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

Argentina - CAEME

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**[1,2,3]	*Multiple national formularies (PAMI and SURGE, or PAMI and PMO formularies) with reimbursement values aligned to treatment cost in case of bundled (e.g., SURGE) National Oncology Drug Bank*	**SURGE** *(Therapeutical Area Bundles Not Always Molecule Specific)* **Drug Banks** *Publicly Available Drug Banks of Relevant Obras Sociales (e.g., IOMA, OSECAC, OSDE)*	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited[1,2,4]	*Listed in at least one of country formularies (e.g., PAMI, PMO, SURGE formularies), and Broad coverage by OSN and prepaid* *Conditions included on SURGE formulary, but with a treatment cost substantially higher than SURGE bundle are considered limited availability*		
	Only Private	*Broad coverage by prepaid plans*		
	Not Available	*ANMAT Approval, no broad coverage by prepaid plans, no national formulary or National Oncology Drug Bank listing Only OOP sales, mostly in the Retail Setting*	ANMAT Website	

[1]SUR / SURGE date of inclusion considered the date when the updated Superintendencia de Servicios de Salud (SSS) resolution is published
[2] PAMI contract execution considered as the date of PAMI formulary inclusion
[3] Full Availability: Consider the date of the most recent formulary inclusion as the date of full availability (i.e., if the product is first included on PAMI and further on SURGE, consider SURGE date as the reference for full availability
[4] Limited Availability: Consider the first formulary date as the reference for limited availability (i.e., if the product is included on PAMI but have a restricted coverage on SURGE, consider PAMI contract date as the reference for Limited Availability)

Brazil - Interfarma

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.

Chile - CIF

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*Broad reimbursement through FONASA formularies (e.g., GES, Ricarte Soto), accounting for approx. >80% of the patient population*	Ricarte Soto website GES website AUGE clinical guidelines, DAC listings Cenabast purchases Public tenders	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available* *Restricted to Public Tenders*
	Limited	*Limited reimbursement of through national reimbursement system (<80% approx.); availability through a specialized programs e.g., DAC – centralized, ministry of health programs, or decentralized local/regional programs* *GES formularies also applies for private insurance companies, but they only reimburse 80% of the total cost* *Also applies whilst decision is pending, where use is restricted to specialists*		
	Only Private	*Covered in multiple ISAPREs, partial or full reimbursement only for patients via CAEC or extracontractual benefit*	Not available	
	Not Available	*Available in the out of pocket market, or is not reimbursed until the evaluation or decision*		

Costa Rica - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full**	*CCSS Basic Formulary (LOM)*	MOH website CCSS Document	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Purchased via Special purchases negotiations, and through judicialization initiated by the patient*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no CCSS formulary*		
	Not Available	*Ministerio de salud approval, no CCSS, no special purchases negotiations, no broad coverage by prepaid plans, Only OOP sales, mostly in the Retail Setting*	Not available	

Colombia - AFIDRO

Country	Availability	Definitions	Public Data	IQVIA Data
	**Full[1]**	*Medicines listed on PBS-UPC and EPI (PAI)*	MinSalud website PBS-UPC Circular	**Retail:** *Available* **Hospital / Non-Retail:** *IQVIA SISPRO / SISMED & NRC*
	Limited[2]	*Medicines available via ADRES / MIPRES, not listed on PBS-UPC* *ADRES / MIPRES uptake considering a minimum and recurrent volume using SISMED information*	MinSalud website ADRES / MIPRES Circular	
	Only Private	*Not Applicable* *Assuming MIPRES overlaps Pre-Pagadas, eventual coverage*	Not available	
	Not Available	*No INVIMA Approval, no MIPRES, not listed on PBS-UPC* *Only OOP sales, mostly in the Retail Setting*	INVIMA Website	

[1]PBS / UPC date of MinSalud Circular containing the updated PBS / UPC drug list to be considered as the date of Full Availability
[2]ADRES / MIPRES date of first minimum and recurrent sales based on SISMED and IQVIA NRC data to be considered as the date of limited availability – in some cases, there might be a delay between INVIMA regulatory approval and date of limited availability

Dominican Republic - FEDEFARMA

<table>
<tr><th>Country</th><th>Availability</th><th>Definitions</th><th>Public Data</th><th>IQVIA Data</th></tr>
<tr><td rowspan="4"></td><td>Full[1]</td><td>Medicines listed on PBS-SISALRIL</td><td rowspan="3">SISALRIL
PDSS[1]
(document)
DAMAC
Website</td><td rowspan="4">Retail:
Available

Hospital / Non-Retail:
Not broadly available</td></tr>
<tr><td>Limited</td><td>Medicines available via High-Cost Medicine Program (DAMAC), not listed on PBS-SISALRIL
Listed on DAMAC LOM</td></tr>
<tr><td>Only Private</td><td>Broad coverage by prepaid plans, no special purchase negotiations, no DAMAC/SISALRIL coverage</td></tr>
<tr><td>Not Available</td><td>Ministerio de salud approval, no DAMAC/SISALRIL coverage, no special purchases negotiations, no broad coverage by prepaid plans
Only OOP sales, mostly in the Retail Setting</td><td>Not available</td></tr>
</table>

[1]PDSS containing the updated PBS medicines list to be considered as the date of Full Availability

Note: Drugs with non-government importation purchases were categorized as only privately available, in absence of additional information provided by manufacturer

Ecuador – IFI-Promesa

Country	Availability	Definitions	Public Data	IQVIA Data
	Full	*Essential list including national institutions (e.g., MSP, IESS, Army)*	MSP IESS (where data is available)	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Not listed but with limited access, typically evaluated through an exception process*		
	Only Private	*Products covered OOP with no possibility for reimbursement, no essential listing*	Not available	
	Not Available	*Pending or not approved by ARCSA, no listing or other access*	ARCSA website	

Mexico - AMIIF

Country	Availability	Definitions	Public Data	IQVIA Data
	Full[1]	*CGS National Compendium & Federal Institution Acquisitions* *Date of first contract (central proc.)* *Federal Institutions contracts to be validated using IQVIA / INEFAM sales data*	Compendium Government Tenders INEFAM (where data is available)	**Retail:** *Available* **Hospital / Non-Retail:** *IQVIA GSDT/Gov Analytics* & NRC*
	Limited[2]	*Decentralized formularies (SENDA, SEMAR, PEMEX, ISSEMYM, ISSSTESON) and/or patient purchase outside of compendium* *Purchasing to be validated using IQVIA other channels data*		
	Only Private	*Large private formularies (GNP, AXA, and MetLife)*	Not available	
	Not Available	*COFEPRIS Approval, no private, decentralized formularies, no compendium, no federal institutional acquisition* *Only OOP sales, mostly in the Retail Setting*	COFEPRIS website	

[1]Date of the first sales to federal institutions IMSS / ISSSTE, assuming a minimum volume, will be considered the date of full reimbursement reflecting the central purchasing or broad but individual federal institutions contracts
[2]A minimum of 2-3 institutions purchasing will be considered as Limited Access, date of the first institution purchasing considered to be timeline benchmark for limited access

Panama - FEDEFARMA

Country	Availability	Definitions	Public Data	IQVIA Data
	Full	*Listed on CSS and ION* Basic Formulary (LOM)*	MOH website CSS Document (LOM) ION Document (LOM)	**Retail:** *Available* **Hospital / Non-Retail:** *Not broadly available*
	Limited	*Medicines available via special purchase process for non-LOM medicines on CSS / ION*		
	Only Private	*Broad coverage by prepaid plans, no special purchase negotiations, no CSS formulary*		
	Not Available	*Ministerio de salud approval, no CSS, no special purchases negotiations, no broad coverage by prepaid plans* *Only OOP sales, mostly in the Retail Setting*	Not available	

**ION Basic Formulary is only for oncologic medicines.*

Peru - ALAFARPE

<table>
<tr><th>Country</th><th>Availability</th><th>Definitions</th><th>Public Data</th><th>IQVIA Data</th></tr>
<tr><td rowspan="4"></td><td>Full</td><td>National petition (PNUME) and its complementary listings, RENETSA/RM purchases</td><td rowspan="2">MOH website
PNUME document
IETSI dictum
INEN evaluation</td><td rowspan="4">Retail: Available

Hospital / Non-Retail: Not broadly available</td></tr>
<tr><td>Limited</td><td>Not listed but with limited access</td></tr>
<tr><td>Only Private</td><td>Products covered OOP with no possibility for reimbursement, no essential listing</td><td>Not available</td></tr>
<tr><td>Not Available</td><td>DIGEMID approval, no listing or other access</td><td>DIGEMID Website</td></tr>
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