White Paper

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

Argentina

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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), (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 , 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

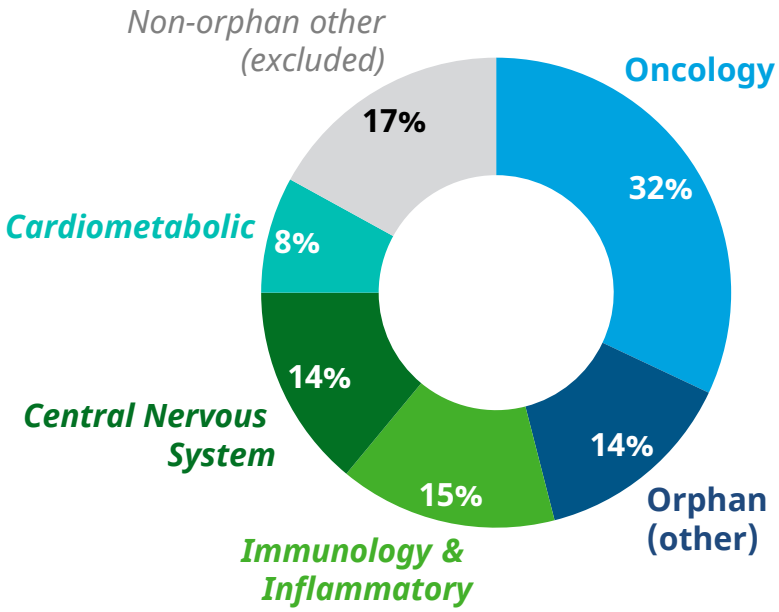


*See appendix for definitions, exchange rates, and indicators
Acronyms: NRC: Non-retail Channels; USD: US dollars; WHO: World Health Organization

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

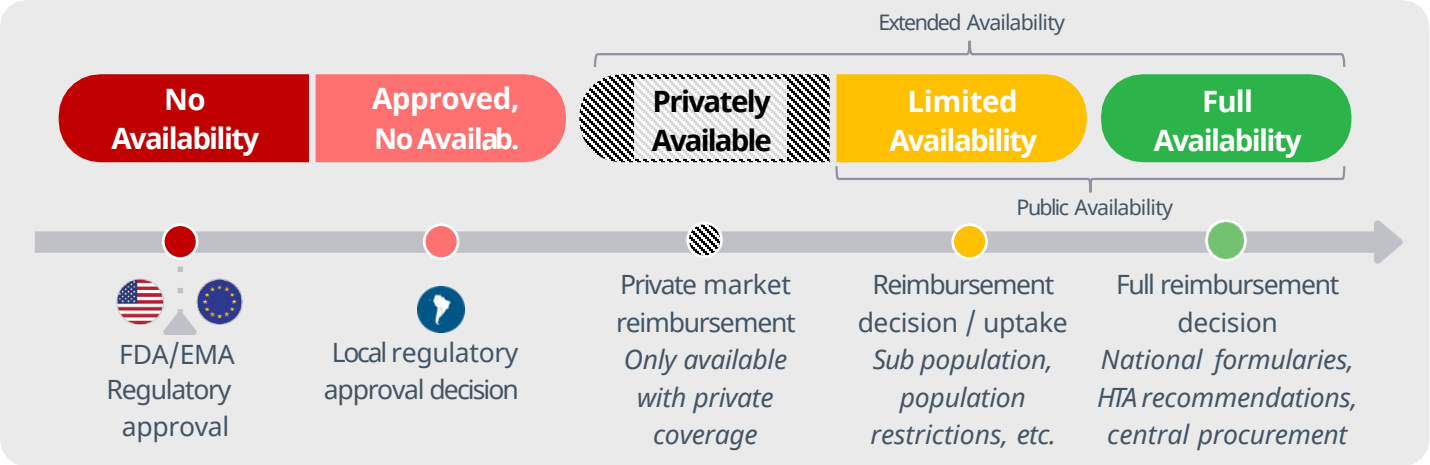
Orphan status may be determined by either the FDA or EMA, as per the first-approved indication

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; TA: 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

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; HTA: Health Technology Assessment

Methodological considerations

The detailed definitions for molecules' availability status in Argentina involved inclusion to public health formularies like SURGE, PAMI, and the PMO

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)

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 - Argentina

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
- Argentina's time to approval is lower than the regional average (31 vs 36 months), while local time to availability remains the same at both country and regional level (32 months)
- Time to availability varies substantially in Argentina across therapeutic areas, with I&I showing the longest delays taking ~41 months to become locally available compared to ~32 months of the regional availability. Oncology therapies are the ones that become locally available faster (60 months from global approval to local availability), followed by CNS (62 months).

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, 61% are approved in Argentina
- 58% of molecules with regional public availability (limited or full availability) have public availability in Argentina
- 68% of molecules approved in Argentina have some level of availability; out of this extended availability, only 6.7% reached full availability status
- The TA with highest number of fully available molecules is oncology (7), while CNS, I&I and CM each have 1 therapy with this availability status

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 2017 are approved in Argentina; more than half of these with limited availability
- For therapies approved globally after 2017, both approval and availability rates decline sharply, both approval and availability reaching 0% by 2025.

Improvement Index

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

- 9% of the molecules in Argentina have improved their availability status over the past year, 2% above the regional average (7%)
- Argentina had 4 newly approved molecules this year

Acronyms: FDA: US Food & Drug Administration; EMA: European Medical Agency; TA: Therapeutic Area; CNS: Central Nervous System, I&I: Inflammation and Immunology, CM: Cardiometabilic

Summary of Regional Root Causes and Opportunity

Innovation is outpacing system capacity, driving saturation and delays

The growing volume of globally approved medicines is increasingly outpacing Argentina's ability to process and absorb innovation, reflected in declining approval rates for recent cohorts and a high concentration of therapies still not approved. While regulatory timelines are relatively competitive, system bottlenecks and backlog pressures persist, widening the gap between global innovation and local access.

Low investment constrains institutions, fragments processes, and reduces competitiveness

Although Argentina's healthcare and innovation spending is relatively aligned with OECD benchmarks, recent budget reductions and resource reallocation have limited effective system capacity, contributing to constraining the ability to translate investment into timely access. These dynamics reduce coordination across stakeholders and create variability in decision-making, ultimately impacting the system's ability to scale innovative therapies

Access improves when clinical value and system readiness are mutually reinforcing

Regulatory approval alone does not ensure access in Argentina. 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 Argentina 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 Argentina 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.

Argentina's access challenges stem from 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 Argentina 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, Argentina'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 Argentina's ability to absorb innovation efficiently, leading to delays, operational misalignment, and uneven access outcomes



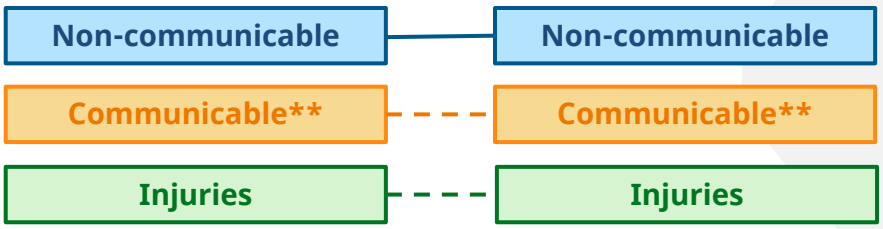
A window for transformation is emerging

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 Argentina's health burden

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

Evolution of Disease Burden in Argentina - 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	Respiratory infections & TB
6	Other non-communicable
7	Diabetes & CKD
9	Neurological disorders
10	Digestive disorders
14	Maternal and neonatal

- Argentina's disease burden is driven by non-communicable diseases. However, Argentina's communicable diseases remain the second most relevant contributor for the country. Creating a double challenge to sustain the need for chronic diseases and infectious and early-life conditions.
- This dual dynamic has critical implications for healthcare systems and pharmaceutical needs. Unlike acute infectious diseases, NCDs are chronic in nature, requiring long-term management. The system must be able to support simultaneously infectious disease control while scaling capacity for chronic disease management.
- Despite the dual burden, the growing importance of chronic diseases means that Argentina's healthcare system is increasingly dependent on access to innovative treatments (e.g., targeted oncology therapies, novel immunomodulators for inflammatory diseases, advanced treatments for metabolic and cardiovascular conditions), while being constrained by competing priorities between innovation and sustaining the current needs.
- 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 diverse 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.

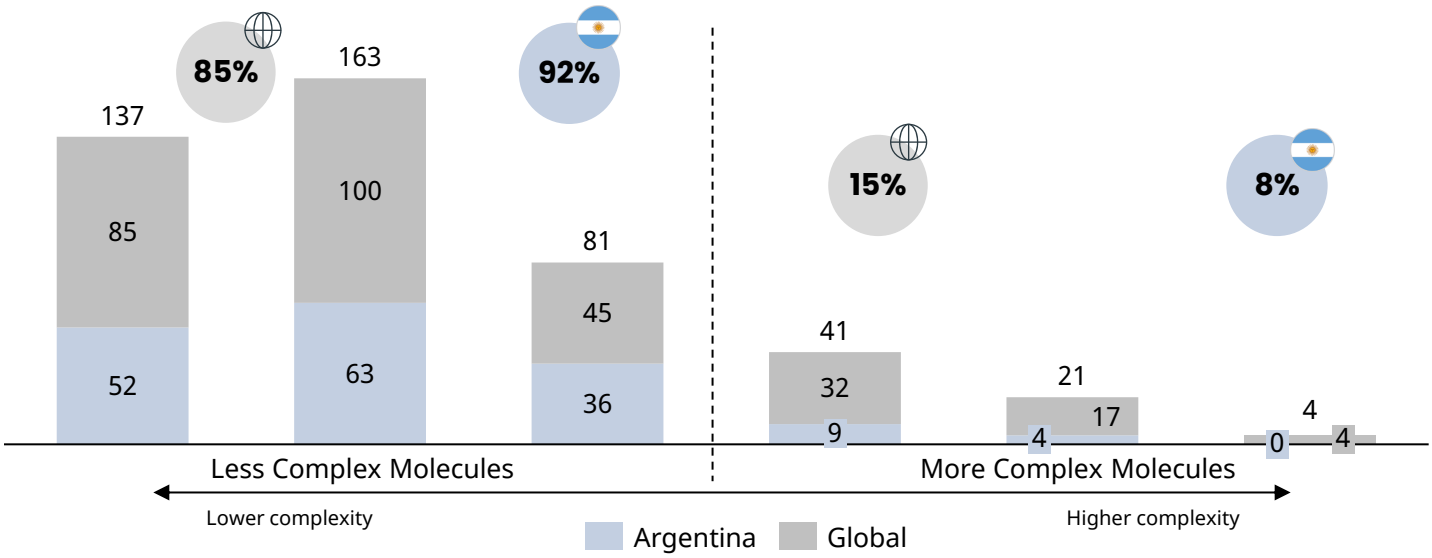
Argentina's dual burden of disease creates a structurally pressured access environment, where competing priorities between communicable and chronic conditions limit access to innovative therapies despite growing demand

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

Complexity introduces additional considerations for systems

Argentina gaps the LATAM complexity distribution, with ~92% 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 amplifies capacity limitations. From a technical perspective, complex molecules pose greater challenges in evidence generation and interpretation.
- Argentina's complexity deviates from LATAM, with ~92% of molecules concentrated in the lower-complexity side versus ~8% in higher complexity, indicating a less mature system relating to the distribution of higher complexity molecules.

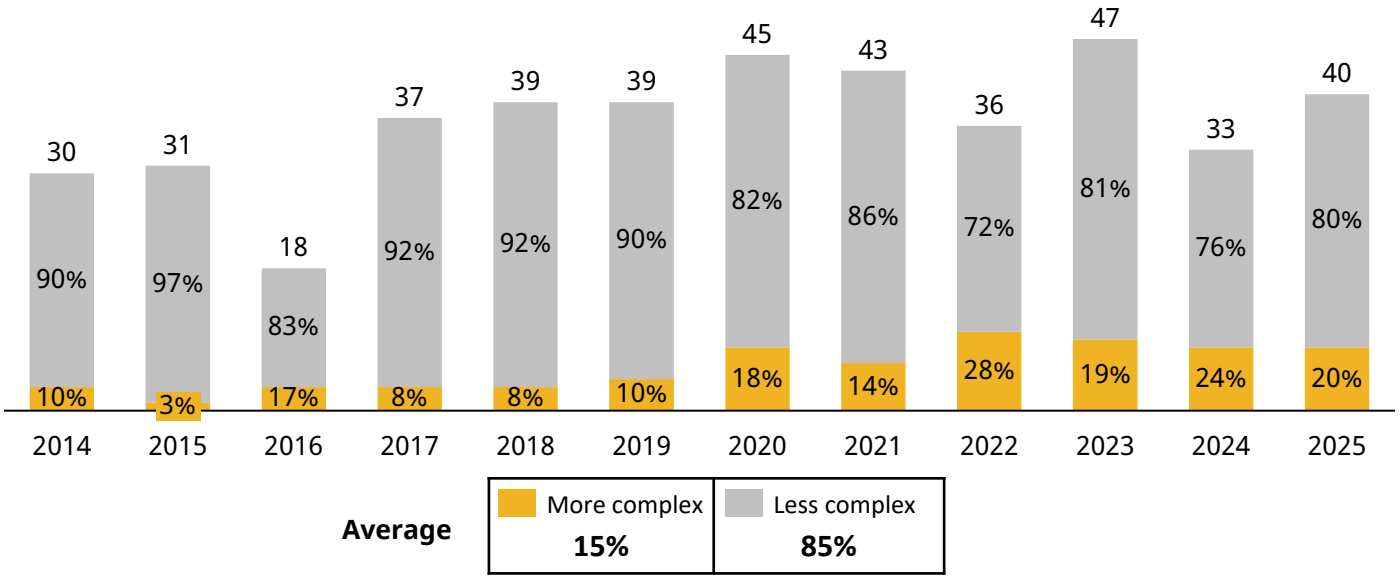
Innovation often introduces technical challenges during evaluation and creates downstream system limitations for regulators, payers, and providers in resource-limited settings

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



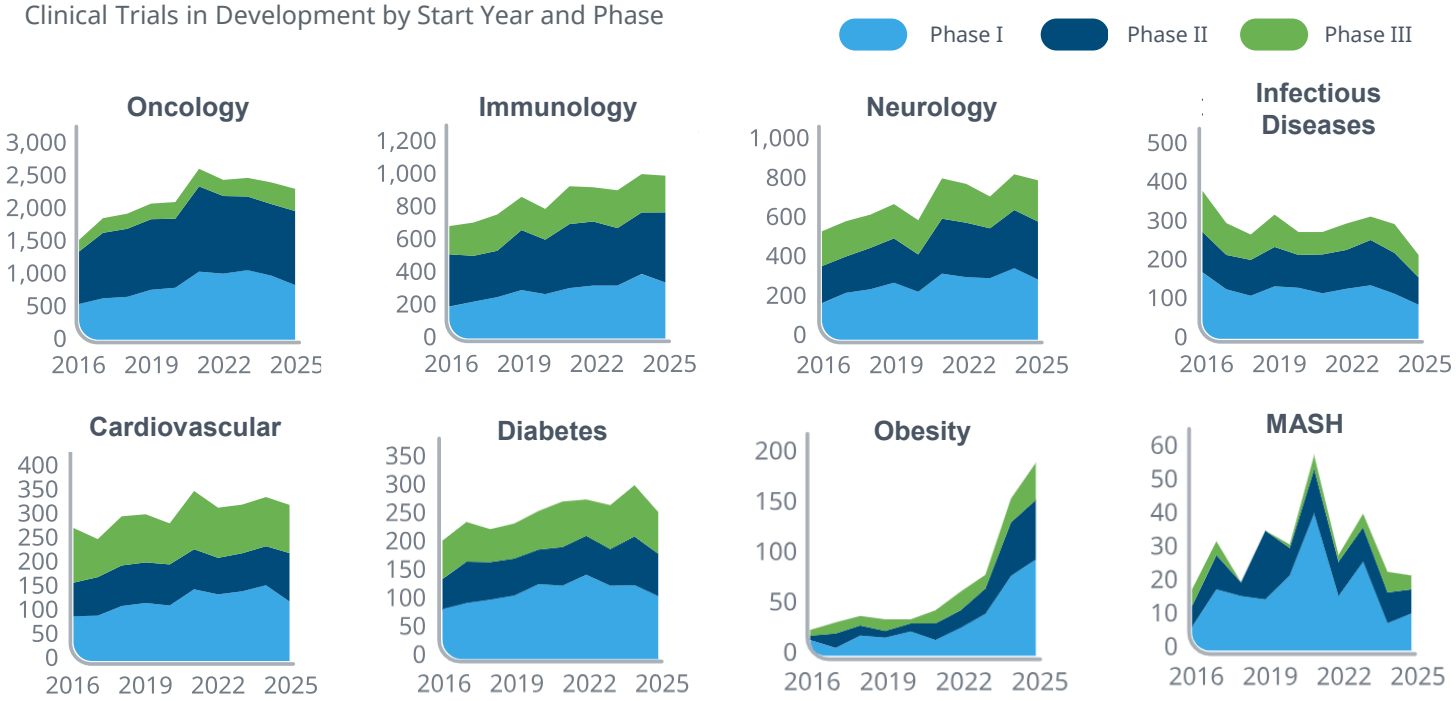
- Among globally approved molecules in this study, the proportion of complex molecules has risen from 10% in 2014 to 20% in 2025. This increase reflects growing reliance on precision medicine, orphan disease therapies, novel mechanisms of action, and advanced modalities (e.g., gene and cell therapies)
- 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

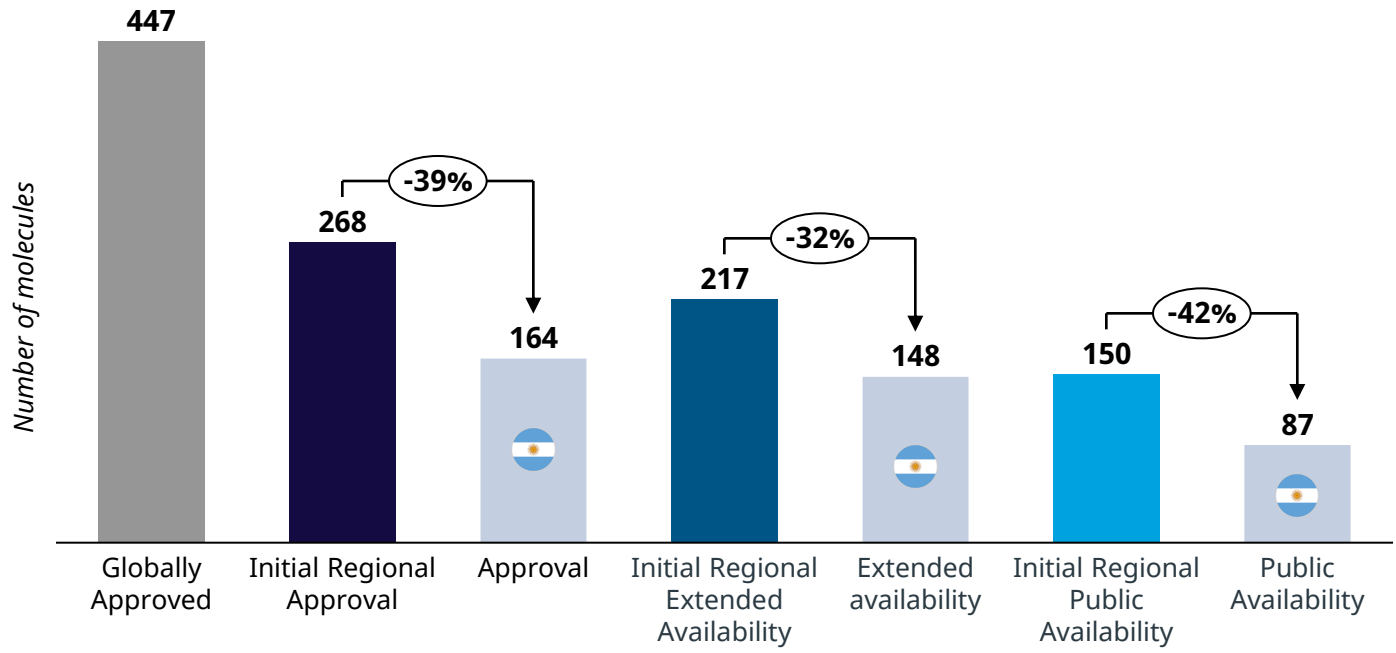
A continued pipeline growth will drive advances in healthcare, but will amplify existing system bottlenecks if unaddressed

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

Argentina’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 Argentina’s status
- Argentina lags the regional approval with only ~61% of the region’s total. However, this rate only diminishes lightly when considering broader availability, indicating higher availability for approved medicines.
- The conversion from approval to extended availability is significant, with ~90% of molecules reaching broader availability, which reflects a strong initial availability in the system.
- There is a significant gap when considering public availability. Where only ~58% of the molecules are available compared to the regional benchmark.
- Argentina in general, has significant constraints in the regulatory stage and performs below the regional benchmark in the early stages of the process, however, it sustains a high rate of availability for the molecules that undergo the regulatory stage
- Argentina’s availability process is in part limited by a fragmented healthcare system which includes divisions between the national government, provincial systems
- With the future changes to the HTA process, it is expected that ANEFiTS would streamline the process with centralized decisions and framework

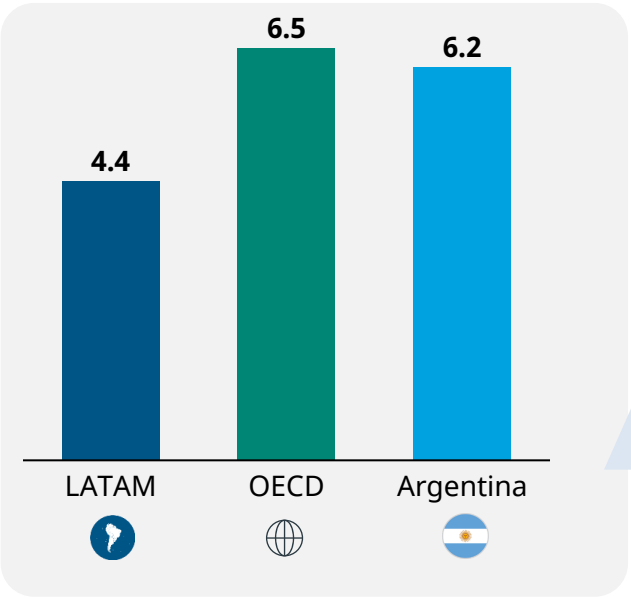
Argentina has challenges in the public availability stage of the process, but maintains a positive trend in approval and extended availability

Acronyms: ANEFiTs: Agencia Nacional de Evaluación de Financiamiento de Tecnologías Sanitarias; HTA: Health Technology Assessment

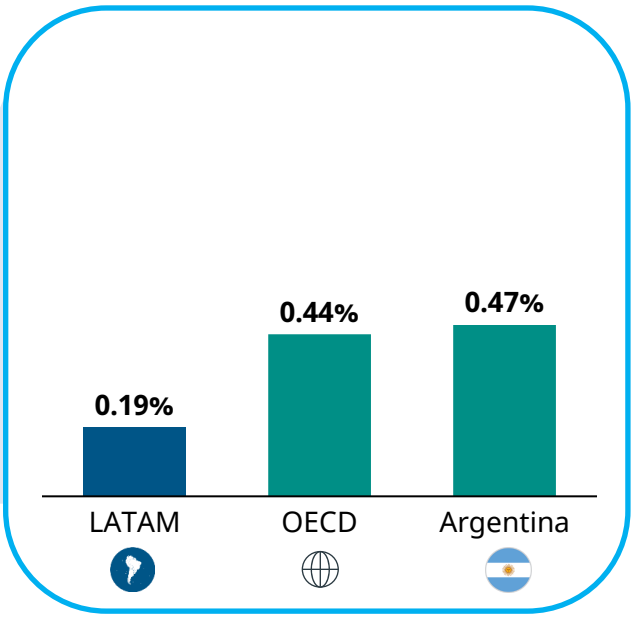
Argentina’s health spending is on par with the OECD target

Public and innovation-specific health spending in Argentina are on par with OECD benchmarks, however this percentage represents a fraction of the previous allocation

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 Argentina is consistent with the recommended 6% GDP share by WHO and the OECD average, but It has significantly decreased form 2023’s budget, reducing it from ~10.3% down to 6.2%
- Argentina allocates a higher share of GDP (~0.47%) to innovative treatments compared to the regional benchmark (~0.19%); and follows the OECD benchmark showing important allocation of resources to the healthcare system
- The budget cuts have aligned Argentina’s allocation to the international benchmarks, but they have created concerns abut the erosion of the system’s efficacy and have created great disruptions on the systems by firing more than 2,000 employees from the Ministry of Health under austerity measures from the current administration
- These measures have unfavorable consequences compromising the population’s health; there has been an upheaval on several communicable diseases such as measles, pertussis, tuberculosis and syphilis, amongst others- however in access it is generally translating to an inefficient spend, as it gives way to legal proceedings

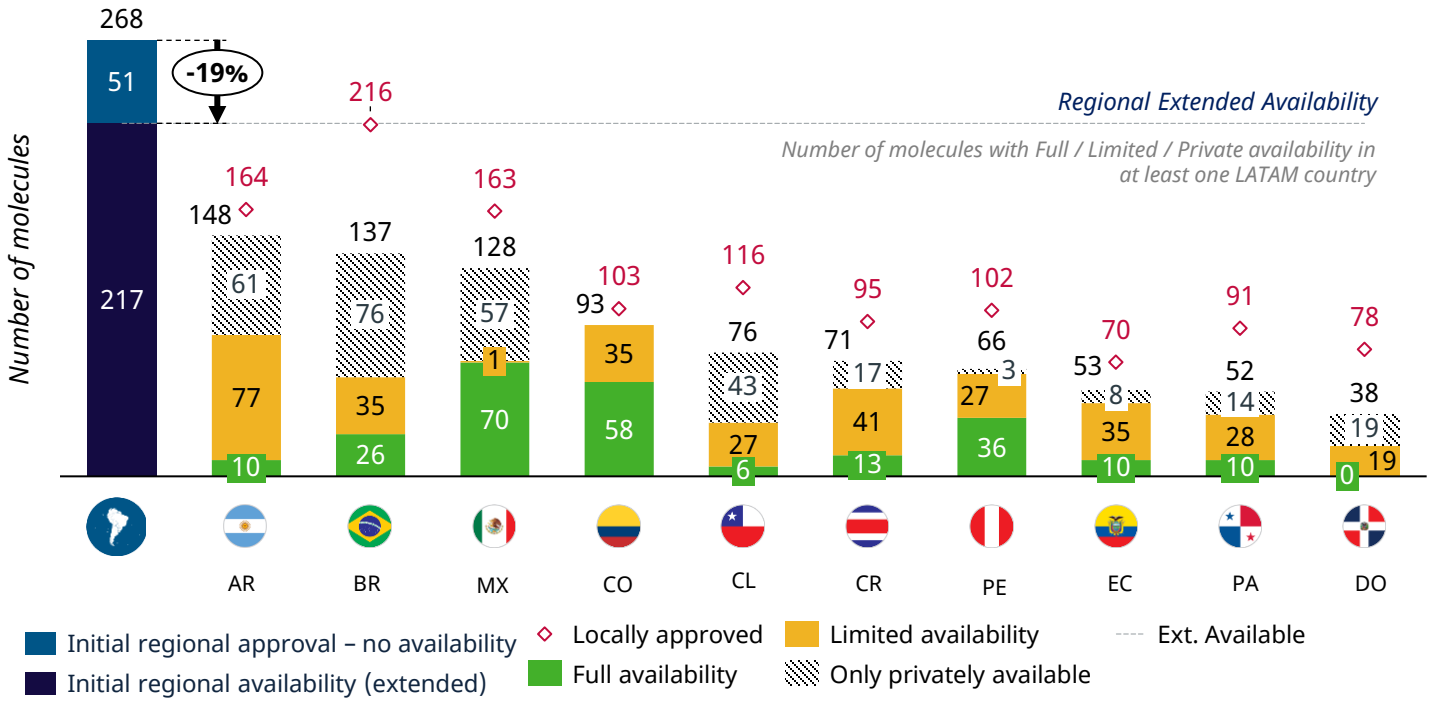
Argentina has undergone important changes to the allocation of resources in recent years, the reduction of size of the budget may impede availability of innovative medicines

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, 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
- 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

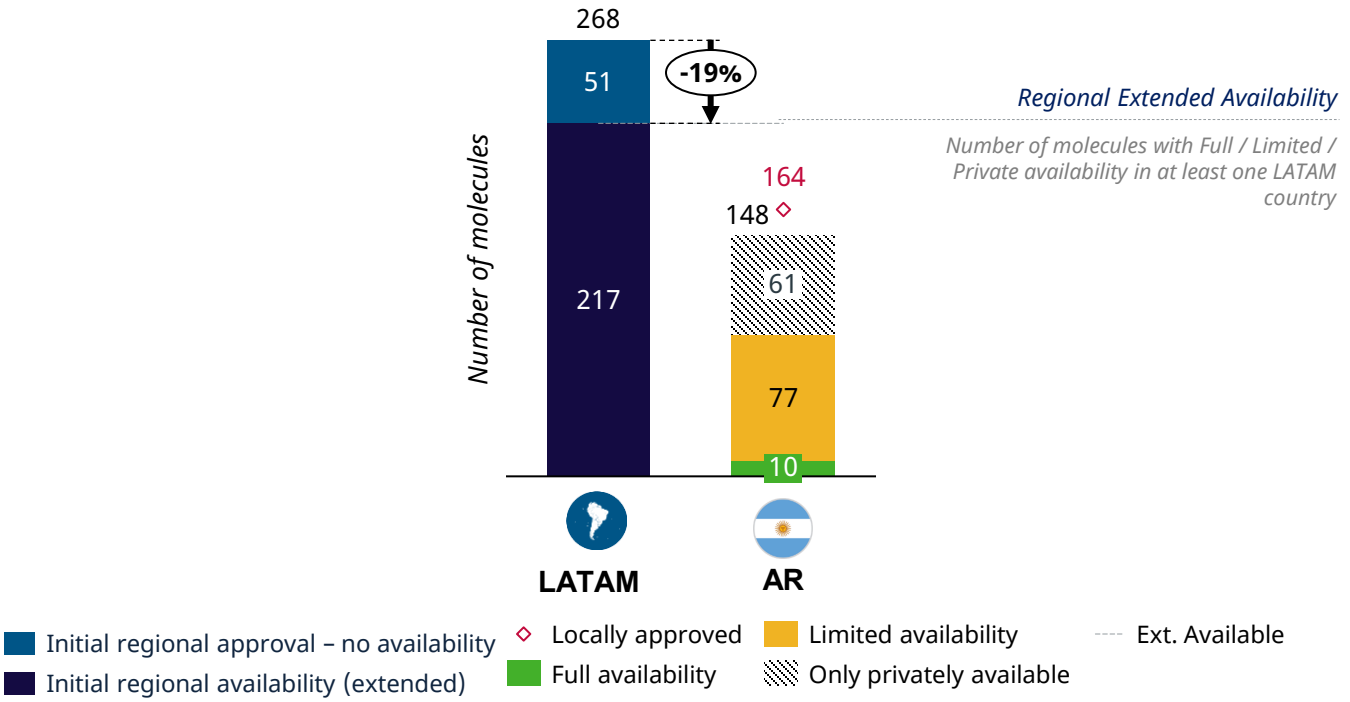
*See appendix for further detail

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

Argentina’s availability and approval remain consistent

Despite lower approval rates, availability of molecules is more consistent but lags significantly on full availability

Breakdown of Local Availability (2014 - 2025) — Combined



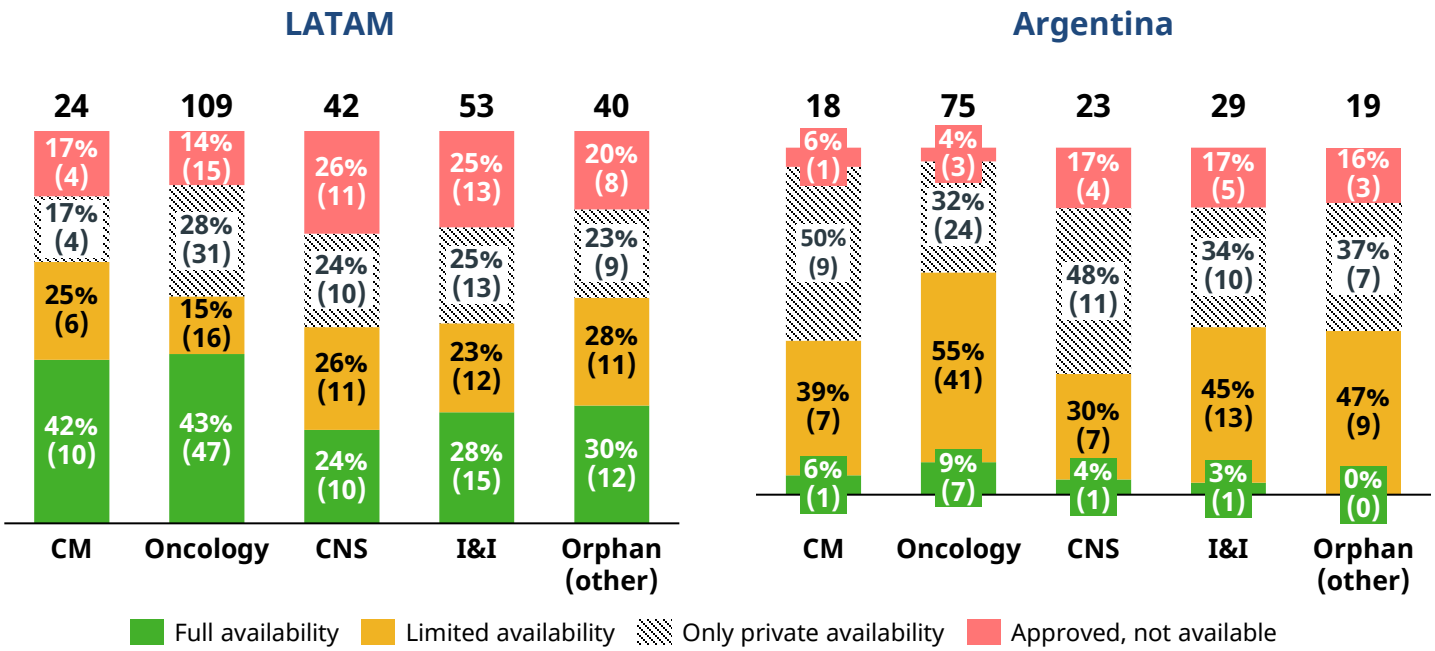
- Argentina has a strong availability panorama when considering extended availability, ~90% of approved molecules are available, but with significant differences on the level of access
- Argentina’s composition of availability reveals a structural imbalance, about 37% of locally approved therapies are restricted to the private-sector access, indicating that innovative medicine is not widely available in the country despite the presence of approved molecules
- Public system uptake remains restrained, as only 6% of available therapies achieve full availability, demonstrating that the different publicly funded systems (Salud Pública, Obras Sociales) have significant challenges
- Argentina's dynamic falls behind the regional one, whereby there are significant gaps in bringing molecules to full availability in the public sector, though fragmented public access exists. The country may be able to attract new innovative therapies but accessibility remains a challenge outside the private sector.

In Argentina, regulatory performance limits the country’s capability for access, and the system fragmentation constitutes a barrier for full availability relying on the private sector for the strong extended availability

Significant differences also exist by therapeutic area

Argentina follows the regional trend, where Oncology leads on full availability; but full availability remains limited overall

Regional and Local Availability Status by Therapeutic Area



- Argentina exhibits a positive outlook on access profile across all therapeutic areas compared to LATAM considering only approved molecules, there is an overall greater extend availability for all therapeutic areas
- However there are significant differences in full availability, particularly in CM (6% vs. 42%) and Oncology (9% vs. 43%), signifying important deficiencies on public access
- CNS and I&I therapies in Argentina face important challenges, only 4% & 3% of molecules are fully available and this therapeutic areas have the largest proportion of molecules approved but not available, limiting the access to these innovative medicines
- Orphan therapies remain highly constrained, with no molecules with full availability and 16% not available, reflecting an important gap to access specific treatments and relying on the private sector for medicine
- Argentina despite a relatively high extended availability benchmark, has systematic limitations to access limited by approval rates and the lack of full availability throughout the therapeutic areas

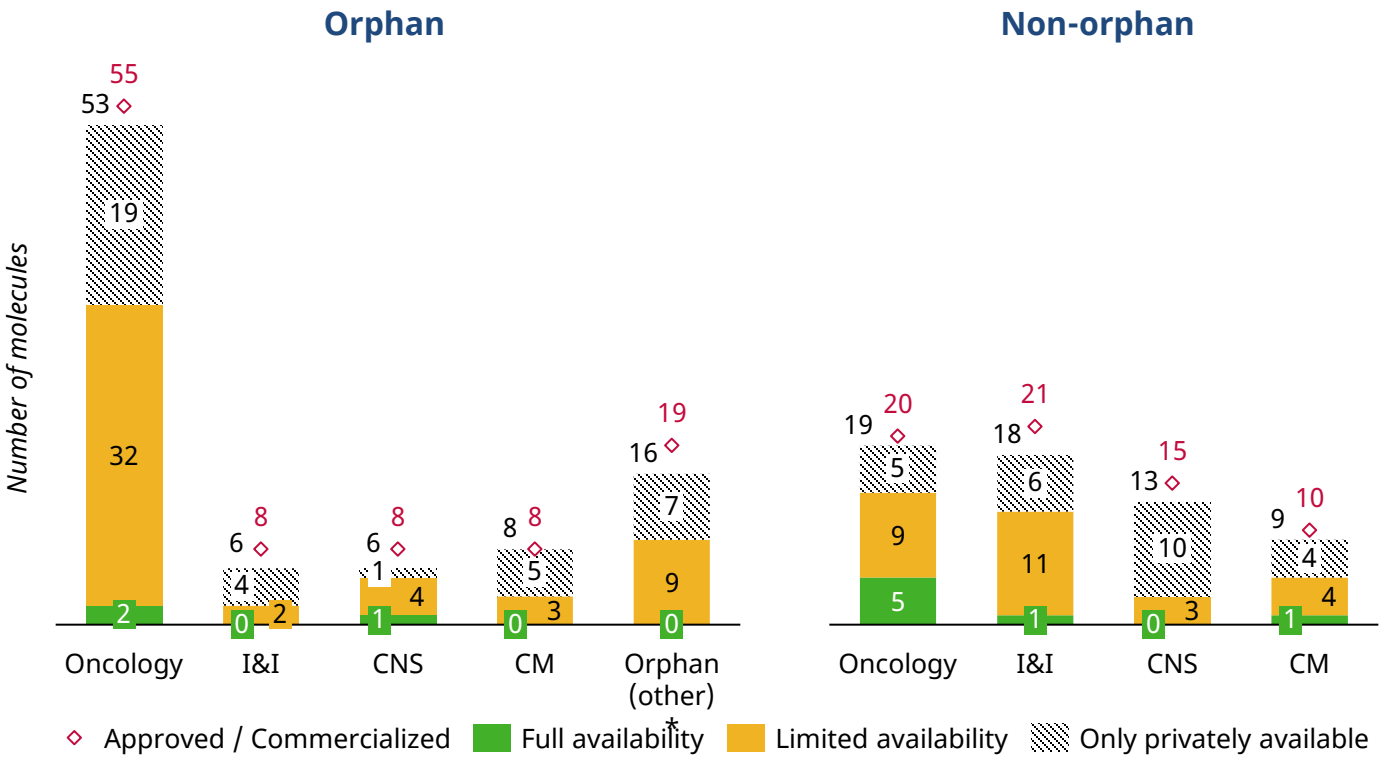
The biggest gaps in Argentina compared to the region are providing full accessibility for already approved molecules; centralized processes can support more broad equitable access

Acronyms: CM: Cardiometabolic; CNS: Central Nervous System; I&I: Inflammation and Immunology; HTA: Health Technology Assessment

Orphan therapies show higher availability

Orphan therapies show relatively strong availability, but access remains partial and fragmented in Argentina

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



- Orphan therapies represent the largest share of the approved treatments, particularly in oncology (55 approved orphan molecules vs. 20 non-orphan)
- Orphan therapies have a significant amount of limited available molecules, specially considering oncology where more than half (~58%) of the sample has limited availability, suggesting:

a. Argentina's system is capable of integrating a significant portion of orphan innovations once approved

b. There are challenges for broad adoption of medicine due to a fragmented (not centralized) payer system

- In contrast, non-orphan therapies show lower levels of general availability and more reliance in private-sector access; in areas such as CNS and CM full availability is limited and a larger share of medicines remains partially accessible reflecting stronger system barriers driven by aggregate budget impact and treatment volume

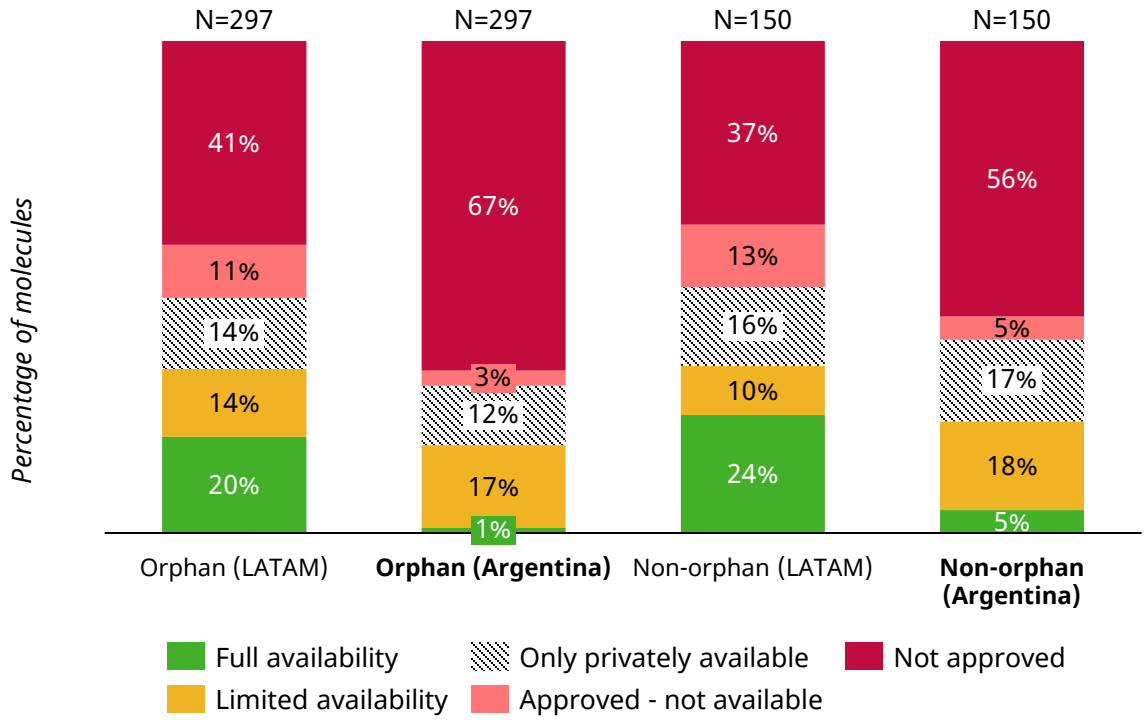
In Argentina, access is not absent but incomplete, characterized by relatively strong full availability for some therapies and widespread reliance on fragmented access pathways across the system

* 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

Argentina demonstrates markedly reduced access and approval across both orphan and non-orphan therapies, with minimal conversion into full availability

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



- Argentina exhibits consistently low full availability across both orphan and non-orphan therapies, with only 1% (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 Argentina, is noted on the Non-orphan drugs, where there is a ~26% difference between the Not-approved medicines.
- Non-orphan therapies in Argentina show slightly better performance than orphan in availability terms limited (~18%) or private-only (~17%) availability, resulting in extended availability difference of 50% vs. 40% respectively, subverting the expectation of lower availability for highly used therapies.
- Across both categories, the distribution of access indicates that reimbursement is a bottleneck in the country, especially on orphan drugs where innovation may be limited by immature / underdeveloped processes of evaluation at a national level

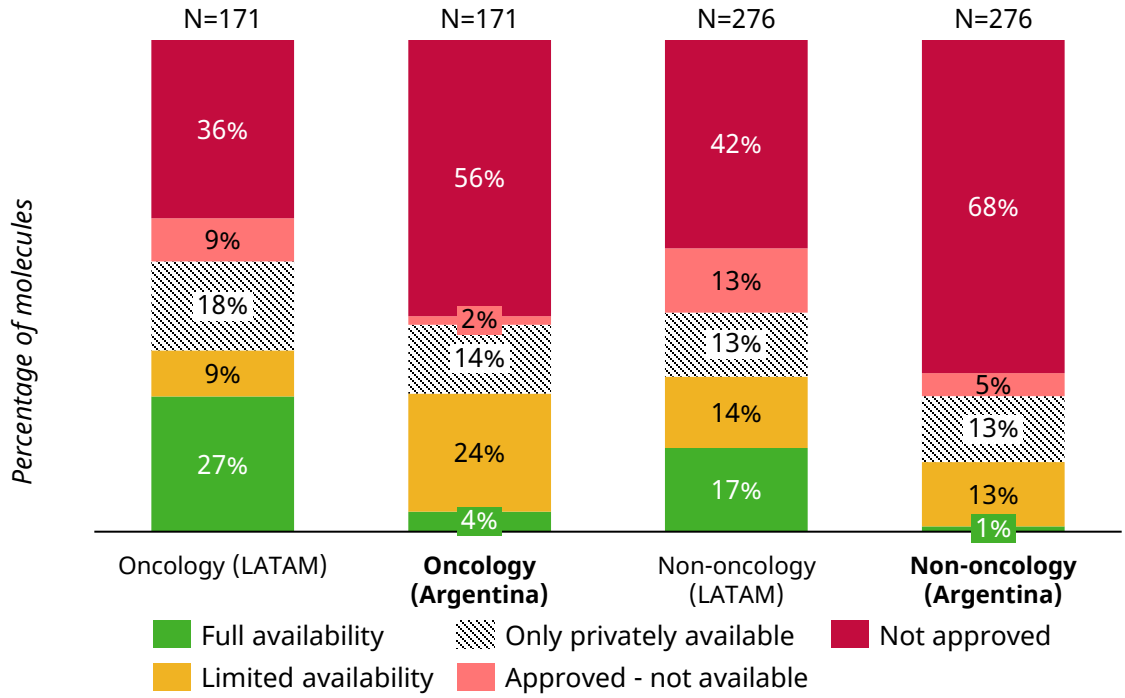
Argentina underperforms across both orphan and non-orphan therapies, though faces more challenges in orphan therapies, suggesting that approval processes which are tailored to orphan drugs are not enough and access remains a structural limitation

Acronyms: HTA: Health Technology Assessment

Access to both oncology and non-oncology is limited

Oncology in Argentina leads slightly in full availability vs. non-oncology; however, extended availability is mainly driven by limited access and secondarily the private sector.

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



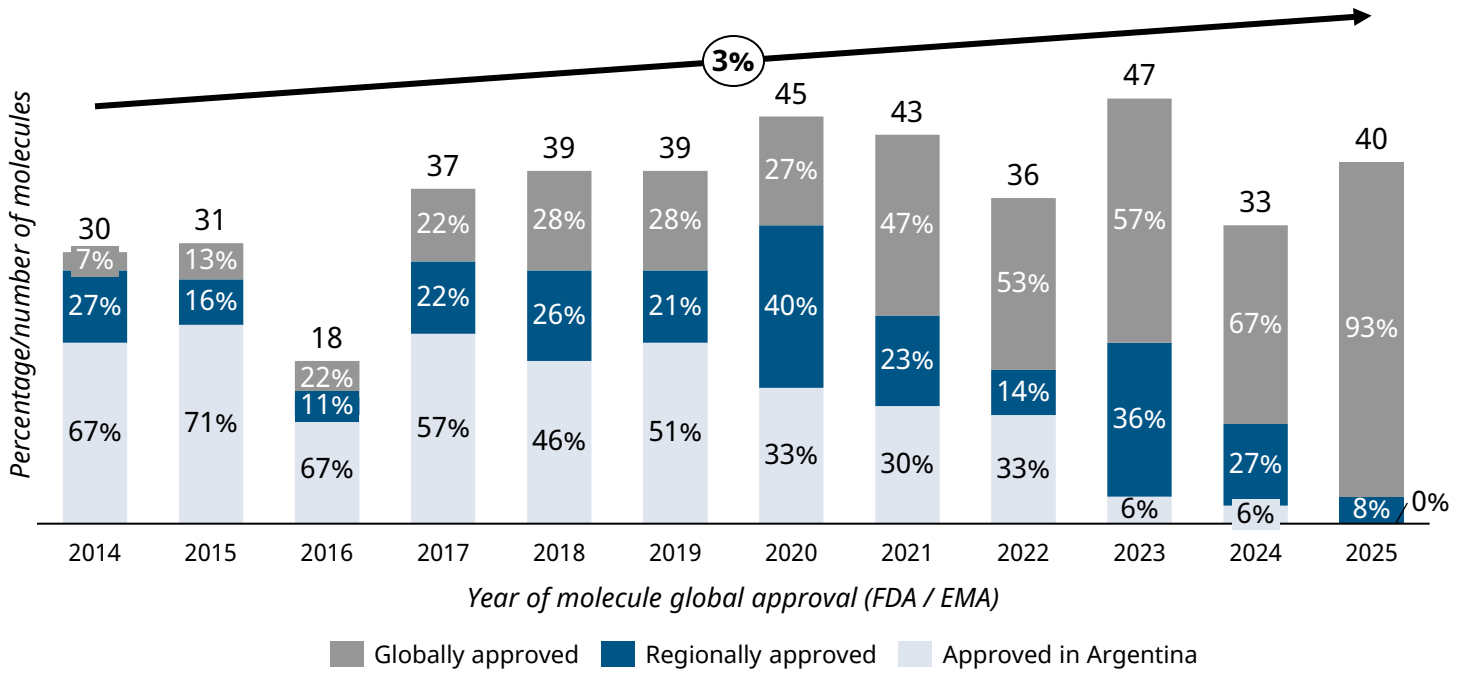
- The availability of oncology therapies is largely limited, with a greater proportion of limited access molecules compared to the LATAM benchmark (~24% vs ~9%), making public access possible but not assured, limiting the overall population with access
- Full public access is severely deficient, with just 4% achieving it; there are funding barriers for sustaining full availability for oncology therapies challenging for the healthcare system, and results in high degrees of legal/administrative processes
- Across both therapy groups, limited availability is the primary way in which patients access treatments, particularly oncology, this indicates that therapies are entering the system and are being used, but under restricted access mechanisms
- Compared to LATAM, one of the most relevant differences is the proportion of therapies that remain not approved; this significantly limits the sized of the accessible pool of molecules and shows the major bottleneck at the early stage of access

In Argentina, oncology slightly outperforms non-oncology in availability, but both are characterized by extremely low full access, with limited availability dominating and a large share of therapies failing to reach the public sector

New medicines increase, approvals are lagging behind

Significant time-lag effects and widening gaps limit the translation of global innovation into regional and Argentina 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
- Argentina follows a pronounced downward trajectory in approvals, with important declines at the same mark as the LATAM benchmark from 2020 onwards
- 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 Argentina, reaching 93% regional and 67% Argentina local approval 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

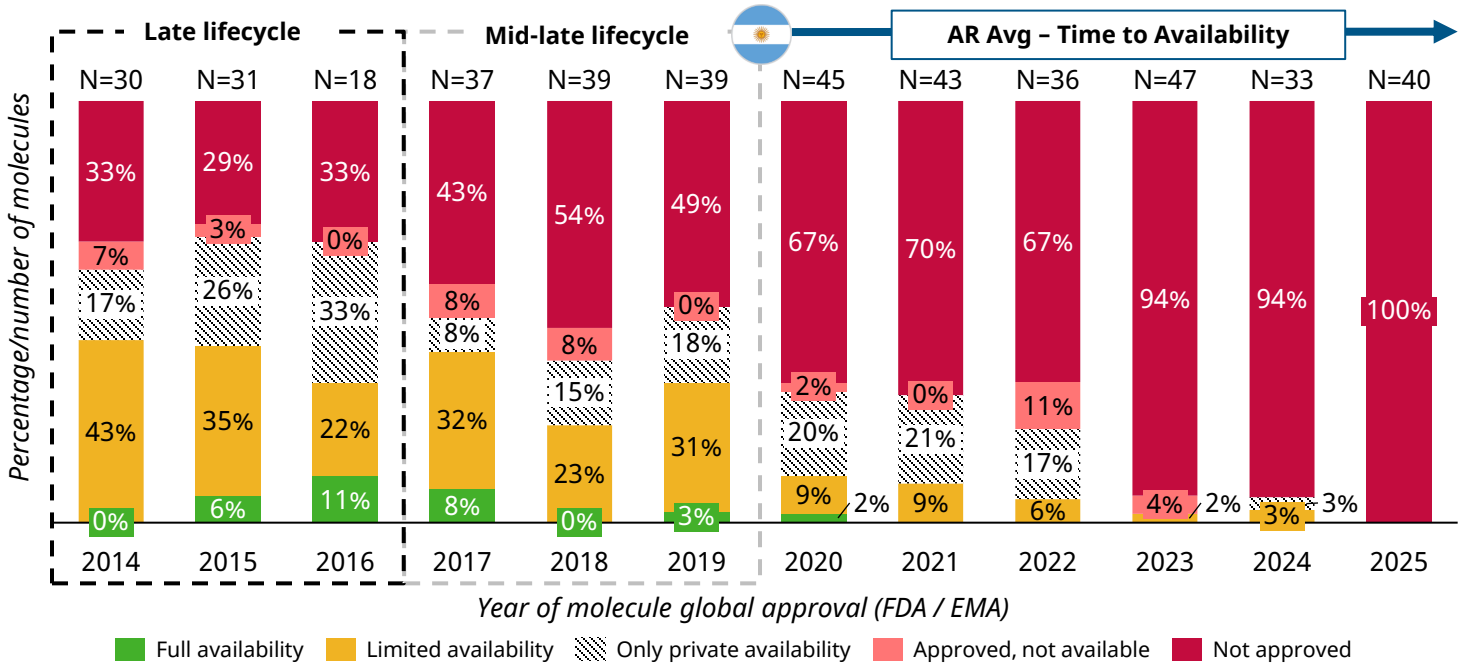
Approval rates are declining in the region, whilst global approvals are increasing; the gap will continue to widen without concerted action

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 Argentina

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



- Full availability remains consistently low across all cohorts and is fully disappeared in recent years, dropping from 11% in 2016 and 8% in 2017 to just 0% from 2021 onwards indicating persistent challenges in achieving broad access
- The share of not approved molecules increases sharply for newer cohorts, rising from 29–33% in 2014–2015 to 67% in 2020, 94% in 2023, and 100% in 2025, highlighting the challenges in reaching consensus on both submission and approval
- Even therapies late in their lifecycle, do not transition into full availability consistently; they remain largely in limited or private access like 2014 with 43% on limited availability and 17% private access only, suggesting additional barriers and not only time for integration into the system
- 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 the not approved category, 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."

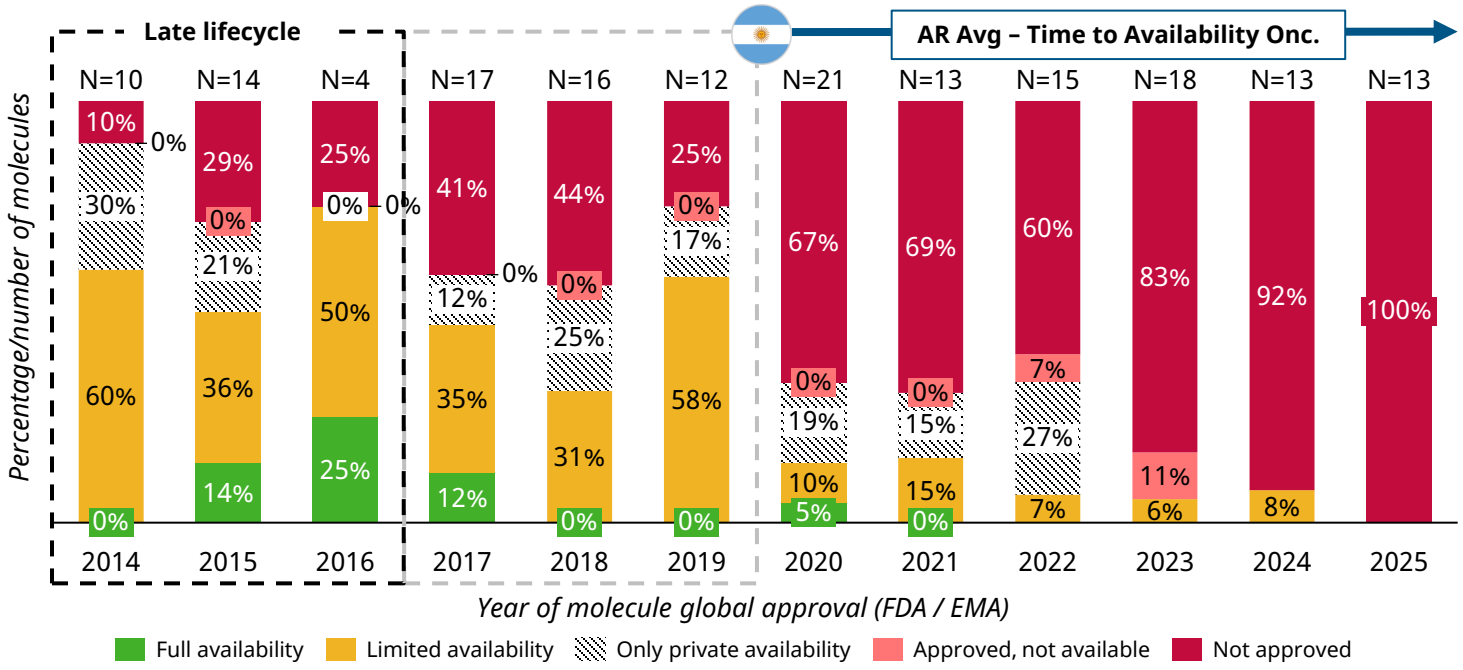
- ex-Minister of Health

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

Oncology availability is limited, without reaching full access

Earlier oncology therapies were accessible primarily through limited and private pathways, but newer cohorts are dominated by not approved statuses, reflecting growing barriers to market entry

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



- Full availability of oncology molecules in Argentina remains very limited, but has some outliers in the trend from 2015 to 2017 which have a greater proportion of fully available molecules ranging from ~12% to ~25%, the rest of the cohorts present near to none fully available molecules
- The share of oncology molecules that are not approved rises sharply in recent years, increasing from 10% in 2014 to 67% in 2020, 83% in 2023, 85% in 2024, and 100% in 2025, highlighting major barriers for newer oncology therapies
- Limited availability represents an important access pathway, accounting for 60% in 2014, 50% in 2016, and 58% in 2019, suggesting that many products reach patients in a fragmented part of the system and there is no general uptake
- However, even limited access is declining, particularly after 2020 where private only availability allows for some access to the molecules; for newer cohorts, these pathways of access are no longer sufficient to absorb incoming innovation
- Oncology access in Argentina reflects several structural gaps, including fiscal pressure limiting system capacity, fragmentation reducing coordinated access pathways and barriers to approval and pricing

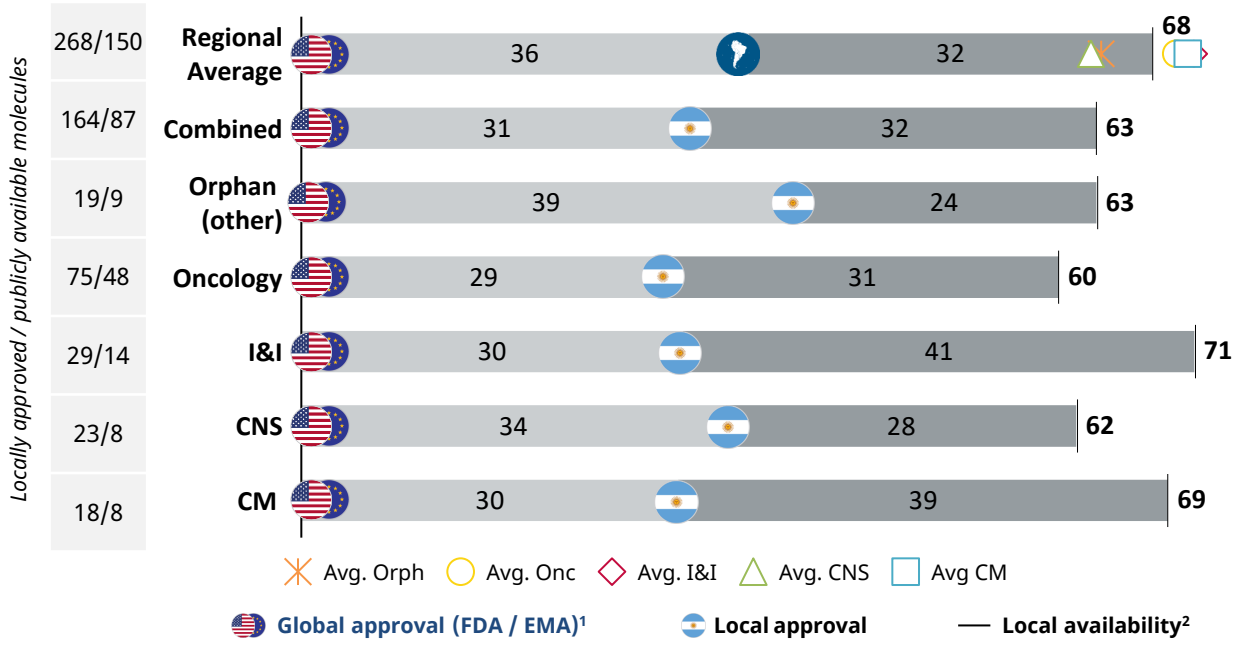
Access to oncology molecules in Argentina has worsened over time, with newer cohorts increasingly concentrated in not approved or restricted-access categories

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

Access is a long and fragmented process

The time to availability in Argentina averages 5.2 years, with a time to approval of 2.5 years and a time to availability of 2.6 years

Time to Availability from Global Approval (2014 - 2025) – Argentina 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 Argentina reaches ~63 months (~5.2 years), closely aligned with the regional average (68 months), confirming that patient access remains significantly delayed despite earlier innovation approvals in Argentina
- Argentina benefits from relatively faster regulatory approval timelines (31 months vs. 36 months regional), highlighting a more efficient review process compared to the regional average
- 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 I&I medicines, despite having a quick local approval time, the total time to availability exceeds the local average by 9 months
- In contrast other therapeutic areas, oncology (60 months) and CNS (62 months), are strikingly quicker to availability

Argentina has very similar timelines for molecules to get from global approval to local approval and then to local availability, as the regional benchmark

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

Timelines lengthened in 2026, driven by post-approval delays

While regulatory timelines improved for all TAs, delays in availability are increasing in Argentina, particularly in high-budget-impact therapeutic areas, reinforcing system strain beyond approval

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

	Approved	Available	Total
Regional average	-5.6%	+9.4%	+1.5%
Combined	-6.5%	+18.8%	+6.3%
Orphan (other)	-2.6%	+4.2%	-
Oncology	-3.4%	+6.5%	+1.7%
I&I	-6.7%	+24.4%	+11.3%
CNS	-5.9%	+46.4%	+17.7%
CM	-27.6%	+38.5%	+10.3%

- Argentina shows a +18.8% increase in time to availability vs. 2025, resulting in a +6.3% overall delay, which equates to approx. 4 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: CNS therapies (+46.4%) showing the largest increase, reflecting high-volume budget pressure and prioritization restrictions; CM (+38.5%) and I&I (+24.4%) also experiencing deterioration, evidencing chronically evolving systemic strain
- Orphan therapies (+4.2%) and oncology (+6.5%) also show an increase in time to local availability but less compared to the other TAs
- There are improvements in the approved percentage, but the overall trend indicates that system capacity is not keeping pace with innovation inflow, resulting in slower transitions from approval to availability

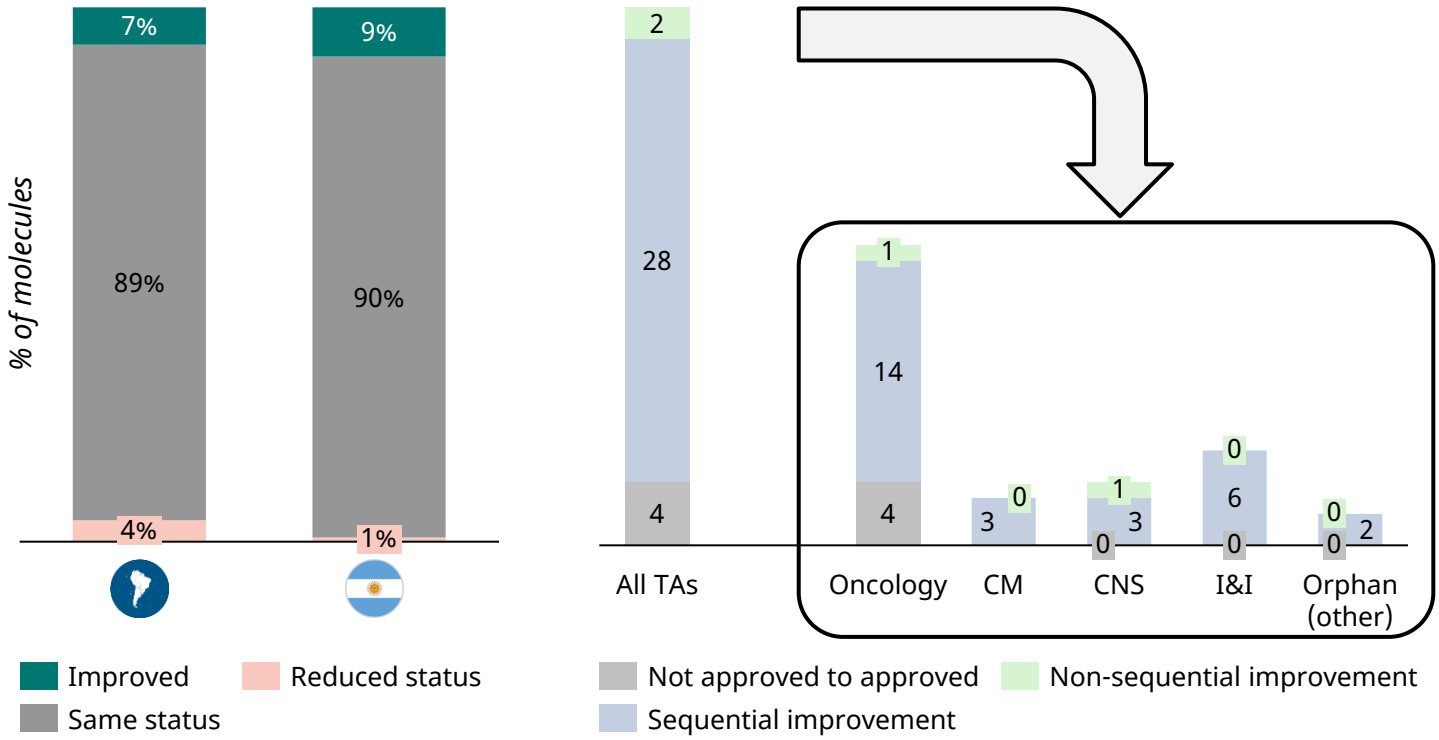
In Argentina, access timelines are increasingly delayed after approval, with system constraints and budget pressures slowing the transition from innovation to patient access, particularly in high-impact therapeutic areas

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

Improvements in status, but largely remains the same

While Argentina slightly outperforms the regional average in improvements, most therapies remain static, with gains primarily driven by incremental progression and concentrated in selected areas

Improvement Index Argentina (2026 vs 2025)



- Argentina falls in line with the regional average in access progression with 9% of molecules improving vs. 7% in LATAM; indicating that improvements exist but are not widespread
- Most molecules (~90%) remain in the same access status, with many remaining unapproved or with limited access, highlighting a structure where the system is largely static and only small fraction of therapies are advancing; the improvements are occurring selectively
- A portion of molecules (~1%) experienced reduced status, showing a slightly better performance 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 orphan, and relatively consistent patterns in other disease areas

Argentina is maintaining a consistent performance with the regional average, but the scale of improvements does not compensate the stagnation of most molecules in status

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

Argentina is strengthening governance frameworks

System sophistication is increasing, but reduced funding and fragmented implementation are slowing access delivery

Recent Health Reforms in Argentina



Argentina has made significant progress on strengthening regulatory and processes

- Severe fiscal contraction limiting access capacity for public sector
- Decentralization increasing system fragmentation, creating deficiencies in a resource-restricted period
- HTA reform (ANEFiTS) propose controversial method which is likely to generate friction and delay potential benefit from centralizing evaluation processes

- Argentina is facing continuity of its government policy around austerity in public spending following the most recent presidential elections, focused on fiscal discipline and rationalization of expenditures
- One of the most severe affectations to the system is the reduction in public health spending, with reported budget cuts of approximately 48% in real terms since 2023, accompanied by workforce reductions and the dismantling and defunding of key programs
- Whilst the direct contraction in the spend may be more visible over the coming years in the data, for the current period spend is likely maintaining based on patients with existing treatment, and access improvements are clearly indicating the impact
- Reduced system capacity to fund innovative medicines is likely to be secondary to maintaining basic healthcare infrastructure, further widening the gap between approval and real-world access
- Argentina's healthcare system is relatively decentralized, where provinces play an increasingly central role in procurement and access decisions; in practice this means atomization of negotiations and purchasing processes rather than through a centralized framework, enabling flexibility during this period of instability in financing, however also significant restrictions overall
- There are also planned institutional reforms such as the establishment of ANEFiTS to replace CONETEC, with the aim of improving coordination in decision-making related to coverage and funding, though HTA prior to regulatory approval is a policy sticking point

Argentina is reforming how decisions are made, but with fewer resources and more fragmentation, the system's ability to deliver access is becoming increasingly restricted

Sources: Global Health Expenditure Database, International Trade Administration, OECD
Acronyms: ANEFiTs: Agencia Nacional de Evaluación de Financiamiento de Tecnologías Sanitarias; CONETEC: Comisión Nacional de Evaluación de Tecnologías Sanitarias y Excelencia Clínica; HTA: Health Technology Assessment

ANMAT is strengthening regulatory alignment

Argentina's regulatory framework is aligned with international standards, but approval and access gaps are driven primarily by fiscal limitation, fragmentation, and system capacity

Global Reliance of Argentina's Health Agencies







Global Reliance

ANMAT operates as a technically established regulatory authority, aligned with regional and international practices, supporting structured review and approval of innovative therapies

- Argentina conducts evaluation through standardized dossier reviews and formal administrative processes similar to other LATAM agencies; compared to regulators in the region it is amongst the most efficient, particularly in orphan disease where there is a designated pathway
- ANMAT leverages external reference decisions, realized by Equivalent Foreign Regulatory Authorities (AREEs), primarily US-FDA, EU-EMA, this reliance is becoming more consistently applied and more formalized
- Argentina is aligned with global standards such as the International Council for Harmonization (ICH) but is not embedded in the main global or accelerated regulatory collaboration networks, limiting the potential for accelerated evaluation
- ANMAT is aligned with PAHO/WHO standards and participates in regional collaboration, but it is not positioned as a reference authority (NRAr), reflecting gaps in global integration, reliance frameworks, and regulatory performance

Argentina's regulatory system is aligned with international standards, but limited integration in global collaboration frameworks and broader system dynamics shape its role in regional approvals

Acronyms: ANMAT: Administración Nacional De Medicamentos, Alimentos Y Tecnología Médica; 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

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